CMS-4068-P-500

Submitter : Ms. Jennifer Spino **Date & Time:** 09/30/2004 02:09:46

Organization : Center for Disability Rights

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-500-Attach-1.doc

September 30, 2004

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

To Whom It May Concern:

I welcome the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I serve as a Systems Advocate for the Center for Disability Rights in Rochester, New York. We advocate for the full integration, independence and civil rights of individuals with disabilities. I am concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

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

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

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

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

experimentation find the medication that is most effective for their circumstance. The consequences of denying the appropriate medication for an individual with a disability or chronic health condition are serious and can include injury or debilitating side effects, even hospitalization or other types of costly medical interventions.

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

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

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:

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

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

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES:

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

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

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

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

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

Thank you for your consideration of our views.

Jennifer Spino
Systems Advocate
Center for Disability Rights

CMS-4068-P-501

Submitter : **Date & Time:** **09/30/2004 02:09:31**

Organization : **North Central Chapter PVA**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file froom the disability community!

CMS-4068-P-501-Attach-1.doc

September 30, 2004

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

To Whom It May Concern:

The North Central Chapter Paralyzed Veterans of America welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The North Central Chapter Paralyzed Veterans of America is a membership organization serving the needs of veterans who suffer from spinal cord injury or disease and individuals with disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

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

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

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

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

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

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

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

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of our views.

Sincerely,

Ryan Green

Government Relations Director
North Central Chapter PVA

CMS-4068-P-502

Submitter : Mr. Dan Morgan **Date & Time:** 09/30/2004 02:09:47

Organization : The Medicine Shoppe

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

The Medicine Shoppe Pharmacy 2145 Englewood Terrace Chesterfield, MO 63017 September 30, 2004 Centers for Medicare and Medicaid Services Department for 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 regulations. 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 noon-preferred pharmacies with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Only preferred pharmacies should count when evaluating whether a plan has met the pharmacy access standards. Allowing plans to count their non-preferred pharmacies conflicts with Congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies. IF A PHARMACY ACCEPTS THE PLANS TERMS AND CONDITIONS THE PLAN SHOULD NOT BE ALLOWED TO CHARGE THE CUSTOMER A DIFFERENT CO PAY FOR UTILIZING THEIR LOCAL PHARMACY FOR THEIR PRESCRIPTION (INCLUDING 90 DAY PRESCRIPTIONS) THAN THE PLAN CHARGES THE CUSTOMER FOR THEIR OWN MAIL ORDER HOUSE! PLEASE INSURE THERE IS A LEVEL PLAYING FIELD! Subpart D: Cost Control & Quality Improvement Requirements for Prescription Drug Plans I appreciate 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 the 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 to let me help my patients make the best use of their medications.. In conclusion, I urge CMS to revise the regulations as I have mentioned. Thank you for considering my view. Sincerely, Daniel Morgan, The Medicine Shoppe

CMS-4068-P-503

Submitter : Mrs. pat wolf **Date & Time:** 09/30/2004 02:09:11

Organization : diabetes resource center at lewistown hospital

Category : Nurse

Issue Areas/Comments

GENERAL

GENERAL

provide coverage for proper needle disposal

CMS-4068-P-504

Submitter : Bill Quinn **Date & Time:** 09/30/2004 02:09:43

Organization : Bill Quinn

Category : Social Worker

Issue Areas/Comments

GENERAL

GENERAL

I would like to submit a comment regarding the propose Medicaid/Medicair Changes to Take Place in 2006. I am greatly fearful that forcing people with disabilities to pay a greater portion of their medical costs will force them into a deeper state of poverty. People with disabilities are among the pooorest and most needy of all populations. They have worked hard to join the working population and the proposed changes will be a very big detriment to their self esteem and working potential. Please reconsider these proposed changes. Sincerely, Bill Quinn

CMS-4068-P-505

Submitter : Mr. David Nash **Date & Time:** 09/30/2004 02:09:40

Organization : The Eastern Band of Cherokee Indians

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4068-P-505-Attach-1.doc

THE EASTERN BAND OF CHEROKEE INDIANS
88 Council House Loop • P.O. Box 455 • Cherokee, N.C. 28719
Telephone: (828) 497-2771 or 497-7000
Telefax: (828) 497-7007

September 30, 2004

Centers for Medicare and Medicaid Services
Department of Health & Human Services
ATTN: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
address for electronic delivery: <http://www.cms.hhs.gov/regulations/ecomments>

RE: Comments on Proposed Rule -- Medicare Part D Permanent Prescription Drug Benefit pursuant to Notice in 69 Federal Register 46632 (August 3, 2004)
File Code CMS-4068-P

Dear Administrator:

On behalf of The Eastern Band of Cherokee Indians, I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

The attached comments address issues related to the impact implementation of the proposed rules will have on American Indian and Alaska Native beneficiaries who are served by pharmacies operated by the Indian Health Service, Indian tribes, tribal organizations or urban Indian organizations (I/T/U pharmacies). As proposed, the rules would have a devastating adverse impact on the revenue collected by the I/T/U pharmacies for their dual eligible Indian patients and must be revised to prevent this outcome. It clearly was not the intent of Congress in enacting the Medicare Modernization Act to reduce revenues to Indian health programs. The United States has a trust responsibility for Indian health, and this responsibility must assure that the Indian health system is not harmed by implementation of Part D.

We urge CMS to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely yours,

David Nash, Attorney General

Attachment -- Part D Comments

COMMENTS REGARDING
PROPOSED REGULATIONS TO IMPLEMENT
THE MEDICARE PRESCRIPTION DRUG BENEFIT UNDER
THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND
MODERNIZATION ACT OF 2003
as published in
69 Fed. Reg. 46,632 et seq. (Aug. 3, 2004)
File Code CMS-4068-P

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part D's implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles" -- conservatively estimated at between $23 million to $53 million. Since the loss of revenue to Indian health was not Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part D does not result in inadvertent and unintended harm to that system.

The regulations governing the Part D prescription drug benefit must be revised to achieve the following goals:

* Guarantee that AI/ANs have a meaningful opportunity to access the benefit through the pharmacies of the Indian health delivery system;

* Require private prescription drug plan sponsors (PDPs) and Medicare Advantage organizations offering prescription drug coverage (MA-PDs) to reimburse or contract with the pharmacies in the Indian health system -- those operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (collectively referred to as "I/T/Us");

* Order Indian-specific terms that must be included in those contracts to guarantee that I/T/U pharmacies can collect from PDPs, building on the experience gained from the Medicare Prescription Drug Discount Card program; and

* Develop a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. One idea for achieving this protection could be modeled on the "hold harmless" mechanism Congress established for FQHCs in Section 237 of the MMA. A less costly and less administratively cumbersome option is to keep AI/AN dual eligibles under State Medicaid plans for drug coverage, since the federal government has full economic responsibility for them under Medicaid (100% FMAP) and Medicare Part D.

In order to fully comprehend the potential adverse impact Part D implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian tribes.1 Pursuant to statutory directive,2 this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); pharmacy operations; an extensive (but underfunded) contract health services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health

education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights3 reveals a number of alarming statistics such as:

* AI/ANs have the highest prevalence of Type II diabetes in the world, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.
* The cardiovascular disease rate among AI/ANs is two times greater than the general population.
* AI/ANs are 770% more likely to die from alcoholism.
* Tuberculosis deaths are 650% higher among AI/ANs than the general population.
* AI/AN life expectancy is 71 years, five years less than the general U.S. population.
* The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
* The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

* The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
* Indian tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
* In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report4, the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.5

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made

IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by IHS and tribes to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. When drug coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that reimbursement for drugs for Indian dual eligibles continues without interruption and without reduction.

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Pharmacy Services for Dual Eligibles

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,9636 and 30,5447 individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918. 8 We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between $23.8 million9 and $53.6 million.10 It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when

dual eligibles are removed from the Medicaid rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

Barriers to Part D access of Indian dual eligibles. There are several reasons why the intended conversion of dual eligibles from Medicaid to Medicare could be extremely problematic in the Indian health system:

* Switching payment sources from Medicaid to PDPs under Part D will hurt AI/AN consumers and Indian health providers because most tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. Dual eligibles in those areas will have difficulty accessing the Part D benefit unless they use an Indian health pharmacy admitted to PDP networks.

* Medicaid revenues have been an important source of income for Indian health facilities. As drug coverage for AI/AN dual eligibles is removed from Medicaid and placed under Medicare, the amount of revenue in jeopardy is estimated to be between $23.8 million and $53.6 million. Reductions in reimbursements for pharmaceuticals cannot be absorbed by raising rates for other services, as Indian patients are served without charge.

* The level of revenue an I/T/U would collect under Part D will very likely be less than it currently collects under Medicaid for dual eligible drug coverage. Therefore a “wrap around” payment from Medicare, consisting of the difference between the PDP/MA-PD contract amount and the amount the I/T/U would have received under Medicaid, must be utilized to “hold harmless” I/T/Us, if an I/T/U contracts with a PDP/MA-PD.

* If private prescription drug plans are not required to contract with I/T/U pharmacies, there will be little incentive for them to do so, as the service population of these pharmacies is comparatively small and the Indian population tends to be sicker. Without network status or payment for off plan services, an I/T/U pharmacy will not be able to collect for drugs dispensed to any AI/AN enrolled in a Part D plan. This would produce three negative results: (1) a loss of revenue to the I/T/U pharmacy; (2) no meaningful opportunity for the enrolled Indian to use his Part D benefit; and (3) a windfall for the PDP who collects premiums from CMS for a dual eligible, but pays no claims.

* Even if private plans are required to contract with I/T/U pharmacies, this command will be meaningless unless the regulations set out terms specifically drafted to address the unique circumstances of the IHS, tribal and urban Indian pharmacies.

* Even if an Indian beneficiary is enrolled in a Part D plan, the I/T/U pharmacy may not know what PDP or MA-PD to bill. Particularly with automatic enrollments, the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delay in accessing the benefit if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. This situation mirrors

the disastrous consequences suffered by the I/T/Us when State mandatory Medicaid managed care enrollment programs were implemented.

* If delays in implementation occur, it is not clear how the I/T/U pharmacies will recoup payment for expenditures made during the period between when the AI/AN is switched from Medicaid to Medicare pharmacy benefits and when the I/T/U pharmacy is an established network provider or able to bill for out of network services. Even if the I/T/U pharmacy is allowed to bill for services provided from the beginning of 2006, they may not have the staff to deal with a backlog of billing. Confusion and lack of information could result in not billing for covered services.

The Part D program will also impact AI/AN Medicare beneficiaries who are not dual eligibles and must pay a premium for Part D participation. Since these individuals receive drugs at Indian Health Service and tribal health pharmacies without charge, there is no incentive for them to pay premiums to enroll in a Part D plan. In order to be able to collect reimbursements for drugs dispensed to those patients, CMS must facilitate group payer options for tribes who wish to pay premiums for these beneficiaries in order for their pharmacy to be reimbursed for drugs dispensed.

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit all Medicare beneficiaries, does not produce the opposite result for Indian Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

ACCESS TO COVERED PART D DRUGS
Comments regarding: Section 423.120: Pharmacy Access Standards

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To guarantee access to Part D prescription drug benefits for AI/AN beneficiaries by requiring private drug plans to contract with those pharmacies which serve the majority of this population -- I/T/U pharmacies.

Access Issue, Pages 46655-57: Should CMS use its authority under Section 1860D-4(b)(1)(C)(iv) of the Act (authorizing the Secretary to establish standards to provide access for I/T/U pharmacies to participate in the Part D program) to require or strongly encourage private drug plan sponsors (PDPs) and MA organizations offering MA-PD plans (MA-PDs) to contract with I/T/U pharmacies?

Comment: In order to realize its goals (as communicated on pages 46655 and 46633 of the Preamble) of ensuring convenient access to covered Part D drugs to plan enrollees and broad participation by

Medicare beneficiaries in the new prescription drug benefit under Part D, CMS must use its authority under Section 1860D-4(b)(1)(iv) of the Act to require PDPs and MA-PDs to contract with I/T/U pharmacies. Without this requirement the private drug plans will have little or no incentive to contract with I/T/U pharmacies.11 This is true because there is no financial incentive for private plans to contract with I/T/U pharmacies since these pharmacies and the AI/AN beneficiaries they serve are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. If PDPs and MA-PDs are merely "strongly encouraged" to contract with I/T/Us12 they will not do so because of the uniqueness and remoteness of Indian health programs the comparatively small and sicker populations they serve, and the perceived cost and time it may take to enter into individual contracts with each I/T/U pharmacy. CMS acknowledges these concerns on page 46657 of the Preamble.13

Failure to include language in the rule requiring private plans to contract with I/T/U pharmacies will have the unintended consequence of denying access to the benefit for a majority of AI/AN beneficiaries. This would be contrary to the access requirements of the Act. If I/T/U pharmacies are not included in the PDP or MA-PD network, an estimated 26,000 AI/AN beneficiaries who obtain their drugs from I/T/U pharmacies will be unable to access the Part D drug benefit. CMS acknowledges this fact on page 46657 of the Preamble by stating that I/T/U pharmacies may be the only facilities available to AI/AN beneficiaries and recognizes that access to I/T/U pharmacies should be preserved because it "would greatly enhance Part D benefits" for AI/AN enrollees.

Access for I/T/U pharmacies to the Part D program is crucial for preserving current revenues. All AI/ANs dual eligibles will lose their Medicaid drug benefits and are required to enroll in a Part D or Part C plan. Those dual eligible who fail to enroll will be automatically enrolled in a private plan. Regardless of such a beneficiary's enrollment in the new prescription drug benefit, an AI/AN beneficiary will continue to utilize his/her I/T/U pharmacy. Absent an agreement with the private drug plans, these pharmacies will be unable to collect reimbursement for prescription dispensed to Medicare beneficiaries. In order for I/T/Us to collect reimbursement for prescription drugs provided to dual eligibles they must be included in the private plan network.

Therefore, it is vital that Section 423.120 be modified to include language requiring PDPs and MA-PDs to contract with I/T/U pharmacies, but required contracting is not enough. The unique status of tribes may become an issue in contract negotiations. The standard PDP/MA-PD contract could prove problematic for I/T/Us as CMS acknowledged in the Preamble on page 46657. In order to assist CMS, PDPs, and MA-PDs in resolving this difficulty, we urge that specific contract provisions, which are contained in the draft language below, be required provisions for agreements between PDPs/MA-PDs and I/T/U pharmacies.14

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) Assuring pharmacy access.

Insert the following new paragraph and re-number all subsequent paragraphs:

"(2) Access to IHS, tribal and urban Indian pharmacies. In order to meet access standards under Section 1860D-4(b)(1)(C)(iv), a prescription drug plan or MA-PD plan must offer to contract with any I/T/U pharmacy in its plan service areas, and such contract must include the elements set out in §423.120(a)(4)."

§423.120(a)(4) Pharmacy network contracting requirements.

Insert the following new subparagraph (iv):

"(iv) Must incorporate in all contracts entered into with I/T/U pharmacies, within the text of the agreement or as an addendum, provisions that:
(A) Acknowledge the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.
(B) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to the tribal or urban Indian organization's pharmacy by the IHS for operation of a health program.
(C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 et seq. and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.
(D) Recognize that I/T/Us are non-taxable entities.
(E) State that IHS, tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
(F) State that a PDP may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
(G) Include confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
(H) State that an I/T/U pharmacy is not subject to the PDP formulary.
(I) State that the Agreement may not restrict access the I/T/U pharmacy otherwise has to purchase drugs from the Federal Supply Schedule or the Drug Pricing Program of Section 340B of the Public Health Service Act.
(J) State that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.
(K) Authorize I/T/U pharmacies to establish their own hours of service."

REGULATIONS MUST PROVIDE A MECHANISM TO ASSURE NO REUDCTION IN REVENUES TO I/T/U PHARMACIES

Comments regarding: §423.120: Access to covered Part D drugs and §423.124: Special rules for access

to covered Part D drugs at out-of-network pharmacies

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To include in the regulation a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. We provide four options in our comments to achieve this goal:

Option 1: In-Network Status + Wrap-Around Payment. One mechanism for achieving this protection would be to require PDP to recognize I/T/U pharmacies as in-network providers and for CMS to provide "a wrap-around payment" modeled on the provision Congress established for FQHCs in Section 237 of the MMA. This payment would supplement the difference between the amount paid by the PDP/MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.

Option 2: Out of Network Status + Wrap-Around Payment. In the event that I/T/U pharmacies are not treated as in-network pharmacies, they should be recognized as out-of-network pharmacies eligible for reimbursement from the private plan under §423.124 and receive a supplemental "wrap around" payment from the federal government which would include any increased differential in cost sharing related to use of out of network pharmacies. This supplemental payment would provide reimbursement for the difference between the out of network plan payment and the amount the I/T/U would have received as an in network provider.

Option 3: Special Endorsement PDP/MA-PD Plans. Specific PDPs could be designated to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Benefit Discount Card program.

Option 4: Exemption of AI/AN Dual Eligibles. Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid. This alternative would allow CMS to avoid the complicated issues of access and revenue loss that we discussed throughout these comments.

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for AI/AN dual eligibles drug costs ranges between $23.8 million15 and $53.6 million.16 It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even if PDPs and MA-PDs are required to contract with I/T/U pharmacies, it is very likely that these contracts will not provide the level of reimbursement I/T/Us currently receive under Medicaid.

We propose that one of the four "hold harmless" provision options be included in the regulation to maintain the current level of revenue I/T/U pharmacies receive under Medicaid.

Option 1: In-Network Status with Wrap-Around Payment

While it would be the responsibility of CMS to establish ways to prevent loss of revenue at I/T/U pharmacies, we propose that CMS:

(a) Require all PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the appropriate rate17, and
(b) Provide a "wrap around" payment for drug coverage services similar to the special payment rules for medical services provided at federally qualified health centers (FQHCs) contained in Section 237 of the MMA.

Reimbursement as In-network Provider. We request that the regulations require PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the Medicaid rates. This provision would prevent agreements in which the PDP/MA-PD agrees to pay an artificially low rate to the I/T/U pharmacy, with the knowledge that the I/T/U pharmacy will receive supplemental payments from CMS.

Wrap-Around Payment. We also propose that an I/T/U pharmacy which provides Part D drug benefits to AI/AN beneficiaries receive a "wrap-around payment" to supplement the difference between what the I/T/U pharmacy is paid from the private plan and the amount the pharmacy would have received for providing this benefit under Medicaid. This mechanism will allow an I/T/U pharmacy to receive payment from the federal government when the amount paid by the private plan is less than the Medicaid amount.

We suggest that the following provision or ones similar in nature be added to the Part D rules:

Section 423.120(a)(1): Convenient access to network pharmacies.

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"§423.120(a)(1)(iv). Any PDP or MA-PD plan with one or more I/T/U pharmacies within its service area shall recognize such I/T/U pharmacies as in-network providers for the purpose of paying claims for pharmaceuticals supplied to any American Indian or Alaska Native enrolled in such PDP or MA-PD, regardless of whether the I/T/U pharmacy submitting a claim is a contracted network pharmacy."

The following language should be inserted into Part 423 at the appropriate place:

§423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 2: Out of Network Status with Wrap-Around Payment

In the even that I/T/U pharmacies are not recognized as in-network providers under Option 1, we propose that the regulations recognize these pharmacies as out of network providers under §423.124 and provide a wrap-around payment to supplement the difference between the out of network reimbursement rate and the Medicaid rate.

We suggest that the following sentence be added to Sec. 423.124(a):

Section 423.124(a) ***

"An I/T/U pharmacy that dispenses covered Part D drugs to an American Indian/Alaska Native beneficiary shall be considered an out of network pharmacy for payment of claims."

Additionally, the following provision should be included in Part 423:

§423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 3: Special Endorsements with Wrap-Around Payment

Designating private plans to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Discount Card program is an alternative that could encourage PDP contracting with I/T/U pharmacies. Specifically identifying the

PDP serving AI/AN will help I/T/Us to identify and bill the correct PDP or MA-PD. Additionally, designating specific PDPs and MA-PDs to contract with I/T/U pharmacies would allow an AI/AN beneficiary to easily identify which plan includes his/her I/T/U pharmacy, avoiding the need for the individual to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. Of course, to ensure that I/T/U revenues do not decrease under this option, the wrap-around payment provision discussed above would be necessary. Designation of specific PDPs would also facilitate development of specific I/T/U contract terms.

If CMS is unable to secure private plans to offer the benefit, then it could either subsidize the benefit or provide a "fall back" plan as authorized by Section 1860D-2(b) of the MMA. The Part D proposed regulations depend on the private market to drive the benefit; however, because of the unique characteristics of Indian health programs, private plans may not have incentive or interest in serving a predominately low-income population. Establishing specific PDPs and MA-PDs to serve the AI/AN population is entirely feasible since PDP and MA-PD regions have yet to be established.18

Option 4: Exemption of AI/AN Dual Eligible Individuals from Part D

We offer an alternative that would allow CMS to avoid the complicated issues of access in Section 423.120, revenue loss to I/T/Us and the "wrap around" mechanism discussed on page 11 of these comments -- Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid.

We believe that exempting AI/AN dual eligibles from mandatory enrollment is an efficient and effective alternative for the following reasons:

> Exemption of AI/AN dual eligibles from mandatory enrollment will prevent any loss of revenue to I/T/U pharmacies that will result if drug coverage for dual eligibles is switched from Medicare to Medicaid.
> Exemption of AI/AN dual eligibles will eliminate the barriers dual eligibles, as well as AI/AN basic beneficiaries, will face in accessing the Part D benefit. For example, the MMA strategy to use private plans as a vehicle to provide prescription drug benefits severely restricts access for many AI/ANs because tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks.
> Exemption of AI/AN dual eligibles from mandatory enrollment will eliminate the detrimental impact on reimbursement levels and the increase administrative costs that will occur when the I/T/U pharmacy does not know what PDP or MA-PD to bill. This is particularly true with regard to automatic enrollments because the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delays if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider.

It is important to recognize that exempting AI/AN dual eligibles from mandatory participation in Part D thereby allowing them to continue to receive prescription drug coverage through the State Medicaid Program will have no budget impact. This is so because prescription drug coverage costs will

be paid by the federal government regardless of whether the benefit is provided under Medicaid at 100% FMAP or Medicare Part D subsidy for dual eligibles.

Exempting AI/AN from enrollment in Part D may be modeled on the existing statutory language exempting AI/AN from enrollment in mandatory Medicaid managed care plans. Section 1932(2)(C) of the Social Security Act, codified at 42 U.S.C. §1396u-2, provides for this exemption in recognition of the many difficulties (similar to the ones we have discussed throughout these comments) facing I/T/Us when dealing with private plans.

I/T/U PHARMACIES AND FEDERAL SUPPLY SCHEDULE (FSS)
Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems

Goal: To ensure that I/T/U pharmacies that participate in PDP pharmacy networks continue to have the option of purchasing prescription drugs for AI/AN Medicare beneficiaries at Federal Supply Schedule (FSS) prices or at the discounts available under the 340B program.

Terms and Conditions Issue, Page 46658: CMS notes that the proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network. CMS seeks comment on whether it should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks.

Comment: As the Preamble recognizes, there are 201 I/T/U pharmacies serving 107,000 elderly and disabled AI/ANs in 27 states (page 46657). These pharmacies currently have access to Federal Supply Schedule (FSS) prices for the prescription drugs they dispense to AI/AN Medicare beneficiaries, or they are covered entities entitled to discounts under the 340B program, 42 U.S.C. 256b, or both. These discounted prices reflect the purchasing leverage of the Federal government and have enabled I/T/U pharmacies to meet the needs of AI/AN beneficiaries, whether or not enrolled in Medicare, in a cost-efficient manner.

We are concerned that PDP sponsors and MA organizations offering an MA-PD plan may require participating pharmacies to purchase drugs through the PDP sponsor or MA organization. This could have the effect of forcing I/T/U pharmacies to choose between participating in Medicare Part D and retaining their current access to FSS prices or 340B discounts, or both. We do not believe Congress intended that I/T/U pharmacies be forced into this choice. We therefore propose that the final rule prohibit PDP sponsors or MA organizations from requiring I/T/U pharmacies to purchase drugs through mechanisms other than FSS or the 340B program. This would not preclude an I/T/U pharmacy that wished to do so from purchasing its drugs through the PDP or MA-PD plan. The option, however, would be that of the I/T/U pharmacy, not the PDP or MA-PD plan.

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans should be revised to read as follows (modifications are italicized):

"(4) Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage –
(i) Must contract with any pharmacy that meets the prescription drug plan's or MA-PD plan's terms and conditions;
(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA-PD plan's network; and
(iii) May not require an I/T/U pharmacy to purchase prescription drugs other than through the Federal Supply Schedule or prohibit an I/T/U pharmacy from receiving a discount as a covered entity under section 340B of the Public Health Service Act, 42 U.S.C. 256b. "

FORMULARY
Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements.

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule.

Goal: I/T/Us should be exempt from formulary requirements and therefore able to utilize permissible substitutes. This exemption is needed to both accommodate the limited stock carried by many small I/T/U pharmacies and dispensaries and to allow I/T/Us to include in their formulary of drugs for which reimbursement will be paid those drugs available through FSS or 340b.

Comment: Section 423.120(b)(1) permits PDP and MA-PD plans to develop formularies so long as they meet the requirements of this section. We are concerned that plans that develop such formularies will make stocking the drugs in the formulary a requirement of its contracts with participating pharmacies. Many I/T/U pharmacies are small and cannot stock a full range of drugs, particularly if the condition the drug is used to treat is one beyond the scope of the I/T/U clinic and its providers. When establishing their formularies, I/T/U hospital and clinic pharmacies also consider aspects of treatment that may not be generally important, such as the extent of monitoring of the patient that may be required. Since many patients live far from the I/T/U pharmacy, this is an important therapeutic factor. Another factor in whether the I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principle sources of drugs purchased by I/T/U pharmacies. See "I/T/U Pharmacies and Federal Supply Schedule (FSS)."

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans in Section 423.120(a)(4) should be further revised to add a new paragraph (iv) to read as follows (new language is italicized):

(v) May not require an I/T/U pharmacy to provide all the drugs in any formulary that may have been adopted by the PDP or MA-PD.

AI/AN beneficiaries often will have access only to an I/T/U pharmacy due to the remote locations where they live and where the I/T/U pharmacies are located. As noted in the Preamble, in the places where there are concentrations of Alaska Natives and American Indians, the I/T/U pharmacies are often the only pharmacy providers (page 46657). It is unfair to the AI/AN beneficiaries and to I/T/U providers to limit reimbursement or increase co-pays when a beneficiary is prescribed a drug that is not on the PDP or MA-PD formulary when that may be the only drug available from the I/T/U pharmacy that provides the same therapeutic effect as the formulary drug. In such cases, the PDP or MA-PD should be required to reimburse the I/T/U as if the drug were on its formulary in an amount equal to that the PDP or MA-PD would have paid for an equivalent drug on its formulary. In this way, neither the PDP or MA-PD or the I/T/U pharmacy is disadvantaged financially, and the patients are able to maintain access and continuity of care.

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (v) to read as follows (new language is italicized):

(vi) Must provide for reimbursement to I/T/U pharmacies for all covered Part D drugs whether or not they are on the PDP's or MA-PD's formulary at an amount not lower than the reimbursement that would have been made for an equivalent drug on the formulary.

BENEFITS AND BENEFICIARY PROTECTIONS
Comments on Section 423.100: DEFINITIONS
"Insurance or otherwise" for purposes of "Incurred costs"

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: To ensure that expenditures by I/T/Us on AI/AN beneficiaries (who do not qualify for the cost-sharing subsidy for low-income individuals) on prescription drugs count toward the annual out-of-pocket threshold ($3,600 in 2006).

Incurred Cost Issue, Pages 46649-46651: CMS notes that, under the proposed rule, AI/AN Medicare beneficiaries who are not eligible for low-income cost-sharing subsidies may receive drug coverage directly from I/T/U pharmacies or under CHS referrals. While these payments will count toward the AI/AN beneficiary's annual deductible, they will not count as incurred cost toward meeting the out-of-pocket threshold ($3,600 in 2006). The reason, in brief, is that "incurred costs" are defined by section 1860D-2(b)(4)(C)(ii) of the Social Security Act to exclude payments by "insurance or otherwise." But this statutory provision does not expressly include the I/T/U programs in this term. Rather, it is CMS,

not the law that has defined what is encompassed by the term “insurance or otherwise”. The agency has chosen to include I/T/U health programs as “insurance or otherwise,” -- but has not explained the basis for that decision, nor analyzed the impacts of it on the IHS-funded system and affected Indian Medicare beneficiaries, nor acknowledged that failing to count I/T/U pharmacy contributions toward "incurred costs" would be a windfall to the PDP in which an affected Indian is enrolled. Perhaps CMS recognized that this matter requires additional thought, as it asks for comments on “how … IHS beneficiaries will achieve maximized participation in Part D benefits.”

Comment: The effect of CMS’s decision to treat I/T/U programs as “insurance or otherwise” is to minimize, not maximize, participation of IHS beneficiaries in Part D benefits. As CMS itself acknowledges, “most IHS beneficiaries would almost never incur costs above the out-of-pocket limit.” (69 FR at 46657). And, as CMS further recognizes, this policy “would likely provide plans with additional cost-savings.” (69 FR at 46657). We do not believe that Congress intended Part D to be administered to minimize participation by AI/AN beneficiaries and to increase revenues for PDP and MA-PD plans at the expense of I/T/U programs. Yet that is precisely the result that the proposed rule achieves.

The proposed rule is not required by the statute. Section 1860D-2(b)(4)(C)(ii) does not expressly prohibit payments by I/T/U programs from being treated as “incurred costs.” By using the phrase “not reimbursed by insurance or otherwise,” Congress intended to give CMS discretion to fashion a sensible definition consistent with federal policy. AI/ANs are not “reimbursed” by their IHS or tribal health care providers or by any insurance. Rather in the case of AI/AN beneficiaries, that federal policy is the trust responsibility of the United States to provide health care to AI/ANs pursuant to laws and treaties. And, as CMS acknowledges in the Preamble at p. 46651, the I.H.S. “fulfills the Secretary’s unique relationship to provide health services to AI/ANs based on the government-to-government relationship between the United States and tribes.” In other words, AI/AN Medicare beneficiaries have a different legal standing than other Medicare beneficiaries.

The proposed rule, however, does not recognize this “unique” legal relationship. Instead, the proposed rule would require those AI/ANs who are Medicare beneficiaries but who are not eligible for the low-income subsidy program to pay substantial amounts out of pocket for their Medicare prescription drug coverage in order to meet the out-of-pocket threshold. In this way, the proposed rule violates the federal trust responsibility, under which AI/ANs are entitled to needed health care services, including prescription drugs, at the federal government’s expense.

Section 1860D-2(b)(4)(C)(ii) specifies that costs shall be treated as incurred if they are paid “by another person, such as a family member, on behalf of the individual.” (emphasis added). In the “unique relationship” between the federal government and AI/ANs, the I/T/Us are the functional equivalent of a “family member.” Their mission, on behalf of the federal government, is to pay for prescription drugs and other health care services needed by AI/ANs. In terms of paying for prescription drugs, there is no functional difference between I/T/Us fulfilling their obligations to AI/ANs and family members fulfilling their obligations to one other. Again, there is nothing in the concept of family members paying incurred costs to suggest that Congress somehow intended that payments by I/T/Us on behalf of AI/ANs

not be treated as incurred costs.

In the preamble, CMS explains that contributions made by charities would be considered "incurred costs" and describes in detail the reasons for a desirable objectives achieved by this decision. Many of the considerations recited there apply to the I/T/U system, particularly the outcome that Medicare beneficiaries who are not eligible for the low-income subsidy would be able to qualify sooner for the catastrophic coverage level. In other words, these beneficiaries would have a better opportunity to fully utilize their Part D benefit.

The outcome is just the reverse with regard to an Indian not eligible for subsidy who is served by an I/T/U pharmacy. That Medicare beneficiary would have to pay the same premium for Part D coverage (or have it paid on his behalf by the I/T/U program as CMS suggests at p. 46651), but the benefit received for that premium would be only slightly more than $1000 -- far lower than that of a non-Indian beneficiary. This is so because this Indian patient would never get out of the "donut hole" and thus would never be able to utilize the catastrophic coverage feature of the Part D benefit.

The proposed rule has the effect of shifting from Medicare Part D and participating private plans to the Indian Health Service, tribes and tribal organizations, and urban Indian programs, the cost of Medicare prescription drug coverage for AI/AN Medicare beneficiaries who are not eligible for cost-sharing subsidies due to low income. This is because the I/T/Us will continue to use their limited appropriated funds to pay the prescription drug costs of these AI/AN beneficiaries – that is the I/T/U mission. As the preamble acknowledges, most of these beneficiaries will never reach the out-of-pocket limit as a result. The I/T/Us will then have to cover the drug costs above the out-of-pocket threshold, absorbing the costs that neither Medicare nor the Part D plans will cover. Given the poor health status of AI/ANs and the demonstrated underfunding of I/T/Us, it is inconceivable that Congress intended that CMS exercise its discretion to achieve this outcome. We therefore urge CMS to make the following revision to the rule:

Section 423.100-“Insurance or otherwise” for purposes of “Incurred Costs”

The definition of “insurance or otherwise” used to define “incurred costs” for purposes of meeting the out-of-pocket threshold should be revised to read as follows (modifications are italicized):

“Insurance or otherwise” means a plan (other than a group health plan) or program (other than a health program operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act , 25 U.S. C. 1603), that provides, or pays the cost of, medical care…, including any of the following: …(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals (other than American Indians or Alaska Natives or urban Indians as those terms are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603).”

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL

Comments regarding Section 423.286 Rules regarding premiums.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: Tribes/Tribal Health Programs should be allowed to pay premiums on behalf of AI/AN (Group Payer) for AI/AN beneficiaries. Either rules or administrative policy should allow Tribes to add AI/AN beneficiaries to the group at any time.

Comment: We urge CMS to include I/T/U and/or tribes as permissible payment options and to remove barriers tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules. Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, would elect to pay premiums themselves.

AI/ANs served in an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the IHS based on the Federal Government's obligation to federally recognized Tribes. CMS recognizes this in the Preamble, page 46651, by stating that "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits". It is unlikely that AI/ANs, who are entitled to health care without cost sharing, would elect to pay premiums themselves, therefore, we request that language be included in the regulations recognizing the ability of I/T/Us to pay premiums if they so choose.

WAIVER OF COST SHARING
Comments on Background at 46651 and Section 423.120(a)(4)

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule and Formulary.

Goal. Assure that I/T/U pharmacies are authorized to waive cost-sharing for AI/AN beneficiaries pursuant to Section 1128B (b)(3)(G) of the Social Security Act, as added by Section 101 of the MMA.

Comment: As discussed in the Preamble, the AI/AN beneficiaries receive health services under a unique government-to-government relationship between the United States and Tribes (page 46651). Under this relationship most care is provided directly by or through contract health services administered by I/T/U providers who provide the care without cost to the AI/AN beneficiary. The benefit plans provided under Medicare Part D contemplate patients sharing in the cost of the care they are provided. This is antithetical to the relationship between AI/AN beneficiaries and their I/T/U pharmacies.

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section

423.120(a)(4) should be further revised to add an new paragraph (vi) to read as follows (new language is italicized):

(vii) Must authorize I/T/U pharmacies to waive all cost sharing obligations of AI/AN beneficiaries.

CREDITABLE COVERAGE
Comments Regarding Section 423.56: Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: IHS coverage should be deemed "credible coverage" therefore making late enrollment penalties inapplicable to AI/AN beneficiaries.

Comment: The CMS TTAG strongly supports the decision of CMS to include in the definition of Creditable Prescription Drug Coverage a "medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U)" in the Medicare Prescription Drug Benefit Proposed Rule at § 423.56(a)(9). The Indian Health Service, Tribe or Tribal organizations, or Urban Indian organizations currently provide pharmaceuticals to AI/AN beneficiaries, either through direct care services or IHS Contract Health Services (CHS), at no cost to the beneficiary. For purposes of not being subject to late enrollment penalties, this Proposed Rule will protect those AI/AN beneficiaries who might not initially enroll in Medicare Part D because, for example, they receive their pharmaceuticals from an I/T/U pharmacy but later relocate off reservation and therefore need prescription drug coverage under Medicare Part D.

This definition is consistent with the definition of creditable coverage for purposes of continued health insurance coverage under the Employee Retirement Income Security Act (ERISA). See the Department of Labor regulations at 29 C.F.R. 2590.701-4 (a)(1)(vi). The DOL regulations include the I/T/U programs under their definition to ensure that when AI/AN beneficiaries relocate off reservation, where for example they had coverage from an IHS facility, that coverage counts as creditable coverage for group health plan coverage under the ERISA.

EXCLUDE CERTAIN INDIAN-SPECIFIC INCOME AND RESOURCES
FOR CONSIDERATION OF ELIGIBILITY OF AMERICAN INDIANS AND
ALASKA NATIVES FOR LOW-INCOME SUBSIDIES
Comments regarding Section 423.772: Premiums and Cost Sharing Subsidies for Low-Income Individuals-Definitions

Goal: To exclude from the income and resources tests for determination of an American Indian or Alaska Native (AI/AN) Medicare beneficiary's eligibility for a low-income subsidy under Part D certain income and assets that are excluded from consideration when determining eligibility for Medicaid.

Comment. CMS has recognized that certain Indian-specific income and assets are to be excluded when determining the eligibility of an AI/AN for Medicaid. See, e.g., CMS State Medicaid Manual Part 3 -- Eligibility, §3810. These same exclusions should apply to the determination of whether an AI/AN qualifies for a low-income subsidy under Part D. Since all dual eligibles will be moved from Medicaid to Part D for prescription drug coverage, it is appropriate that the same federally-established exclusions should apply to the affected AI/AN dual eligibles.

In Sec. 423.772, the definitions of "income" and "resources" should be revised to exclude income that derives from tribal lands and other resources currently held in trust status, from judgment funds awarded by the Indian Claims Commission and the U.S. Claims Court, and from other property held in a protected status, as specified in the Medicaid Manual. In addition, cultural objects, as specified in the Medicaid Manual, should also be exempted from the definitions of these terms.

ELIGIBILITY AND ENROLLMENT
Comments regarding Section 423.48: Information about Part D.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to the I/T/U at no cost.

Comment: Without outreach, education and enrollment assistance from Indian health programs, AI/AN are unlikely to enroll in Medicare Part D or Part C. AI/AN are entitled to receive free health care at I/T/Us and through Contract Health Services, thus they have no incentive to enroll in programs requiring premiums and cost sharing. I/T/Us know who may be eligible for new Medicare programs and how to contact them. AI/ANs trust I/T/U health workers. Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to I/T/U at no cost. As CMS states on Page 46642 of the Preamble, “we would undertake special outreach efforts to disadvantaged and hard-to reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate.” In implementing this provision CMS must reach out to AI/AN beneficiaries.

Attachment 1.

INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____(herein "Plan" or Plan Sponsor") and _____ (herein "Provider") for administration of Transitional Assistance under the Prescription Drug Discount Card program authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 at pharmacies and dispensaries of Provider. To the extent that any provision of the Special Endorsed Plan Master Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Special Endorsed plan Master Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Plan Sponsor" means _____ which operates the Prescription Drug Discount Card Plan defined in subsection (b).

(b) The terms "Prescription Drug Discount Card Plan" and "Plan" means a Prescription Drug Discount Card Plan operated by Plan Sponsor that is approved by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and holds a special endorsement from CMS to administer the Transitional Assistance feature of the Prescription Drug Discount Card program at pharmacies or dispensaries operated by the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations (hereafter "I/T/U endorsement").

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25

USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

/_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Co-pays, deductibles.

The parties agree that the Provider may waive any co-payments for any Indian who is enrolled in the Plan when such Indian receives services pursuant to the Plan at any pharmacy or dispensary of Provider.

5. Persons eligible for services of Provider.

(a)The parties agree that the persons eligible for services of the Provider under the Special Endorsed Plan Master Agreement and all addenda thereto shall be governed by the following authorities:

(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations
(2) Sec. 813 of the Indian Health Care Improvement Act, 25 USC §1680c

(3) Part 136 of Title 42, Code of Federal Regulations
(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program, including one or more pharmacies or dispensaries.

(b) No clause, term or condition of the Special Endorsed Plan Master Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

(1) The Indian Self-Determination and Education Assistance Act,
25 USC §450 et seq.;
(2) The Indian Health Care Improvement Act, 25 USC §1601, et seq.;
(3) The Federal Tort Claims Act, 28 USC §2671-2680;
(4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
(5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

(1) The Indian Health Care Improvement Act, 25 USC §1601, et seq.;
(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
(3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;
(4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

Provider is a non-taxable entity and as such shall not be required by Plan or Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. A Provider which is an urban Indian organization

which holds designation as a Federally Qualified Health Center shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify Plan or Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located, and shall be deemed qualified to provide services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided that such employee is currently licensed to practice pharmacy in any State. To the extent that any State exempts from state regulation a direct employee of Provider, such employee shall be deemed qualified to perform services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements pursuant to 42 CFR §431.110, the Provider shall not be required to hold a State license to receive any payments under the Special Endorsed Plan Master Agreement and any addendum thereto.

11. Re-Enrollment Period.

The Centers for Medicare and Medicaid Services has established as a matter of policy that an enrollee eligible for services from an I/T/U pharmacy shall be permitted to disenroll from a prescription drug discount card plan that does not hold a special I/T/U endorsement and to re-enroll in a plan that has received such endorsement at any time during the life of the Medicare Drug Discount Drug Card Program. Nothing in the Special Endorsed Plan Master Agreement or any other addendum thereto shall be interpreted to impede this right of re-enrollment.

12. Dispute Resolution.

Any dispute arising under the Special Endorsed Plan Master Agreement or any other addendum thereto shall be resolved through negotiation rather than arbitration. The parties agree to meet and confer in good faith to resolve any such disputes.

13. Governing Law.

The Special Endorsed Plan Master Agreement and all addenda thereto shall be governed and construed

in accordance with Federal law of the United States. In the event of a conflict between the Special Endorsed Plan Master Agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

14. Pharmacy/Dispensary Participation.

The Special Endorsed Plan Master Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the Schedule B to this Indian Health Addendum.

15. Acquisition of Pharmaceuticals.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in the Special Endorsed Plan Master Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

16. Formulary.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's formulary. The Provider is exempt from any provision of the Special Endorsed Plan Master Agreement and all addenda thereto requiring compliance or cooperation with the Plan Sponsor's or Plan's formulary, drug utilization review, generic equivalent substitution, and notification of price differentials.

17. Transitional Assistance Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim. When the toll-free number is used for non-electronic claims, Plan will verify the balance of an enrollee's Transitional Assistance subsidy remaining as of that time and obligate funds from that subsidy for payment of the Provider's claim at the point of sale. Instructions for filing and adjudicating non-electronic claims are attached as Schedule C.

18. Payment Rate.

Claims from the Provider for Transitional Assistance benefits shall be paid at the same rates as the State Medicaid program fee-for-service in the State where the Provider's pharmacy or dispensary is located, pursuant to Schedule A of this Addendum.

19. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Plan shall be supplied by Plan to Provider in paper and electronic format at no cost to the Provider. Provider shall have the right to convert such materials as it deems necessary for language or cultural appropriateness.

20. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At the request of the Plan, Provider shall provide written notification of its hours of service to the Plan.

1 See, e.g., 25 U.S.C. § 1601.
2 42 U.S.C. § 2001.
3 U.S. Commission on Civil Rights, Broken Promises: Evaluating the Native American Health Care System, July 2, 2004 (staff draft).
4 U.S. Commission on Civil Rights, A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country, July 2003.
5 Federal Disparity Index Report for 2002, showing an expenditure of $1,384 per HIS user compared to a benchmark price of $2,687 per user.
6 This number represents 85 percent of the three-year total of active users.
7 This is the number of active users, defined as at least one visit in the past three years.
8 From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.
9 This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.
10 This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.
11 Allowing the private plans to count I/T/U pharmacies toward access standards may provide incentive for private plans to contract with a few I/T/U pharmacies but only where the private plan needs the I/T/U pharmacy to meet the Tricare access standards. It will not be an incentive to contract with all I/T/U pharmacies.
12 CMS proposes this option in 69 FR at 46657.
13 One way to decrease administrative costs while at the same time assuring access for AI/AN beneficiaries who use I/T/U pharmacies is to create special endorsement PDPs and MA-PDs to serve AI/AN beneficiaries similar to the mechanism used in the Temporary Prescription Drug Discount Card Program. This matter is discussed further in our comments regarding §423.120(a)(1).

14 We submit as Attachment 1 a model tribal addendum prepared by the CMS Tribal Technical Advisory Group to be utilized by tribal and urban Indian pharmacies participating in the Temporary Prescription Drug Discount Card Program.
15 This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.

16 This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.
17 Washington State Administrative Code provides a precedent and contains sample language for this provision. WAC 284-43-200 Network adequacy. "(7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility."

18 In creating special endorsements for AI/AN CMS could establish:
* A pool of Indian-specific PDP/MA-PD who would serve regions that mirror IHS Areas, or
* Nationwide PDPs/MA-PDs to serve AI/AN in all fifty states
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Comments by The Eastern Band of Cherokee Indians
File Code CMS-4068-P

CMS-4068-P-506

Submitter : Dr. Stephen Soumerai **Date & Time:** 09/30/2004 03:09:53

Organization : Harvard Medical School

Category : Academic

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

CMS-4068-P-506-Attach-1.doc

September 29, 2004

Benzodiazepines (BZDs) are among the most widely used drugs in the elderly. They are important, low-cost, and effective medications for the treatment of seizure disorders, anxiety, panic attacks, sleep disorders and bipolar illness. BZDs also have potential for inappropriate use and misuse and are therefore targeted in drug utilization review programs.

Unlike most private insurers, which recognize the effectiveness of appropriate BZD use in a variety of conditions and provide coverage for them, they are not covered by the new Medicare prescription drug benefit. Based on almost 20 years of research on prescription drug coverage policies and BZD use conducted by the Harvard Medical School Drug Policy Research Group, we conclude that the exclusion of Medicare coverage for this important class of drugs will raise costs and reduce quality of care for Medicare beneficiaries.

This conclusion is based on the following:

1. We have shown that exclusion of coverage of older, off-patent drugs for Medicare beneficiaries results in substitution of more expensive, newer agents which are often less appropriate. (Soumerai et al, JAMA 1990; 263(6): 831-839.)

2. Restrictions on coverage of effective psychoactive drugs, such as BZDs, can exacerbate chronic mental illness and increase use of expensive, acute care services which cost many times more than any savings in use of inexpensive medications. (Soumerai et al, N Engl J Med 1994; 331:650-655.)

3. We have demonstrated that only a tiny fraction (less than 5%) of BZD recipients escalate doses or engage in problematic use. Almost all patients receiving such drugs receive very small doses. (Soumerai et al, Psychiatric Services 2003, 54(7): 1006-1011.)

4. In a large study, we found that a New York State surveillance regulation that reduced utilization of BZDs by one-half statewide had its largest impact on appropriate use and African Americans. (Ross-Degnan et al, Int J Psychiatr and Med; in press)

5. Most dual-eligibles who are now covered for BZDs and face a sudden termination of BZDs in 2006 can not afford to pay for BZDSs out-of-pocket. (Soumerai, New Engl J Med 1987; 317:550-556.) Therefore, many long-term recipients of BZDs may withdraw suddenly, causing severe withdrawal reactions, seizures, and acute escalation of symptoms, resulting in use of costly emergency room services and hospital admissions.

In summary, there is no clinical or economic rationale for excluding BZDs from coverage. Such a policy will have large, costly, unintended consequences that dwarf the savings from reduced use of these relatively inexpensive agents. A most effective approach is to use the new medication quality-improvement resources (targeted to the QIDs) to build physician education interventions (e.g., academic

detailing) that help clinicians to prescribe these drugs for the right patients, at the right doses, and for clinically appropriate durations.

We look forward to providing any additional information that might be useful in addressing this important issue.

Stephen B. Soumerai, ScD
Professor of Ambulatory Care and Prevention
Harvard Medical School and Harvard Pilgrim Health Care
Director, Drug Policy Research Group

CC: Mark McLellan MD, CMS
David Gross, PhD

CMS-4068-P-507

Submitter : Jeffrey Hall **Date & Time:** 09/30/2004 03:09:00

Organization : Jeffrey Hall

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 we 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?ve had HIV since 1986; AIDS since 1995. I currently use nineteen different prescription drugs to manage my disease, and related side effects. All of these medications are vital to my survival and modest quality of life. Here, in California, our cost of living is very high, and the cost of healthcare is very high too. I currently have full coverage between ADAP, MediCal, and Medicare. If this Medicare Drug Program goes into effect without a provision for PWAs as a special population, I will lose my home, my credit, most of my healthcare (I won?t be able to pay for it), and ultimately my life ? all in fairly short order. This Prescription Drug Program has been a potent source of anxiety and depression, for me, since initial details of the plan made its way into the public while it was being debated in the Senate. If this program is implemented without modifications for PWAs, what little dignity I have left will be stripped away and I will die before I have too.

This Drug benefit, without considering the special needs of PWAs, like myself, is not a benefit at all.

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

CMS-4068-P-508

Submitter : Dr. Gregory Mitchell **Date & Time:** 09/30/2004 03:09:35

Organization : Medicine Shoppe

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

see addendum for a specific letter to CMS

CMS-4068-P-508-Attach-1.txt

CMS-4068-P

September 21, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
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 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. In order for my patients to continue to use my pharmacy, plans must meet a
standard on a local level to ensure that all beneficiaries will have convenient and acceptable access to a local pharmacy. By permitting plans to evoke requirements based on overall service will not permit the patient equal access to services.
This 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. A similar system is being used now by many PBMs where they will
coerce patients to use their pharmacy by lower co-payments and permitting three month dispensing verses only one month locally. Any pricing difference must be related to services provided not the cost of the drug product. Plans will identify
one preferred pharmacy to use as their pharmacy thus negating the benefit of the access standards. Congress' promise was to provide patients a fair access to local pharmacies and pharmacists, but allowing Plans to count their non-preferred
pharmacies conflicts this intent. CMS should require plans to offer a standard contract to all pharmacies for their acceptance and permit beneficiaries to have a fair and equal access to services of their choice.

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

I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as health assessment, a medication 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. Less qualified providers may be defined by their training
and expertise to the way these services would be given.

Pharmacists as professionals are trained for the purpose of providing MTM services and determining which services each beneficiary needs. Because I have been trained as a clinical pharmacist,
I am able to provide MTM services in my practice which includes diabetes, asthma, anticoagulation, pulmonary, hypertension, heart failure, depression, gastrointestinal and other therapy consultations and monitoring. Plans should be encouraged to
use my services- permitting me to provide the best MTM service that will yield positive outcomes regarding the use of their medications.

In conclusion, I urge CMS to revise the regulation
to include pharmacy access standards that are in-fact standard to level the playing field
permit equal access for beneficiaries to utilize any pharmacy or pharmacist they wish to use for prescription
services
include MTM services to be provided by qualified pharmacy professionals enabling PBMs to make all decisions regarding drug distribution and MTM will not serve the beneficiaries well. Thank you for considering my opinions.

Sincerely,

Gregory E. Mitchell,
Pharm. D.
Medicine Shoppe
1120 Franklin
Lexington, Missouri
64067

CMS-4068-P-509

Submitter : Mr. Ivan Womboldt **Date & Time:** 09/30/2004 03:09:15

Organization : Cancer and Blood Institute

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

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

To Whom It May Concern:

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

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

It is imperitive that Doctors be able to treat unfettered by restriction, in this highly drug resistant population.

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

Sincerely,

Ivan Womboldt

CMS-4068-P-510

Submitter : Steve Waldron **Date & Time:** 09/30/2004 03:09:19

Organization : Steve Waldron

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am a Benefits Specialist providing services to persons with disabilities on SSI/SSDI under the Benefits Planning, Assistance, and Outreach (BPAO) program. I work with many individuals who are dual eligibles (concurrent SSI and SSDI beneficiaries) and require extensive and/or expensive prescription medications. I am only representing my self and am not representing my BPAO in this e-mail comment. However, I do want you to know my background which gives me special insight into the needs of these dual eligibles.

Under the proposed rules for MMA and the Medicare drug formulary, it appears that a significant number of dual-eligibles who require multiple medications will likely not have access to all the specific medications they require.

I encourage you to revise the your rules to ensure barrier free access to necessary prescription medications for these beneficiaries with disabilities.

Thank you for your consideration of my comments.

Sincerely,
Steve K. Waldron
Highland Springs, VA 23075

CMS-4068-P-511

Submitter : Gus Sorenson **Date & Time:** 09/30/2004 03:09:54

Organization : Wisconsin Paralyzed Veterans of America

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from Wisconsin PVA.

CMS-4068-P-511-Attach-1.txt

CMS-4068-P

September 30, 2004

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

Dear Sir or Madam:
The Wisconsin Paralyzed Veterans of America [WPVA welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. WPVA is a non-profit Veterans Service Organization [VSO]. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

Targeted and hands-on outreach to Medicare beneficiaries with disabilities, especially those with low-

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

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

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

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

people who are dually eligible for Medicare and Medicaid
people who live in nursing homes, ICF-MRs
and other residential facilities, people who have life threatening conditions
people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS. Impose new limits on cost management tools: In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug. We urge CMS to prohibit or place limits on the use of certain cost containment policies, such as unlimited tiered cost sharing, dispensing limits, therapeutic substitution, mandatory generic substitution for narrow therapeutic index drugs, or prior authorization. We are also concerned that regulations will create barriers to having the doctor prescribe

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

Thank you for your consideration of our views.

With kindest regards,
Gustave R. "Gus" Sorenson,
Government Relations Director
Wisconsin Paralyzed Veterans of America

CMS-4068-P-512

Submitter : Thomas Nitschke **Date & Time:** 09/30/2004 03:09:26

Organization : The Kolbe Project

Category : Social Worker

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.

The HIV+ population is on the rise. It is only right that this population have access to Medicare/Medicaid to continue their drug regimen.

CMS-4068-P-513

Submitter : Miss. Kim Ruff-Wilbert **Date & Time:** 09/30/2004 03:09:22

Organization : United Spinal Association

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disablity community

CMS-4068-P-513-Attach-1.doc

September 30, 2004

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

To Whom It May Concern:

The United Spinal Association welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. United Spinal Association, a national veterans service and disability rights organization, is dedicated to enhancing the quality of life for individuals with spinal cord injury or spinal cord disease by assuring quality health care, promoting research, and advocating for civil rights and independence by educating the public about these issues and enlisting their help to achieve these fundamental goals. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

DELAY THE IMPLEMENTATION OF THE PART D PROGRAM FOR DUAL ELIGIBLES

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

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

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

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

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

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

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

* Individuals who are dually eligible for Medicare and Medicaid

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

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS

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

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES

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

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

REQUIRE PLANS TO DISPENSE A TEMPORARY SUPPLY OF DRUGS IN EMERGENCIES

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

United Spinal believes it is imperative that CMS look at delaying the implementation of the Part D program for dual eligibles and expanding outreach to Medicare beneficiaries with disabilities. In addition, we recommend CMS designate special populations who will receive affordable access to alternative formularies, impose new limits on cost containment tools, strengthen and improve inadequate and unworkable exceptions and appeals processes, and require plans to dispense. Thank you for your consideration of United Spinal Association’s views. If you have any questions, you may contact us at 202-331-1002.

Sincerely,

Jeremy Chwat
Director of Public Policy
United Spinal Association

Submitter : Ms. Robert Narveson **Date & Time:** 09/30/2004 03:09:56

Organization : Ms. Robert Narveson

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

I work for a small chain of pharmacies that primarily service the rural market place. Many times the needs of rural consumers are forgotten and treated like second rate citizens. As the regulations are currently written and being proposed, community pharmacy is being dealt several severe blows; please consider the following issues so we can help keep rural pharmacy services alive. Here are key issues that need to be addressed with CMS.

1. Many times this is the only pharmacy in town and access is critical. Mail order cannot serve the immediate needs of a customer for a pain med, ant-biotic, etc. The proposed regulations do not properly implement the so-called TriCare pharmacy access standards that are in place today, and therefore would seriously reduce the ability of patients to obtain their prescriptions from their trusted local community pharmacist.
These standards need to be set at the minimum distance we currently are seeing PBM contracts that use much lower standards to force patients to use their own mail order programs. A standard that requires a senior to drive 60 miles mid winter to receive their prescription is clearly not putting the needs or health of the consumer first.

2 The new regulations should prohibit plans (PBMs) from using economic incentives that coerce beneficiaries to use mail order services to obtain their medications. Please include needed safeguards that coerce patients into mailorder.
We must also closely scrutinize the program to assure that contracts offered to providers for mail order match what the PBM?s own mail facility accepts. I feel the best method to prevent fraud would be to not allow the plan providers mail order pharmacy to fill prescriptions in that region. A system of rebates, spread pricing and private NDC?s is a recipe for disaster. PBM?s and drug manufacturers are already among the highest earning companies in the country. If the door is left open rest assured their will be additional costs.

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

4. The government needs to be allowed to use its purchasing power to negotiate its prices with the manufacturers.

We currently have a system that is full of questionable practices rebates, spread pricing, kick backs where the plan pays more for the drug than the provider is paid. The Medicare system needs to make sure that we are putting the concerns of the patient first rather than the profits of the PBM's, if this happens rural pharmacy services will be dealt a blow that they will not be able to survive.

CMS-4068-P-515

Submitter : **Daniel Carpenter** **Date & Time:** **09/30/2004 03:09:46**

Organization : **Cardinal Health Nuclear Pharmacy Services**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

Thank You for allowing me to take this instance to express my serious concerns on the proposed regulation to implement the Medicare prescription drug benefit. Please accept the following comments for consideration as CMS develops the final regulation.

Medication Therapy Management Program:
My primary concern lies in the proposed Medication Therapy Management Program. I strongly believe there needs to be improvements to who is eligible for these services, how they are identified and how both patients and providers are informed.

Patients at the mercy of two or more chronic diseases or on two or more drugs should qualify for the medication therapy management services (MTMS). Patients with a chronic disease that leads to other health issues, as they often do, should also qualify for MTMS. An example would be a diabetic patient. Once a beneficiary becomes eligible for MTMS, the beneficiary should most certainly be eligible for an entire 12 months.

The plan must be required to identify new targeted beneficiaries on a monthly basis, as personal health is always changing. It is pharmacists and physicians that should identify if and when a patient becomes eligible for MTMS. The plan should be required to inform patients, pharmacists and other providers when a patient becomes eligible for MTMS. The plans also must be required to inform patients about their choices (including their LOCAL pharmacy) for obtaining MTMS and covering MTMS even if patients reach the "donut hole".

Finally, Pharmacists should be allowed to provide MTMS to non-targted beneficiaries and CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries.

Thank you for your time and consideration of my concerns.

Sincerely,
Daniel E. Carpenter, RPh., B.C.N.P.
Executive Board Member for The Connecticut Pharmacists' Association
Home
112 Belle Woods Drive
Glastonbury, Ct. 06033
860-633-1334
Work
628 Hebron Ave Bldg. #4
Glastonbury, Ct. 06033
860-657-2520
Daniel.Carpenter@Cardinal.com

CMS-4068-P-516

Submitter : Mr. James Toews **Date & Time:** 09/30/2004 04:09:33

Organization : OR Dept of Human Services

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file

CMS-4068-P-516-Attach-1.pdf

Oregon
Theodore R. Kulongoski, Governor

Department of Human Services
Seniors and People with Disabilities
500 Summer Street NE, E02
Salem, OR 97301-1073
Voice (503) 945-5811
Voice 1-800-282-8096
Fax (503) 373-7823
DHS

September 29, 2004

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C5-11-24
Baltimore, Maryland 21244-1850

Dear Dr. McClellan:

Thank you for the opportunity to review and comment on the proposed regulations for the Medicare program: Medicare Prescription Drug Benefit.

Although we support some of the proposed regulations, we have many concerns about the impact of the regulations on beneficiaries. Our comments are attached.

We look forward to the expanded access this will provide many Oregonians in need of prescription drugs.

Thank you for your consideration of our comments on behalf of Oregon's Medicare beneficiaries.

Sincerely,

Lynn Read

Lynn Read, Administrator
Office of Medical Assistance Programs

James Toews, Assistant Director
Seniors and People with Disabilities

Enclosure

Oregon Department of Human Services Comments on the following proposed CMS rules:

42 CFR Parts 403, 411, 417, and 423
[CMS-4068-P]
RIN 0938-AN08
Medicare Program; Medicare Prescription Drug Benefit
Centers for Medicare & Medicaid Services (CMS), HHS.

Overview of Comments and Concerns

- Allow states to meet their statutory requirement to perform low-income subsidy eligibility determinations with the current state processes for determining Medicaid eligibility for dual eligible beneficiaries. These current processes will form the basis for deeming eligibility to a majority of Medicare beneficiaries who will receive the low-income subsidies. (#1)
- Include ICF/MR and Home and Community Based Services (HCBS) waiver facilities in the definition of "long term care facility" and enrollees in HCBS waivers as "institutionalized". (#2)
- Allow Home and Community-Based waiver clients to be considered "institutionalized" and not pay copays. (#2)
- Assure access to long-term care pharmacies for all residents of nursing facilities, ICF/MRs, and HCBS facilities and homes, at no additional cost, at least for dual eligibles. (#2&3)
- Require Part D plans to grandfather coverage of medications for current recipients of anti-psychotics, anticonvulsant, and other specified medications to avoid access and treatment disruptions. (#4)
- Require Part D plans to use evidence-based information in the development of the formularies and establish stronger beneficiary safeguards in the selection of the formulary. (#5)
- Require Part D plans to reimburse current pharmacies for current medications for at least 6 months for dual eligibles, in order to ease the transition impact. (#6)
- Develop a system to notify all facilities of their residents' choice of plans. (#6)
- Clarify the definition of "Full benefit dual individual" to include 1915c waiver programs and 1619(b) and other Medicaid-protected classes of clients. (#10)
- Eliminate burdensome PACE administrative requirements. (#11)
- Additional Beneficiary Protections, particularly with Coverage Determinations and formulary exceptions (#12 & 13)

Oregon Department of Human Services detailed comments on the following proposed rules:

42 CFR Parts 403, 411, 417, and 423
[CMS-4068-P]
RIN 0938-AN08
Medicare Program; Medicare Prescription Drug Benefit
Centers for Medicare & Medicaid Services (CMS), HHS.

Issue 1: The MMA requirement on states to do eligibility determination is an unfunded mandate.
Sections in proposed rules: Pg 549 (General Provisions) & Pgs 678-680 (General Provisions) & Pg 796 (General Provisions) & 423.774(a) and 423.904 & 423.774(c)

Concern: Both the MMA and the proposed regulations give responsibility to the State Medicaid offices and the Social Security Administration (SSA) to determine eligibility for the low-income subsidies for beneficiaries up to 150% FPL. This will increase workload and yet federal funds are only available to cover ½ of the cost. This requirement to serve a new population is a significant unfunded mandate and requires states to provide eligibility determination for a population unknown to Medicaid offices, using criteria not used by these offices, through an information system not yet developed.

This unfunded mandate includes the following:

- *Central administration.* There is an increased burden in staff time to
    - develop and maintain a system to implement the subsidy eligibility determination, collect the information, and communicate data back to CMS,
    - notify deemed subsidy eligibles of their subsidy eligibility and
    - provide training necessary to ensure that field staff properly implement the subsidy determination.

- *Assisting current clients.* For known clients (usually between 0 and 135% FPL in Oregon), there will be increased workload in providing clients with information and performing appeals.

- *Determining subsidy eligibility for unknown clients.* A portion of the population eligible for the low-income subsidies – mainly those beneficiaries with incomes between 135% and 150% of poverty – will be a new population not currently seen in Medicaid offices. In Oregon, we estimate this to be an additional 26,000 clients. If verbal CMS communication and the Medicare Issue Paper #4 are accurate and states are allowed to simply collect applications and ship them to SSA for determination and redetermination, the regulations need to reflect this. Otherwise, we estimate this increased responsibility to cost the State an additional $4 million in the next biennium. If the regulations are not changed to make it clear that states do not have to determine eligibility for populations currently unknown the Medicaid offices, even if States may send most applications to SSA, States will still be required to develop the system, adopt the administrative rules,

and provide the training just in case some clients demand that the Medicaid office performs the eligibility determination.

Proposed changes:

- 423.774(a) and 423.904 should allow states the option to either make the eligibility determination or collect applications and send them to SSA for determination and redetermination. Although MMA gives the responsibility to both SSA and state Medicaid offices, state Medicaid agencies already determine eligibility for programs which result in beneficiaries being deemed eligible for Part D for income levels between 0 and 135% FPL. Thus, we believe that states have already met the MMA statutory intent of completing low-income subsidy eligibility.

  434.774(a) should state, "Determinations of eligibility for subsidies under this section are made by the State under its State plan under title XIX if the individual is found eligible for a Medicaid program with the Medicaid agency, and if not, the Commissioner of Social Security . . . . "

- If the regulations are revised to make it clear that States are allowed to forward applications for the low-income subsidy to the Social Security Administration for determination, the regulations should specify that the States do not also have responsibility for redeterminations and appeals for those applications and that there is no expectation that States screen those applications for Medicare buy-in programs.

Issue 2: The definitions of "long term care facility" and "institutionalized" are too limited, requiring copayments on many dual eligibles served in the community.
Sections in proposed rules: Page 98 (General Provisions) & 423.100, 423.772, & 423.782 (a)(2)(iii)

Concern:

- The definitions of "long-term care facility" and "institutionalized individual" include only hospitals and nursing facilities and those in them, not ICF/MRs. In Oregon, a significant portion of our population (70%) in an ICF/MR is also Medicare eligible.

- The definition in the regulation also does not include beneficiaries served in Medicaid home and community-based services (HCBS) waivers. States have to assure CMS that individuals in waiver programs would be institutionalized if not receiving waiver services and are receiving needed services. Many waiver participants reside in facilities (Assisted Living Facilities and Residential Care Facilities) and homes that use long-term care (LTC) pharmacies and Oregon's licensing requirements for these waiver facilities require many of the same pharmaceutical protections as do nursing facilities, such as Medication Administration Records and unit-dose packaging.

Many of these individuals reside in facilities that have many similarities to nursing homes and ICF/MRs. Because of centralized ordering of medications by the facility, deliveries of medication directly to a central office in the facility, and medication administration by the facility, the individual beneficiary may have no contact with the pharmacy. Expecting these facilities to collect copays is not reasonable.

CMS also required that individuals pay into the cost of these waiver services and allows a medical deduction for all copays. Payment of the copays by these individuals will directly come out of their pay-in and therefore, reduce funding available through long-term care Medicaid, causing another cost shift to State Medicaid.

Proposed changes: Include clients enrolled in HCBS waivers and, at a minimum, those receiving care in an ICF-MR in the definitions of "long term care facilities" and "institutionalized", in order to assure access to LTC pharmacies and exempt the populations from copays.

Issue 3: The rules do not assure access to long-term care pharmacies
Sections in proposed rules: 423.120 & 423.124

Concerns:

- Individuals in nursing homes, ICF/MRs, and other community-based care homes and facilities need to be assured access to long term care pharmacies because of the protections and services provided, such as unit-dose packaging, Medication Administration Records, emergency deliveries, etc. This is particularly true in Oregon where so many dual eligibles receive care in such facilities under 1915(c) HCBS waivers. Continued access of these individuals to long-term care pharmacies is important for their health and safety and helps states assure CMS of waiver compliance.

- The access to out-of-network pharmacy protections in 423.124 will not protect nursing facility residents' access to long-term care (LTC) pharmacies, much less residents in other facilities. Oregon licensing rules require all facilities to provide consumer choice of pharmacy. The "reasonably be expected" standard will not assure access to this important safeguard.

- The services from LTC pharmacies must be at no additional cost to dual eligibles. Residents in Medicaid LTC services are only allowed a small monthly allowance for personal expenses (in nursing facilities, $30); the remainder of their funds contributes to their cost of care. Passing those additional costs to the beneficiary is untenable. For those in community-based care who have some funds, a portion of those costs will become a cost shift to states through the allowable medical deduction of the client pay-in.

- LTC facilities typically contract with LTC pharmacies, and these are typically multi-year contracts. Ultimately, the clients will suffer if the regulations do not protect access to these pharmacies.

- As the additional cost of these pharmacies is included in the state's base pharmaceutical costs used in the calculation of the State Phase-down Contribution, not including this requirement will cause States to double pay for these services – once through the Phase-down Contribution and then again directly through the LTC rates, in order to protect the beneficiaries' health.

Proposed changes:

- 423.120 needs to assure access to LTC pharmacies for individuals residing in these sites, at no additional cost for, at least, dual eligible beneficiaries. Without this requirement, PDPs will have a financial incentive to not contract with these pharmacies – both because of the increased cost of these pharmacies but also as a "cherry-picking" mechanism for a very costly population, causing discrimination. Not to assure this access will endanger their health and safety and also result in a cost-shift to states in Medicaid LTC.
- There should be adequate reimbursement or an enhanced dispensing fee associated with these clients to offset the higher cost of dispensing and services required.
- The assurance of access to a LTC pharmacy needs to include not only residents of nursing facilities, but also other residential services and facilities funded through HCBS waivers.
- Drug plans need to demonstrate their ability to serve LTC beneficiaries.

Issue #4: Formularies and lack of grandfathering of beneficiaries medications will cause disruptions in drug access

Sections in proposed regulation: 423.120 (b) (2)

Concern: Although a formulary can be a great cost-containment tool and can direct initial prescriptions, there are certain medications that can be dangerous to change, once the medication is started. In particular, anti-seizure, atypical antipsychotic, antidepressant, and mood stabilizing medications should not be limited for current recipients of these medications. Similarly, other medications not covered by Medicare part B including HIV, transplant, hemophiliac and cancer drugs should not be disrupted for beneficiaries during the initial enrollment period. Failure to grandfather these medications will pose significant risks to beneficiaries, and result in a cost-shift to States to provide LTC to those individuals harmed by the transition.

> **Proposed changes:** At a minimum, the regulations should require PDPs to provide current medications to current recipients of antipsychotic, antidepressant, mood stabilizing, anticonvulsants, HIV, transplant, hemophiliac and cancer medications through a grandfathering process.

Issue # 5: Address the negative incentives that will create ongoing formulary issues

Section in proposed regulation: 423.120 (b)(2)

Concern: PDPs are not at risk for the down-stream health costs from an inadequate drug formulary. There is also an incentive to restrict access in drug classes in order to negotiate better prices from manufacturers.

Only requiring two drugs per class does not provide enough flexibility to craft a formulary that promotes the health and safety of the beneficiaries. For example, more than two options are necessary in classes such as anticonvulsant, atypical antipsychotic, transplant, HIV, cancer, antidepressant, mood stabilizing, and anti-hemophilic medications. Only two opioid analgesics is inadequate considering the variation in individual response to pain, allergies, and the need to have both long-acting and short-acting products by various routes.

Proposed changes:
The regulations could be revised to establish the following additional criteria for the formulary development process:

- require the use of evidence-based drug reviews by the pharmaceutical and therapeutics committee,
- require transparency in decision-making
- require conflict of interest policies for decision-makers on the pharmaceutical and therapeutics committee,
- require PDPs to monitor feedback from providers, health plans and beneficiaries, on formulary adequacy and needed changes, and
- Establish standards for a formulary exception process prior to appeal hearings.

Issue # 6: Transitioning all duals successfully will not be possible under current timelines.
Section in proposed regulations: 423.104

Concerns:

- The transition of dual eligibles into Part D will adversely impact a very vulnerable population unless adequate provisions are made. This is an incredibly complicated system change and occurs over the holiday season. At best (which is highly unrealistic), dual eligibles will have 3 weeks in order to identify which current medications do not match their new plan's formulary, contact their physician and obtain a new prescription, and send that new prescription to their new pharmacy and pick up their medications. In addition, they may need to switch the remaining prescriptions to an in-network pharmacy. When you consider dual eligibles who reside in some sort of congregate care, either nursing facilities or a variety of community based care settings, this becomes even more troublesome. Facilities frequently use one major pharmacy and in this transition, there will have to be extensive, timely work with residents to ensure that appropriate plans are chosen or facilities will have to develop business relationships and communication with numerous, potentially unknown pharmacies.

- Currently auto-assignment into Drug Plans is set for May 2006 for dual eligibles. This will result in a serious lapse of coverage for beneficiaries who do not choose a plan and subsequently, a significant risk to their health.

Proposed changes: In order to protect the health and welfare of the most vulnerable beneficiaries, CMS should incorporate the following protections:

- Require Part D plans to reimburse **current pharmacies** for **current medications** for at least 6 months. This will allow a smooth transition for all parties and allow

prescriptions to be switched to formulary medications and allow everyone to switch to in-network pharmacies in a manner that does not endanger health.

- CMS must develop the system to notify the facilities of the residents' choice of plans.
- The auto-assignment date should be changed to December 1, 2005 to prevent any loss of coverage but allow a window for some to choose a plan that best meets their needs, while allowing notification to auto-assigned individuals of their Drug Plan and a minimal opportunity to switch prescriptions to match the new formulary.

Issue #7: The rules contain many additional pharmacy access issues

PDP pharmacy provider contracts, *423.120(a)(4)(i)*.
Concern: The regulations do not adequately protect access to LTC pharmacies.

Proposed changes:

- PDP plans should be required to contract with LTC pharmacies, and CMS should provide a model addendum to the standard contract (similar to the one considered for I/T/U facilities) with an enhanced dispensing fee or reimbursement to LTC, ICF/MR, Indian Health Service/Tribal Clinic/Urban Indian Clinics **(**I/T/U) and Rural Health Pharmacies.
- PDP plans should not be allowed to refuse pharmacy participation of pharmacies that agree to the standard contract terms, so CMS review should ensure that contract and model addendum do not allow discrimination against special needs populations and the facilities and pharmacies at which they seek services.

Rural Health Clinics (RHCs)
Concern: It's unclear as to why 422.316 and 422.527 only lists FQHCs. Some Medicare certified RHCs do have pharmacies and provide valuable access in areas that frequently lack sufficient health care. RHCs under PPS states are required to provide 100% cost based reimbursement.

Proposed change: Medicare certified RHCs should also be reimbursed at 100% of their rate of reimbursement.

Home delivery/ mail order pharmacy services, *423.120 (a)(2) and (6)*.
Concern: Oregon agrees that mail order should be an available option, but not mandatory. Oregon disagrees that the client should be required to pay a differential between mail order and retail services. Mail order should be encouraged through service and the ability to get up to three months supply.

Proposed change: Specify in the regulations that clients do not pay a differential between mail order and retail services and that clients have access to three-months supply of drugs through mail order.

Issue #8: Current Phase-Down State Contribution calculation may not save Oregon funds
Section in proposed regulation: Subpart S – Special Rules for States Eligibility Determinations for Subsidies and General Payment Provisions (423.900 et seq) address the clawback provisions]

Concern: CMS' estimates of cost savings will not materialize in Oregon because Oregon does not have a State Pharmacy Assistance Programs (SPAP), and our Public Employees Retirement system will not save. Additionally, there could be a potential cost to Oregon depending on how the Phase-Down State Contribution is calculated.

Proposed changes:

- Include provisions to allow states to make adjustments for third party collections received after 2003 for pharmacy services provided during 2003.

- Provide clarification in the regulations that sufficient flexibility will be allowed in the calculation of the Phase-Down State Contribution to account for differences between state programs

Issue #9: Including QMB, SLMB, and QI beneficiaries as full subsidy
Sections in proposed regulations: Pg 545 (General Provisions) and 423.773(c)

Oregon is pleased that the Secretary elects to exercise the authority to treat QMBs, SLMBs, and Q1s as full subsidy individuals. Without that protection, individuals may seek waivered services that are marginally, if at all, needed services in order to become a "Full benefit dual individual" and have better access to medications.

Issue #10: Definition of full benefit dual individual should be clarified further.

Sections in proposed rule: Pg 545 (General Provisions) and 423.772

Concern: The regulations do not specify that individuals receiving care in 1915c waiver programs are included in the definition of "Full benefit dual individual," while 1115 demonstrations are mentioned. If this is not correct, that would create significant difficulties. In addition, it is assumed that 1619(b) and other Medicaid-protected classes of clients are also considered as to be "receiving benefits under the SSI program" and therefore, eligible for full subsidies.

Proposed change: The regulations should confirm that all Medicare beneficiaries eligible for Medicaid coverage are eligible for the full subsidies, including 1915 c waiver programs and 1619(b) and other Medicaid-protected classes of clients.

Issue #11: PACE Administrative Requirements are burdensome.
Sections in proposed regulations: Pgs 698 through 715 (General Provisions) and 423.265 (c) (3)

Concern: PACE is a unique service delivery model. Requiring these organizations, in order to only continue business as usual, to first, develop a bid and second, to have it actuarially certified is administratively burdensome and costly.

Proposed changes:

- CMS intended automatic waivers should be implemented.
- PACE plans should be exempted from developing an actuarially certified bid.

Issue #12: Rights of PDP enrollees needs to be strengthened
Sections in proposed regulations: 423.44 (d), 423.562 and 423.578

Concern: Involuntary disenrollment, particularly for disruptive behavior, could pose significant financial, person, and medical hardship on a beneficiary likely to be experiencing mental health difficulties. This dual population contains beneficiaries with cognitive and psychiatric disabilities who may be perceived by others as being willfully disruptive. Dual eligibles who are losing Medicaid coverage for their medications cannot lose access to important medications because they are disenrolled from drug plans without an alternative.

Proposed change: Remove "disruptive behavior" from the reasons for disenrollment, at least for people with cognitive or psychiatric impairments, or provide an alternative form of medication coverage that is available without a lapse in coverage.

Concern: This vulnerable population's ready access to medications can be vital to their health. Any process that does not give an immediate answer to the request for any medication at the point of sale will create an unnecessary burden to beneficiaries and a barrier to access. The exception process must be appropriate and timely.

Proposed change: A definition of "timely" should be created to include an immediate reply at the point of sale for specific prescriptions. The exception process (anticipated to be a prior authorization process) should be within the timeframe of the CMS Medicaid requirement of a 24 hour turnaround when adequate information is submitted.

Concern: Coverage determinations including the formulary exception process (423.578) need flexibility to support beneficiary continuation of benefits and consideration of the specific circumstances of a particular beneficiary.

Proposed change: Formulary exception criteria needs explicit flexibility to consider the specific circumstances of a particular beneficiary.

Concern: During this coverage determination process, clients could be adversely impacted by a change in their drugs without continuation of their disputed medications.

Proposed change: The regulations should provide adequate protection for clients to continue to receive their disputed drugs during the grievance process. This is a right Oregon now provides for our clients.

Issue #13: Tribal Issues.

Indian Health Service/Tribal Clinic/Urban Indian Clinic (I/T/U) pharmacies 423.120(a)(1)

The Federal government has a historical and unique legal relationship with the American Indian/Alaska Native people, as reflected in the Constitution, treaties, Federal laws, and the course of dealings of the US with AI/AN Tribes, and the United States' resulting government to government and trust responsibility and obligations to the AI/AN people. Medicare Part D contains language or in some cases lacks language necessary to assure adequate access for AI/AN elders, minimize financial burdens and hardships for the AI/AN Tribes and their members.

These recommendations are made with the understanding that they apply to AI/AN people as defined in 43 U.S.C.:
(a) A member of a federally recognized Indian tribe, band or group;
(b) An Eskimo or Aleut or other Alaska native enrolled by the Secretary of the Interior pursuant to the Alaska Native Claims Settlement Act, 43 U.S.C. 1601; or
(c) A person who is considered by the Secretary of the Interior to be an Indian for any purpose.

Concern: The Indian Health Care Improvement Act is designed to assure improved health care for AI/AN. Imposing premiums, deductibles and co-payments on AI/AN Elders will create access and financial barriers.

> **Proposed change:** AI/AN population should be exempt from premiums, deductibles and co-payments.

Concern: CMS interpretation of IHS coverage as excluded from the true out-of-pocket effectively denies catastrophic coverage to Indian health program users.

> **Proposed change:** CMS interpretation should be reversed to allow I/T/U drug expenditures to be included in the true out-of-pocket expenditures cumulated to activate catastrophic coverage.

Concern: Geographic, financial and health care infrastructures vary widely throughout Indian country. Not having the choice based upon infrastructure to contract as a network pharmacy or alternatively be an out-of-network pharmacy able to address the reasonable needs of the AI/AN beneficiaries would potentially create financial hardships on the I/T/U Pharmacy and consequently the beneficiaries that they serve.

> **Proposed change:** I/T/U Pharmacies should be given the choice based on the individual sites' infrastructure whether to be included in the PDP pharmacy networks (with a similar model addendum to the standard Plan contract contemplated for the Long term Care Pharmacies) or be designated at an "Out of Network" site provided regulations explicitly allow culturally appropriate services to be included in consideration when enrollees cannot reasonably be expected to obtain such drugs at a network pharmacy (423.124(a)).

Concern: As mentioned above in Issue #7, it's unclear as to why 422.316 and 422.527 only lists FQHCs. Some Medicare certified RHCs do have pharmacies and provide valuable access in areas that frequently lack sufficient health care. RHCs under PPS states are required to provide 100% cost based reimbursement. Additionally, most Tribes that receive any IHS funding are designated 638 facilities, which are reimbursed at 100% of costs.

Proposed change: I/T/Us should be assured 100% of their I/T/U rate of reimbursement.

Concern: CMS rule discussion suggest that I/T/U pharmacies may be included by PDPs to meet the Plan's rural access requirements despite the understanding that AI/AN beneficiaries enrolled with a Plan will seek their services through IHS/Tribal and Urban Indian facilities. A number of sections of the Medicare Part D bill contain language that could potentially shift costs of the program to the Tribes.

Proposed change: Tribes should be consulted on whether or not their lands are to be included in a CMS service area. CMS has no authority to designate AI/AN lands as service areas without explicit permission from the AI/AN Tribe.

CMS-4068-P-517

Submitter : **Tracey Carpenter** **Date & Time:** **09/30/2004 04:09:25**

Organization : **Medicine Shoppe Pharmacy**

Category : **Pharmacist**

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

Thank You for allowing me to take this instance to express my serious concerns on the proposed regulation to implement the Medicare prescription drug benefit. Please accept the following comments for consideration as CMS develops the final regulation.

Medication Therapy Management Program
My primary concern lies in the proposed Medication Therapy Management Program. I strongly believe there needs to be improvements to who is eligible for these services, how they are identified and how both patients and providers are informed.

Patients that are the mercy of two or more chronic diseases or on two or more drugs should qualify for the medication therapy management services (MTMS). Patients with a chronic disease that leads to other health issues, as they often do, should also qualify for MTMS. An example would be a diabetic patient. Once a beneficiary becomes eligible for MTMS, the beneficiary should most certainly be eligible for an entire 12 months.

The plan must be required to identify new targeted beneficiaries on a monthly basis, as personal health is always changing. It is pharmacists and physicians that should identify if and when a patient becomes eligible for MTMS. The plan should be required to inform patients, pharmacists and other providers when a patient becomes eligible for MTMS. The plans also must be required to inform patients about their choices (including their LOCAL pharmacy) for obtaining MTMS and covering MTMS even if patients reach the 'donut hole'.

Finally, Pharmacists should be allowed to provide MTMS to non-targted beneficiaries and CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries.

Thank you for your time and consideration of my concerns.

Sincerely,

Tracey L. Carpenter, RPh.
Home
112 Belle Woods Drive
Glastonbury, Ct. 06033
860-633-1334
Work
Medicine Shoppe Pharmacy
27 Hayes St.
Manchester, Ct. 06040
860-649-1025

CMS-4068-P-518

Submitter : Mr. Peter Sposato **Date & Time:** 09/30/2004 04:09:47

Organization : Cardinal Health Nuclear Pharmacy Services

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

Thank You for allowing me to take this instance to express my serious concerns on the proposed regulation to implement the Medicare prescription drug benefit. Please accept the following comments for consideration as CMS develops the final regulation.

Medication Therapy Management Program
My primary concern lies in the proposed Medication Therapy Management Program. I strongly believe there needs to be improvements to who is eligible for these services, how they are identified and how both patients and providers are informed.

Patients that are the mercy of two or more chronic diseases or on two or more drugs should qualify for the medication therapy management services (MTMS). Patients with a chronic disease that leads to other health issues, as they often do, should also qualify for MTMS. An example would be a diabetic patient. Once a beneficiary becomes eligible for MTMS, the beneficiary should most certainly be eligible for an entire 12 months.

The plan must be required to identify new targeted beneficiaries on a monthly basis, as personal health is always changing. It is pharmacists and physicians that should identify if and when a patient becomes eligible for MTMS. The plan should be required to inform patients, pharmacists and other providers when a patient becomes eligible for MTMS. The plans also must be required to inform patients about their choices (including their LOCAL pharmacy) for obtaining MTMS and covering MTMS even if patients reach the "donut hole".

Finally, Pharmacists should be allowed to provide MTMS to non-targted beneficiaries and CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries.

Please don't waste America's most accessible resouce on medication and its proper usage.

Thank you for your time and consideration of my concerns.

Sincerely,

Peter J. Sposato RPh, BCNP

CMS-4068-P-519

Submitter : Mr. Erick Duarte **Date & Time:** 09/30/2004 04:09:21

Organization : Blue Grass Care Clinic/Lexington Ky

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I am responding to the proposed rule "MEDICARE PROGRAM; MEDICARE PRESCRITION DRUG BENEFIT, 69FR 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 deignate people living wth HIV/AIDS as a SPECIAL POPULATION and ensure they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the PUBLIC HEALTH SERVICE HIV treatment guidelines.
I am a Medicare recipient as well as a consumer for this medications and this reform will affect me in a detrimental way.
Thank you for considering my comments as you finalize the regulations.
Erick C Duarte
6414 Lakeview Dr
Catlettsburg, Ky 41129
606 739 0386 (home)
704 451 7098 (cell)

Submitter : Mr. Timothy Cornell **Date & Time:** 09/30/2004 04:09:41

Organization : UNM

Category : Other Health Care Professional

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

? I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as performing a health assessment, formulating a medication treatment plan, monitoring and evaluating a patient?s response to therapy, etc.
? Face-to-face interaction between the beneficiary and the patient is the preferred method of delivery whenever possible. The initial assessment should always be face-to-face.
? I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004.

GENERAL PROVISIONS

? I want to be able to serve my patients. To do that, CMS should revise the pharmacy access standard to require plans to meet the TRICARE requirements on a local level, not on the plan?s overall service level. Requiring plans to meet the access standard on a local level is the only way to ensure that all beneficiaries have convenient access to a local pharmacy.
? If plans are only required to meet the pharmacy access standard ?on average? across the plan?s service area, the plan will have less incentive to offer pharmacies acceptable contracts to enroll them in the plan?s pharmacy network. Requiring plans to provide patients fair access to their pharmacy was a promise made by Congress that CMS should honor.
? I am concerned that the proposed regulation allows plans to establish preferred and non-preferred pharmacies. This could affect my ability to continue to serve my patients.
? Allowing plans to distinguish between pharmacies could allow plans to drive beneficiaries to a particular pharmacy. This goes against Congressional intent. Congress wanted to ensure that patients could continue to use the pharmacy and pharmacist of their choice.
? Only preferred pharmacies should count when evaluating whether a plan?s pharmacy network meets the pharmacy access standard. That will help patients access a local pharmacy for their full benefit.
? ?Access? isn?t ?access? if my patients are coerced to use other pharmacies.
? If plans are allowed to charge a higher price for an extended supply obtained from a community pharmacy, CMS should clarify that the price difference must be directly related to the difference in service costs, not the cost of the drug product.
? Congressional intent, as identified in the colloquy of Senators Grassley and Enzi, opposes making the cost-difference a tool for coercing beneficiaries away from their pharmacy of choice.
? Patients with two or more chronic diseases and two or more drugs should qualify for medication therapy management services (MTMS).
? Who will benefit from MTM can change, so plans should be required to identify new targeted beneficiaries on a monthly basis.
? Plans should be required to inform pharmacists who among their patients are eligible for MTM.
? Pharmacists and physicians should also be able to identify eligible beneficiaries.
? Plans must be required to inform beneficiaries when they are eligible for MTMS and inform them about their choices (including their local pharmacy) for obtaining MTMS.
? Once a beneficiary becomes eligible for MTMS, the beneficiary should remain eligible for MTMS for the entire year.
? CMS must clarify that plans cannot prohibit pharmacists from providing MTMS to non-targeted beneficiaries. Pharmacists should be allowed to provide MTMS to non-targeted beneficiaries. Because MTMS is not a covered benefit for non-targeted beneficiaries, pharmacists should be able to bill patients directly for the services.
? Pharmacists, the medication expert on the health care team, are the ideal providers of MTMS.
? CMS must clarify that plans cannot require beneficiaries to obtain MTMS from a specific provider (such as a preferred pharmacy). Requiring beneficiaries to obtain MTMS from a specific provider would disrupt existing patient-pharmacist relationships.
? Plans must be required to pay the same fee for MTMS to all providers. For example, plans should be prohibited from paying pharmacists at non-preferred pharmacies less than pharmacists at preferred pharmacies for the same service.
? CMS must carefully evaluate each plan?s application to provide an MTM benefit. CMS must examine whether the fee the plan proposes to pay for MTM services is high enough to entice pharmacists to provide MTMS.
? MTM services are independent of, but can occur in conjunction with, the provision of a medication product.

CMS-4068-P-521

Submitter : Ms. Ana Rivera **Date & Time:** 09/30/2004 04:09:28

Organization : The Arc Gloucester

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

CMS-4068-P-521-Attach-1.rtf

September 30, 2004

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

To Whom It May Concern:

The Arc Gloucester is a nonprofit organization serving people with mental retardation and related developmental disabilities and their families through education, advocacy and direct services. We are concerned about the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. It does not provide sufficient protections for the 13 Million Medicare beneficiaries with disabilities and chronic health conditions.

The Arc Gloucester strongly supports open access to medically necessary medications and strong consumer protections in the regulations. Every person with a developmental disability is a unique individual, with different medical problems, which mirror the health problems that occur in the general population.

Delay the implementation of the Part D program for dual eligible individuals: Dual eligible individuals make up a significant proportion of the population served by Mental Retardation and/or Developmental Disabilities state agencies. They have more extensive needs and lower incomes; and rely extensively on prescription drug coverage to maintain basic health needs. We are concerned that there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on January 2, 2006. We recommend that transfer of drug coverage from Medicaid to Medicare for dual eligible individuals be delayed by at least six (6) months. This is critical to the successful implementation of the Part D program and essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries.

Fund collaborative partnerships with organizations representing people with disabilities are critical to an effective outreach and enrollment process: We strongly urge CMS to develop a specific plan for facilitating the enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

Designate special populations who will receive affordable access to an alternative, flexible formulary: We strongly support the suggestion that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. To ensure that these special populations have adequate, timely, and supportive access to medically necessary medications, they must be exempt from all formulary restrictions and they must have access to all

medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations:
* People who are dually eligible for Medicare and Medicaid
* People who live in nursing homes, ICF-MRs and other residential facilities
* People who have life threatening conditions
* People who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes: We strongly recommend that CMS establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors and includes a truly expedited exceptions process for individuals with immediate needs. Under the proposed rule, there are too many levels of internal appeal that a beneficiary must request from the drug plan before receiving a truly independent review by an administrative law judge and the timeframes for plan decisions are unreasonable long. The exceptions process only adds to the burden on beneficiaries and physicians by crating an ineffectual and unfair process before an individual can access an already inadequate grievance and appeals process. We recommend that CMS revamp the exceptions process to: establish clear standard by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

Require plans to dispense a temporary supply of drugs in emergencies: For many individuals with disabilities treatment interruptions can lead to serious short term and long term problems. The final rule must provide for dispensing an emergency supply of drugs pending the resolution of an exception request or pending resolution of an appeal.

Sincerely,

Ana Rivera,
Executive Director,
The Arc Gloucester

Submitter : Mrs. Heather Cooper **Date & Time:** 09/30/2004 04:09:55

Organization : ASP-APhA/TPA

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I think that the current Medicare rx drug benefit is a false sense of security for seniors. There are plans out there that offer better discounts for seniors and are easier to obtain.

CMS-4068-P-522-Attach-1.doc

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

Dear Sir or Madam:

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

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

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a "clinical pharmacist." I recommend changing "clinical pharmacist" to "pharmacist." CMS should not limit monitoring to "clinical pharmacists," as all pharmacists are qualified by virtue of their education

and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a “Clinical Pharmacist” in its rules and regulations. Nationally, there is no clear definition of a “clinical pharmacist.”

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create “preferred” pharmacies and “non-preferred” pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one “preferred” pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only “preferred” pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan’s standards terms should be allowed to provide the same copays to the patient population.

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

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Heather R. Cooper

CMS-4068-P-523

Submitter : **Date & Time:** 09/30/2004 05:09:30

Organization :

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

Dorothy Reaves
502 Palmetto St
Conway,SC29526

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.

This morning we transported a young lady to the doctor, she was told that without monies they would withhold her RX. Her CD # is 9. The amuont she needed was $10.00 and she needed return tomorrow and follow-up the the HIV Spec. Which she need $10.00 again.

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

Sincerely,

Dorothy K. Reaves

CMS-4068-P-524

Submitter : Mrs. Patricia Hertz **Date & Time:** 09/30/2004 05:09:29

Organization : St JUstin's Center of Learning

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file

CMS-4068-P-524-Attach-2.doc

CMS-4068-P-524-Attach-1.doc

Date September 29,2004

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

To Whom It May Concern:

The St Justin's Center of Learning welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The St Justin's Center of Learning is a Religious based program providing continuing education to persons with developmental disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

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

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

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

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

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

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

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

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

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

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

* people who are dually eligible for Medicare and Medicaid

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of our views.

Patricia E. Hertz
Coordinator of Religious Education
170 Cranberry Rd
Toms River, NJ 08753

Date September 29,2004

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

To Whom It May Concern:

The St Justin's Center of Learning welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The St Justin's Center of Learning is a Religious based program providing continuing education to persons with developmental disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

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

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

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

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

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

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

Thank you for your consideration of our views.

Patricia E. Hertz
Coordinator of Religious Education
170 Cranberry Rd
Toms River, NJ 08753

CMS-4068-P-525

Submitter : Mikel Azar **Date & Time:** 09/30/2004 05:09:14

Organization : Mikel Azar

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

I am responding to the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am concerned that the current rule does not provide sufficient protection for people with HIV/AIDS who will receive their treatment through this benefit.
CMS must designate people living with HIV/AIDS as a "special population" and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing. This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.
Thank you for considering my comments as you finalize the regulations.

Sincerely,

CMS-4068-P-526

Submitter : Dr. Brent Thompson **Date & Time:** 09/30/2004 05:09:12

Organization : Dr. Brent Thompson

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Please consider it vital that access to Pharamcy services be garaunteed at the local level, not at a determined service level. In order for patients to recieve better care, under this proposal, access to the Pharmacists they have gained trust in.

I'm also concerned the current proposal leaves too much unsaid with regard to plans having preferred and non-preffered Pharmacies. These plans should be required to have a minimum number of preferred Pharmacies, to avoid the chance that patients will be coerced into changing their Pharmacy through lower copays. The contracts these plans offer also should be standard for all pharmacies.

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

The current proposal for MTM leaves the plans responsible for who should provide MTM service. CMS has appropriately recognized that Pharmacists would likely provide the service. I'm concerned if this is not specified in the proposal, plans could select less qualified persons to provide the care to my patients. Pharmacists are the most qualified to monitor, evaluate, and manage medication therapy and do it cost effectively. The multiple studies and projects which have already concluded Pharmacists can decrease the cost of medication therapy, also show the impact we can have on improving patient's lives. Thank you for taking the time to review my comments and I hope we all keep our patients needs in mind before moving forward.

CMS-4068-P-527

Submitter : Mrs. Mary Simeone **Date & Time:** 09/30/2004 05:09:32

Organization : Voice Of the Retarded

Category : Intermediate Care Facility for the Mentally Retarded

Issue Areas/Comments

Issues 1-10

ELIGIBILITY, ELECTION, AND ENROLLMENT

DATE 9-30-2004

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,

NAME Mrs.Mary Simeone
TITLE VOR Member
ADDRESS 2251 Verdun Dr. Joliet, IL. 60435
PHONE/FAX/E-MAIL 818-609-5612 mssimeone@comcast.net

CMS-4068-P-527-Attach-1.doc

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

September 22, 2004

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

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

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

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

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

VOR strongly agrees. As noted later in the regulations –

"It is particularly important to ensure that the drug needs of institutionalized Part D enrolles – most of whom are dually eligible for Medicare and Medicaid – are met. The institutionalized population is generally more sensitive to and less tolerant of many medications." [69 Fed. Reg. 46661 (Tuesday, August 3, 2004)].

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

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

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

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

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

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

Peabody, MA 01960
978-535-2472 phone
978-535-0472 fax

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

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

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

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CMS-4068-P-528

Submitter : Bekah Yates **Date & Time:** 09/30/2004 05:09:10

Organization : UT College of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

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

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a ?clinical pharmacist.? I recommend changing ?clinical pharmacist? to ?pharmacist.? CMS should not limit monitoring to ?clinical pharmacists,? as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a ?Clinical Pharmacist? in its rules and regulations. Nationally, there is no clear definition of a ?clinical pharmacist.?

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create ?preferred? pharmacies and ?non-preferred? pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one ?preferred? pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only ?preferred? pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient population.

Thank you for considering my comments,

Sincerly,
Bekah Yates

CMS-4068-P-529

Submitter : Miss. Rebecca Sherman **Date & Time:** 09/30/2004 06:09:42

Organization : Bay Area & Western Paralyzed Veterans of America

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-529-Attach-1.doc

September 30, 2004

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

To Whom It May Concern:

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

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

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

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

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

collaborative partnerships with state and local agencies and disability advocacy organizations.

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

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

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

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

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of our views.

CMS-4068-P-530

Submitter : Dr. John Lamb **Date & Time:** 09/30/2004 06:09:00

Organization : Dr. John Lamb

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Sir or Madam:

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

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

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a ?clinical pharmacist.? I recommend changing ?clinical pharmacist? to ?pharmacist.? CMS should not limit monitoring to ?clinical pharmacists,? as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a ?Clinical Pharmacist? in its rules and regulations. Nationally, there is no clear definition of a ?clinical pharmacist.?

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create ?preferred? pharmacies and ?non-preferred? pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one ?preferred? pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only ?preferred? pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail a

CMS-4068-P-531

Submitter : Mr. John Weber **Date & Time:** 09/30/2004 06:09:55

Organization : Independent Living Resource Center San Francisco

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Independent Living Resource Center San Francisco
649 Mission Street, 3rd Floor, San Francisco, CA 94105
415.543.6222 Fax 415.543.6318 TTY 415.543.6698

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

To Whom It May Concern:

The Independent Living Resource Center San Francisco, ILRCSF welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. ILRCSF has served consumers with disabilities for over 26 years. In fact, our agency has a cross- disability and cross-cultural focus. In 2003, ILRCSF served over 4,000 consumers with disabilities and responded to over 14,000 information and referral requests. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

ILRCSF strongly contests the new proposed Medicare rules. These proposed rules grossly undermine recent state and federal improvements of work and health incentives for persons with disabilities who depend on Medicare. In fact, these proposed rules will have an especially negative impact on dual eligibles and SSDI beneficiaries. For example, many of our consumers who receive SSDI will be expected to pay a 17.5% increase in out-of-pocket Medicare premiums. The 17.5% increased premium cost will place this public health benefit out of reach for tens of thousands of persons with disabilities. The Medicare Modernization Act (MMA) will place an enormous undue financial burden on the very individuals the MMA was intended to help. Millions will face the choice between food, and shelter or medications. Dual eligibles are at greater risk of not being able to shoulder this financial burden. For instance concurrent recipients who receive both Medi-Cal and Medicare will be forced to pay for Medicare premiums that were once paid by Medi-Cal.

These consumers accessed the Medi-Cal benefits due to significant lack of resources and income. It will be virtually impossible to cover the financial cost of the current Medicare premiums. How will this consumer group afford the proosed17.5% increase? Furthermore, under these new proposed rules, Medicare is banned from negotiation of the high cost of medication with pharmaceutical companies. This rule benefits the pharmaceutical companies and not beneficiaries and persons with disabilities.

ILRCSF submits the following recommendations:
1. Delay the implementation of the Part D program for dual eligibles until consequences can better assessed.
2. Designate special populations who will receive affordable access to an alterative formulary.
3. Impose new limits on cost management tools to prohibit any prescription drug plan to impose a 100% cost sharing for any drug.
4. Strengthen and improve inadequate and unworkable exceptions and appeals processes
5. Require plans to dispense a temporary supply of drugs in emergencies.

We strongly hope that you will consider our recommendations and the negative impact the Medicare Modernization Act will have on beneficiaries and persons with disabilities.

_____
John Weber, Benefits Coordinator

_____
Bridgett Brown, Eligibility Specialists

CMS-4068-P-531-Attach-1.doc

649 Mission Street, 3rd Floor, San Francisco, CA 94105
415.543.6222 Fax 415.543.6318 TTY 415.543.6698

October 26, 2004
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

The Independent Living Resource Center San Francisco, ILRCSF welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. ILRCSF has served consumers with disability for over 26 years. In fact, our agency has a cross-disability and cross-cultural focus. In 2003, ILRCSF served over 400 consumers with disabilities and responded to over 14,000 information and referral requests. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

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

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

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

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

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

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

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of our views.

John Weber, Benefits Coordinator
Independent Living Resource Center San Francisco

Bridgett Brown, Eligibility Specialist
Independent Living Resource Center San Francisco

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CMS-4068-P-532

Submitter : Donna Perkins **Date & Time:** 09/30/2004 06:09:27

Organization : Saint Louis University

Category : Academic

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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 woudl have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV Treatment Guidelines.

People living with HIV disease need to have full access to all antiretrovirals, due to variations in the disease and disease progression, regardless of ability to pay. Thank you for your consideration.

CMS-4068-P-533

Submitter : Ms. Shella Comin-DuMong **Date & Time:** 09/30/2004 06:09:44

Organization : Ms. Shella Comin-DuMong

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

RE: Dual Eligibles with Developmental Disabilities

1. Delay the implementation of the Part D Program for dual eligibles;

2. Fund collaborative partnerships with organizations representing people with disabilities (which are critical to effective outreach and enrollment processes);

3. Designate special opoulations (those with developmental disabilities) who will receive affrdable access to an alternative, flexible formulary;

4. Impose new limits on cost management tools;

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

6. Require plans to dispense a temporary supply of drugs in an emergency;

7. Place stronger consumer protections in the regs.

Thank you.

CMS-4068-P-534

Submitter : **Beata Karpinska** **Date & Time:** **09/30/2004 06:09:45**

Organization : **Beata Karpinska**

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

Dear CMS Representative:

Thank you for an opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. I am very concerned that the proposed PART D rule will deny the important protections for 7 million dually eligible participants who will lose Medicaid prescription drug benefits that they now have, if this program goes into an effect. Therefore please DO NOT IMPLEMENT THE PART D PROGRAM FOR DUAL ELIGIBLES without a careful study of the impact of PART D on work incentives such as PASS, Ticket to Work and Social Security work incentives.

People who are dually eligible experience much lower incomes than the rest of the population relying on Medicare. They also rely on prescription drug assistance and are among the most impoverished Medicare beneficiaries. I am convinced that, despite the best intentions of CMS, the PART D will eliminate important benefits for 7 million people with disabilities, previously available through Medicaid, resulting in detoriation of health, reduced access to healthcare, risk of entering institutions due to homelessness, because community living will become unaffordable to them due to medical expenses. This will contradict the Olmstead decision and the Freedom initiative supported by CMS.

In last 10 years many disincentives to working have been successfully removed and the Part D Program will substentially undermine these important efforts. The loss of health care coverage will make people more dependent on benefits and less likely and able to work.

I urge you to make appropriate changes in this legislation to maintain important health benefits, and subsequently work benefits and incentives.

Thank you for your consideration in this matter.
Sincerely,
Beata Karpinska

CMS-4068-P-535

Submitter : Lalenja Harrington **Date & Time:** 09/30/2004 06:09:23

Organization : The Arc of High Point

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community

CMS-4068-P-535-Attach-1.doc

CMS-4068-P-535-Attach-2.doc

September 30, 2004

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

To Whom It May Concern:

The Arc of High Point welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Arc of High Point is a non-profit agency designed to support individuals with developmental disabilities in our community. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

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

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

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

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

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

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

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* people who are dually eligible for Medicare and Medicaid

* people who live in nursing homes, ICF-MRs and other residential facilities
* people who have life threatening conditions
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Thank your for time and consideration.

Sincerely,

Lalenja Harrington
Director of Outreach
The Arc of High Point

CMS-4068-P-536

Submitter : Ms. sidney schwartz **Date & Time:** 09/30/2004 07:09:49

Organization : united cerbral palsy ass'n of nassau county

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-536-Attach-1.doc

9/30/04

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:

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

Every person with a developmental disability is a unique individual, with different medical problems, which mirror the range of health problems that occur in the general population. Cerebral palsy is often associated with neurological conditions that require medication treatment, increasing the risk for drug interactions. A recent study found that approximately 38% of children with cerebral palsy have epilepsy. Many individuals with cerebral palsy also use medications to treat dystonia and muscle spasticity As a result, we strongly support open access to medically necessary medications and strong consumer protections in the regulations. The following are critical recommendations:

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

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

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

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

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

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

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

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

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of our views.

Submitter : Mr. Allan Bergman **Date & Time:** 09/30/2004 06:09:19

Organization : Anixter Center

Category : Other Health Care Provider

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-537-Attach-1.doc

September 30, 2004

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

Dear Dr. McClellan:

Anixter Center welcomes 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.

Anixter Center's mission is to assist people with disabilities to live and work successfully in the community. We are a leading provider of high-quality vocational, residential and educational options, substance abuse prevention and treatment, and health care for people of all ages and types of disability. We are also an advocate for the rights of people with disabilities to be full and equal members of the community. Many of our program participants are eligible for both Medicaid and Medicare, and so it is from this context that we share the below-noted concerns about how the new prescription drug benefit impacts the populations we serve.

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

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

disabled beneficiaries have problems with mental functioning (Kaiser Family Foundation, 1999).

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

Coverage of Dual Eligibles. Ensure continuity of care for dual eligibles by:
* extending the deadline for switching their coverage from Medicaid to Medicare; and
* grandfathering coverage of medications on which mental health consumers have been stabilized.

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

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

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

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

Coverage of Dual Eligibles (§ 423.34)

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

We 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: "[i]f 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. We urge that the regulations be revised to provide for "grandfathering" coverage of mental health medications for dual eligibles into the new Part D benefit, as a number of states have done in implementing preferred drug lists for their Medicaid programs.

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

We 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 we 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, we 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.

Our 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.

We are 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:
o documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities in accordance with the Americans with Disabilities Act; and

o 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:
o Advance notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment;
o Notice of intent to request CMS' permission to disenroll the individual; and
o 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.

We 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 our comments.

Sincerely,

Allan I. Bergman
President and CEO

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-538

Submitter : **Date & Time:** 09/30/2004 07:09:04

Organization :

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

September 29, 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:
As future pharmacy care professionals, the students of the Idaho State University College of Pharmacy thank you for the opportunity to comment on the proposed regulation for implementation of the Medicare prescription drug benefit. We offer the following comments for consideration as CMS develops the final regulations.

Subpart C: Benefits & Beneficiary Protections

Patients were assured by Congress that they would retain fair access to their pharmacy of choice. For this to adequately be enforced, the TRICARE requirements need to be met on a local level. If access standards are evaluated ?on average?, smaller, more rural areas will likely not meet the requirements, while more urban areas will make up for the difference and meet the average requirement. Meeting the access standards on the local level is needed to ensure patients will maintain their right of use for their convenient pharmacy of choice.

CMS should require plans to offer standard contracts to all pharmacies to discourage the implementation of preferred and nonpreferred pharmacies. If plans are allowed to distinguish between pharmacies, patients will be guided toward certain pharmacies, essentially limiting their access. Preferential pharmacy plans would negate the congressional intent of maintaining patient access to pharmacy and pharmacist of choice.

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

CMS has recognized that pharmacists will likely be the primary MTM providers. However, if the decision of who will provide the MTM is left in the hands of the plan, underqualified personnel may be allowed to provide these services. If providers other than pharmacists are allowed to provide MTM services, patient care may be compromised. Pharmacists are well trained, highly educated, medication experts. CMS should recognize pharmacists as the ideal provider of MTM and mandate the use of pharmacist services by the plans.

Patient freedom of selecting their provider of MTM services must be preserved as well. CMS needs to clarify that patients will not be required to receive MTM services from a specific provider (such as a preferred pharmacy), so long as that provider be a pharmacist.
In conlusion, we encourage CMS to revise the implementation to:

- meet TRICARE requirements on a local level
- discourage plans from developing preferred and non-preferred pharmacies
- recognize pharmacists as the MTM providers.

On behalf of the students of Idaho State University College of Pharmacy, we appreciate you considering our views.

Sincerely,

Donovan M. Victorine
Idaho State University College of Pharmacy
Pharm D. Candidate 2006
Professional Pharmacy Student Alliance - Executive Officer

Kory VanderSchaaf
Idaho State University College of Pharmacy
Pharm D. Candidate 2006
Professional Pharmacy Student Alliance ? Executive Officer

Aaron Long
Idaho State University College of Pharmacy
Pharm D. Candidate 2006
Professional Pharmacy Student Alliance ? Executive Officer

CMS-4068-P-539

Submitter : Dr. Jennifer Gores-Todd **Date & Time:** 09/30/2004 07:09:53

Organization : Aurora Health Care

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I would like to thank the CMS for providing an opportunity for pharmacists to state their opinion on the Medicare Part D legislature. All pharmacists would like to see this work. Please remember that this affects both community and hospital pharmacists and that reimbursement for MTM should apply to both types as pharmacists as well.

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

In order to establish continuity of care it is imperative that patients are allowed to choose where that care occurs. I urge the CMS to require plans to ensure pharmacy access by adhearing to the TRICARE requirements.

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

In my practice as a clinical pharmacist I help to manage patient medication therapy on a daily basis. Practice MTM duties include: checking for drug interactions, medication education, ensuring proper compliance, resolving drug-related problems, assuring appropriatness and safety of medication regimens, blood pressure monitoring and education, diabetes screening and education, osteoporosis screening and education, smoking cessation counseling, administering immunizations, and asthma education. These duties improve patient outcomes and reduce overall healthcare costs. The reimbursement for MTM needs to be at a level that will encourage pharmacists to provide these patient care activites. There also should be reimbursement for all pharmacies regardless if it is a preferred pharmacy or not. I support the Medication Therapy Management Services Definition and Program Criteria developed and adopted by 11 national pharmacy organizations in July 2004. (See www.aphanet.org/lead/MTMS_definition_FINAL.pdf.)

CMS-4068-P-540

Submitter : Dr. Gary Smith **Date & Time:** 09/30/2004 07:09:24

Organization : University of Maryland School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I offer the following comments that relate to specific sections but not sure which specific issues they fall into so will provide them here.

Regarding targeted beneficiaries CMS is saying that they are relying on the drug plan sponsor to determine who the targeted beneficiaries are for MTMS. They suggest it may be determined based on ?high annual Costs?. I am concerned that this will be used as an exclusive mechanism rather than from a perspective of who could benefit the most from a quality of care perspective. I think the targeted eneficiaries should be, i.e. those with specific chronic diseases regardless of their cost of therapy. In most cases these folks may well have the highest costs but not always. For example all diabetics and asthmatics should receive this therapy as should patients with heart disease, etc. Some patients may well have only one or two chronic diseases but still need help with their medications in order to prevent further complications or diseases.CMS should solicit guidance from the pharmacy profession as to who the beneficiaries should be and not leave it up to the PDA.

I am pleased to see that impersonal telephone services are listed as only one mode and that face to face relationships are encouraged. this needs to stay in.

MMS Fees: I believe that CMS should develop some sore of fee structure for MMTS and not leave it up to the provider organization. This should be set at a reasonable hourly rate and perhaps tied to expected time for each funciton. For example an allocation of 45 minutes could be made for an initial educational session for a patient with multiple medicaition for 2 or more disease states. The fee should be set at a rate that is fair and provide the pharmacist with an incentive to participate. The rate could be determined based on what a salary is of a pharmacist plus benefits and overhead.

CMS-4068-P-541

Submitter : Mr. Brian Esterly **Date & Time:** 09/30/2004 07:09:41

Organization : excelleRx

Category : Hospice

Issue Areas/Comments

GENERAL

GENERAL

I am attaching comments under separate attachment. Thank you.

CMS-4068-P-541-Attach-1.pdf

530 Walnut Street, Suite 550
Philadelphia, PA 19106
Phone: 215.282.1600
Fax: 215.282.1586

hospice pharmacia • MedRxperts • PainRxperts

Passionate for the Appropriate Use of Medication

September 20, 2004

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

Re: CMS-4068-P

Dear Sir or Madam,

Thank you for the opportunity to comment on the proposed regulation to implement the Medicare prescription drug benefit. excelleRx is a specialty pharmacy that provides medication therapy management services to patient populations with significant medication needs including patients who are terminally ill (that is, hospice patients), patients who suffer from chronic pain, recipients of organ transplant and community-dwelling frail elderly. The excelleRx medication therapy management system combines cutting-edge technology with peer-reviewed, evidence-based, clinical practices resulting in optimal clinical and quality outcomes and medical cost effectiveness.

excelleRx currently serves more than 40,000 patients per day. Using our medication therapy management system, we have been able to achieve measurable improvements in quality and significant costs savings without resorting to the use of a formulary. In fact, the goal of our system is best captured in our Mission Statement, ***"Passionate for the Appropriate Use of Medication."*** We achieve total medical cost savings and improve quality outcomes, often while adding adjuvant therapies, because we address the issues of medication "mis-adventuring," that is the unintended misuse, overuse and under-use of medications that is rampant in today's healthcare system. This mis-adventuring includes 1) misuse of medications, which is a well documented major cause of preventable death and injury, 2) overuse of medications through duplicate therapy or the use of more expensive products when clinically equivalent alternatives are available, both of which wastes valuable healthcare resources and 3) under-utilization of proven treatments, which can result in increased downstream medical costs due to poorly managed conditions. Finally, because our decision support tools are evidence-based our specially trained pharmacists are not unduly influenced by pharmaceutical manufacturer marketing efforts.

Based upon our extensive experience in medication therapy management we provide the following comments:

1. Subpart D, Section 423.153(d): Medication Therapy Management Program (MTMP)

Under the Medicare Modernization Act (MMA) and proposed Section 423.153(d), each Prescription Drug Sponsor and every Medicare Advantage organization offering a Medicare Advantage Prescription Drug Plan (MA-PD) must have a Medication Therapy Management Program (MTMP) that assures that drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use, and reduce the risk of adverse events, including adverse drug interactions.

By definition, targeted beneficiaries are Part D eligible enrollees who have multiple chronic diseases, are taking multiple covered Part D drugs and have high drug costs. Targeted beneficiaries, therefore, are among the heaviest users of health care services, including prescription drugs.[1] This population is also the most susceptible to medication mis-adventuring.[2] Therefore, a robust medication therapy management program that is built upon commonly accepted evidence-based practice standards is critical to ensuring that enrollees with high cost, chronic care needs obtain optimal, cost-effective drug therapy.

While we commend CMS for identifying requirements for an MTMP, we believe that CMS must do more to ensure that PDPs and MA-PDs develop and implement MTMPs that will be effective in addressing the needs of targeted beneficiaries. Specifically, CMS must identify the basic elements of an MTMP plan and must hold plans accountable for MTMP activities and associated health and quality outcomes. This is especially critical given the structure of the new Part D benefit, which gives PDPs financial incentives to control costs through restrictive formularies and coverage denials, but does not hold them accountable for adverse health outcomes that are likely to result when authorization for needed drug therapy is withheld or delayed.

Under the proposed rule, CMS is requiring MTMPs to meet two requirements 1) improved medication use that optimizes therapeutic outcomes, and 2) reduced risk of adverse events. We view these two components as goals or outcomes to be achieved by an MTMP. However, they are not themselves elements of an MTMP. To ensure that plan sponsors meet these goals, we strongly suggest CMS identify specific elements of an MTMP. Additionally, CMS should require plan sponsors to collect and report data to ensure that the MTMP is being implemented. The data can also be used to drive quality improvement by informing beneficiaries which plans best meet the goal of improving medication use, optimizing therapeutic outcomes and reducing the risk of adverse events.

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[1] Individuals with chronic illness account for 88 percent of all prescriptions filled. Partnership for Solutions, *"Chronic Conditions: making the Case for Ongoing Care,"* The Robert Wood Johnson Foundation, (Dec. 2002).

[2] About 1.8 million adverse drug events (ADEs) occur per year in the elderly. *Jerry Gurwitz MD, Incidence and Preventability of ADEs Among Older Persons In the Ambulatory Setting. JAMA. 2003:289:1107-16. March 5, 2003.* Sixty% of ADEs are preventable and due to the selection of one or more inappropriate drugs. *Tejal Gandi MD, MPH, N Engl J Med 348:16;1556. April 17, 2003.* For every additional medication added to the regimen, the chance of Adverse Drug Events increases by 10%. *Gandi, R.K., Weingart S.N., Borus, J., et al. (April 17, 2003). Adverse drug events in ambulatory care. N Engl J Med 348(16): 1560.* One in twelve office visits results in an inappropriate Rx (especially in women), which is unchanged since a comparable 1995 study. *M Goulding, PhD, CDC. Arch Intern Med/ 164:305. Feb 9, 2004.*

Elements of a Medication Therapy Management Program

The excelleRx MTMP program is based upon elements identified in the clinical research and revised over years of experience.[3] We define those elements in terms of activity and process.

The activity elements include the following:

Initial Assessment: Foremost, the MTMP must assure that appropriate drugs are prescribed in the first instance through initial assessment. The traditional assumption that a written prescription always is accurate must be challenged. Rather than simply require that drugs provided to targeted beneficiaries be appropriately *used*, the first requirement should be that drugs prescribed to targeted beneficiaries *are appropriate*.

The appropriateness of a particular course of therapy can be assured through collaboration between the prescriber and the pharmacist on an initial assessment. From this beginning point, appropriate use can then be monitored. It is also important to define the parameters for appropriate drug use. Appropriate drug use should be defined as that which meets the therapeutic goals of the patient. What is the patient expecting to achieve out of the therapy? Which drug or mix of drugs can achieve the goal, if any? What other social or environmental changes are necessary to occur in order for the drug to achieve the patient defined therapeutic goal?

Data Tracking: As technology become more sophisticated, data tracking becomes integral to appropriate prescribing, optimized outcomes, and reduced adverse events. By tracking a patient's demographics, pharmacotherapy history, and the results of that pharmacotherapy, practitioners position themselves to optimize clinical care by basing treatment decisions on the evidence, while reducing adverse events. Expert systems that assist in data tracking and provide the practitioner with real-time reporting on endpoints and outcomes become essential to this process. Important data to track includes:

- Patient demographics, comorbidities, and in the near future, germane pharmacogenomics (e.g., does this patient have the genotype to produce the liver enzymes to convert codeine to morphine?).
- Patient's pharmacotherapy history, fully linking each medication to a symptom (e.g., ICD-9 tagged). This data includes specificity on discontinuation of medications.
- Results of patient's pharmacotherapy history in two domains:
    - Endpoints—quantitative clinical benchmarks such as pain level or anxiety level.
    - Outcomes—qualitative, quality of life benchmarks, such as mood, appetite, or interaction with others.

[3] Nash, DB, et al. *Why the elderly need individualized pharmaceutical care.* Office of Health Policy and Clinical Outcomes, Thomas Jefferson University, April 2000; Strand LM, Cipolle RJ, Morely PC . *Pharmaceutical Care: An Introduction,*. The Upjohn Company, 1992; Knowlton CH, Penna RP *Pharmaceutical Care,*. American Society of Health-System Pharmacists, 2003.

Symptom-based treatment algorithms: Treatment decisions and the care process are based on step-care protocols that facilitate evidence-based medication therapy management. The algorithms are formulated using pertinent literature, abstracts, and comparative data harvested from a suitable database. To be valid the algorithms must be published, subject to peer review, void of drug industry influence, and regularly updated.

These activities are carried out in four phases or processes. We refer to them as the ABCS of pharmaceutical care.

Assessment: Upon admission and for each change in status for a patient, an assessment of the patient is completed. This requires the prescriber to collaborate with the pharmacist to identify each symptom, establish therapeutic goals and manage each symptom through appropriate medication therapy. From this collaboration, a medication care plan is generated. Each change in a patient's clinical status may result in a modification of the care plan.

Bottling: Ultimately, the right medication has to make it to the patient at the right time. This can be achieved by requiring interventions to assure quality in dispensing and access. Bar code tracking and an effective pharmacy QA system can be required to reduce dispensing errors. When appropriate, the patient or practitioner is counseled on the best access options. Regardless of the plan or payment system prescription data needs to be used not only as a transaction data for reimbursement, but also clinical data that can be used to support the medication management platform. Specifically, real time dispensing data and historical dispensing data provides the information required for conducting assessments based upon medication histories, performing additional quality assurance checks and monitoring refill activities, which becomes a proxy for patience adherence.

Counseling: In the counseling phase the practitioner implements a feed-back loop to refine a patient's medication care plan and perform additional patient education. Counseling can take many forms. It can be prompted from information retrieved by health care diaries or electronic health care data collection devices. It can be through patient outreach programs as well as through patient generated requests. The key is to target counseling regarding medication effectiveness to the populations who are least likely to succeed with adherence and who have the greatest negative health outcome as a result of non-adherence.

Surveillance (monitoring): Monitoring is the process of obtaining and evaluating clinical indicators and other relevant information. In the monitoring phase, the practitioner tracks patient results (endpoints and outcomes). Effective use may be made of electronic reporting systems to ensure participation. An effective method would be to have all data entered into a web-based database that is HIPAA secure and accessible to the stakeholders in the care process (e.g. physician, local pharmacy, nurse, etc.). These data not only enable patient specific outcomes tracking, but macro level evaluation of plans, physicians, etc. to enable quality reporting and comparison benchmarking. Finally, the data becomes a further research tool that can be used to refine evidence-based guidelines.

The above medication therapy management model ensures the appropriate use of medication and has been widely adopted by the physicians excelleRx supports. For example, we find that 95%

of our prescription recommendations are accepted. These recommendations adhere to evidence-based guidelines and we know that actual practice patterns frequently deviate from accepted standards.[4] A collaborative practice model where the physician pre-approves the pharmacotherapy guidelines and thereby enables pharmacotherapy treatment for patients that follow the standards is a tremendous way to save physician time, improve adherence to national standards and reduces practice variation.

Specific Recommendations:

1) Delete Section 423.153(d) and amend as follows:

Section 423.153(d)(1) – *A medication therapy management program must meet the requirements of Section (2) and be designed to optimize therapeutic outcomes, improve medication use and reduce adverse drug interactions and events for targeted beneficiaries.*

(2) A medication therapy management program, at minimum, must include the following:

(i) An assessment of each targeted beneficiary's drug therapy that meets the following requirements:

- *(A) Is conducted by a pharmacist who is knowledgeable regarding the targeted beneficiary populations to be served by the MTMP (that is, a pharmacist who has received specially designed geriatric pharmaceutical care supplemental training),*
- *(B) Is conducted upon admission to service and whenever a change in drug therapy is prescribed,*
- *(C) Is designed to assure that the drugs prescribed are appropriate for the beneficiary's therapeutic needs and meets the beneficiary's therapeutic goals,*
- *(D) Includes the beneficiary's history of drug therapy and assesses social and environmental changes necessary in order for the prescribed drug therapy to achieve its therapeutic goal.*
- *(E) Promotes collaboration between the prescriber and the reviewing pharmacist.*

(ii) A system for assuring that the right medication is dispensed to the right beneficiary in the right amount and right form and at the right time, including provisions for assuring that emergency needs of targeted beneficiaries are met.

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[4] Only 50% chance of receiving recommended care in U.S. *Kerr, E.A., McGlynn, E.A., Adams, J. et al. (2003, Sept/Oct). Profiling the quality of care in twelve communities: Results from the CQI study. Health Affairs 23(5):247-256); Fischer, M.A., Avorn, J. (2004, April 21). Economic implications of evidence-based prescribing for hypertension: Can better cost less? JAMA 291(15):1850-1856; McGlynn, E.A., Asch, S.M., Adams, J. et al. (2003, June 26). The quality of healthcare delivered to adults in the United States. N Engl J Med 348(26):2635-2645;* Landrow, L. (May 6, 2004) Wall Street J (D3). *A carrot for the right prescription.*

(iii) A program of patient outreach and counseling to promote understanding and compliance with medication therapy among targeted beneficiaries.

(iv) A system for data tracking, monitoring, evaluating and reporting patient demographics, pharmacotherapy history, clinical indicators and health outcomes, including adverse drug reactions, drug errors etc.

Additional comments:

1) Qualifications - Based on our experience, we believe that MTMP services must be furnished by a licensed pharmacist . The licensed pharmacist must have specialized experience in addressing the specialized needs of older patients with chronic conditions.
Therefore, we would delete proposed section 423.153(d)(1)(iii) and replace with the language set forth above.

2) Ambulatory versus institutional setting - Section 423.153(d)(1)(iv) states that an MTMP may distinguish between services in ambulatory and institutional settings. While there may be administrative advantages to this distinction, it is unimportant to clinical care. The important clinical question, in either setting, is the appropriateness of the medication therapy. The MTMP needs to always address that fundamental question. Therefore, we recommend that Section 423.153(d)(1)(iv) be deleted.

2. Subpart D, Section 423.153(b): Cost-effective Drug Utilization Management Program (CDU)

Under the MMA and proposed Section 423.153(b), each PDP or MA-PD plan must establish a cost-effective drug utilization management program that 1) includes incentives to reduce costs when medically appropriate; and 2) maintains policies and systems to assist in preventing over/under utilization of prescribed medication. CMS notes in the preamble a number of examples of incentives including: use of different dispensing fees to encourage use of multiple source drugs; prior authorization; step therapy; tiered cost-sharing and other tools to manage utilization. While these incentives can result in cost savings, they focus only on the cost of medications themselves and not the total medical costs associated with treating a particular beneficiary. Effective medication therapy management could very well increase medication costs (for example, by adding adjuvant therapies for untreated symptoms or conditions), but will reduce total system-wide medical costs through decreased medication caused health events. By focusing only on the cost of medications, CMS may perpetuate a system where providers have an incentive to under-treat or ineffectively treat patients in order to demonstrate cost control. In reality, however, when patients are under-treated or ineffectively treated, the costs will show up in increased physician and hospital utilization.

Elements of a Drug Utilization Management Progam

excelleRx's drug utilization management program is designed to promote cost effective drug utilization without compromising clinical quality. We do not use prior authorization, formularies, or tiered cost-sharing. Instead, our program relies upon the following elements:

Clinical outcomes monitoring: Clinical endpoints and outcomes are collected from healthcare providers as well as the patients themselves (or the patient's non-healthcare caregiver). These endpoints and outcomes are diagnosis specific so that our hospice minimum data set (MDS) is different than our chronic pain MDS, which is different than our Chronically Ill Elderly MDS. The data must be available to perform analysis and generate insights at different levels including the: patient, health plan, healthcare provider, clinical diagnosis, and medication or therapeutic class.

Total cost savings: Pharmacist-led interventions have consistently shown improved health outcomes, decreased overall health care resource utilization, and reduced health care and pharmacy costs. An effective medication management therapy program helps control total health care costs in the following ways.

- Consideration of patient goals in establishing targets and responsibilities
- Appropriate medications dispensed the first time
- Reduction in therapy changes
- Emergency avoidance
- Reduced hospital admissions
- Reduced demands on clinician time
- Reduced administrative costs
- Electronic reporting

Quality Report Card: It is important that when the clinical outcomes are collected that they be used not only to optimize the treatment of a beneficiary (that is, using data to guide future clinical decisions), but also be available to assess the relative quality of one entity against another (for example, risk adjusted comparisons of the quality of one health plan over another or one physician over another).

Enhanced payment for excellent results: Essentially, this is a traditional reimbursement model. However, instead of an incentive to provide less care, this model is an incentive to provide exceptional care. Using a quality report card or similar benchmarking device, health care providers are measured on an objective scale. Providers who consistently post exceptional scores are given an increased reimbursement for their service.

Given that PDPs have a built in financial incentive to undertreat Medicare Part D enrollees, CMS should ensure that PDP drug utilization management programs are structured to incorporate clinical benchmarks and total pharmacy costs. If CMS emphasizes the total-medical cost, providers will have an incentive to control the health care spent on medications by providing appropriate and effective care the first time.

Specific recommendations:

1) Change Section 423.153(b)(1) as follows: *"Include incentives to reduce costs only when medically appropriate."*

(2) Change Section 423.153(b)(2) as follows: *Maintain policies and systems to:*

(i) promote evidence-based prescribing,
(ii) reduce therapy changes,
(iii) reduce emergency room visits or hospital admissions,
(iv) reduce demands on clinician's time,
(v) reduce administrative costs, and
(vi) reduce occurrence of documented adverse drug events.

Subpart D: Quality Assurance (QA)

The MMA and Section 423.153(c) requires each PDP and MA-PD plan to have a quality assurance program that includes measures to reduce medication errors and adverse drug interactions. We appreciate that CMS has described a number of desirable elements for QA systems. However, we do not believe CMS has gone far enough to identify the elements of a quality assurance program or to mandate that plans collect data and respond to identified issues.

Quality assurance systems act as both an internal and external check on quality. Under existing Medicare rules, for example, Medicare Advantage plans must have quality assurance and performance improvement plans that meet CMS requirements. For example, plans must:

(1) measure performance using standard measures that are defined by CMS that relate to:

(a) clinical areas including effectiveness of care, enrollee perceptions of care and use of services,
(b) non-clinical areas including access to and availability of services, appeals and grievances, and organizational characteristics; and

(2) Achieve minimum performance levels that CMS establishes locally, regionally or nationally with respect to the standard measures;

At-risk PDP plans must be held to similar standards.

In addition, with respect to clinical areas including effectiveness of care and use of services, there are a number of clinical decision support systems that we find critical to the QA process.

Symptom based treatment algorithms: The most significant clinical decision support system is a peer-reviewed, evidence based, algorithm that provides best-practice guidelines for the practitioner. It is important that the algorithm be regularly reviewed and updated to keep it current with advances in science. When properly used, these algorithms reduce errors, improve time to therapeutic goals, enhance patient satisfaction and contribute to optimal care by standardizing best practice.

Clinical monitoring of a patient's therapeutic endpoints and outcomes, is another critical component of an effective QA system. Knowing where the patient is from a clinical perspective and where they want to be with therapeutic goals helps to clarify and set appropriate expectations as well as establish responsibilities for achieving stated goals.

Operational system benchmarks with a communication loop that insures that process related information regarding the health care operations is reported in a standard system and that such reported QA events are directed back into the system so that remedial action can be taken to prevent further such events in the future.

Specific recommendations:

Change Section 423.153(c) to read as follows: *A quality assurance program must:*

> *(1) Measure performance using standard measures that are defined by CMS that relate to:*
>
> > *(a) clinical areas including effectiveness of care, enrollee perceptions of care and use of services,*
> > *(b) non-clinical areas including access to and availability of services, appeals, grievances and exceptions, and organizational characteristics; and*
>
> *(2) Achieve minimum performance levels that CMS establishes locally, regionally or nationally with respect to the standard measures.*

Finally, we recommend that CMS establish a process, such as a public forum or meeting, to solicit additional input from pharmacists and other experts regarding MTMP, drug utilization management and quality assurance programs and the standard performance measures or benchmarks that CMS should adopt for PDP and MA-PD plans serving Medicare beneficiaries. We, at excelleRx would welcome the opportunity to participate in such a process.

Again, we thank you for the opportunity to comment on this important rulemaking. Please do not hesitate to contact us if you have questions regarding our comments or would like additional information.

Sincerely,

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CMS-4068-P-542

Submitter : Mr. Phillip Martin **Date & Time:** 09/30/2004 07:09:47

Organization : Mississippi Band of Choctaw Indians

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4068-P-542-Attach-1.doc

MISSISSIPPI BAND OF CHOCTAW INDIANS
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September 30, 2004

Centers for Medicare and Medicaid Services
Department of Health & Human Services
ATTN: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014
address for electronic delivery: <http://www.cms.hhs.gov/regulations/ecomments>

RE: Comments on Proposed Rule -- Medicare Part D Permanent Prescription Drug Benefit pursuant to Notice in 69 Federal Register 46632 (August 3, 2004)
File Code CMS-4068-P

Dear Administrator:

On behalf of the Mississippi Band of Choctaw Indians, I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

The attached comments address issues related to the impact implementation of the proposed rules will have on American Indian and Alaska Native beneficiaries who are served by pharmacies operated by the Indian Health Service, Indian tribes, tribal organizations or urban Indian organizations (I/T/U pharmacies). As proposed, the rules would have a devastating adverse impact on the revenue collected by the I/T/U pharmacies for their dual eligible Indian patients and must be revised to prevent this outcome. It clearly was not the intent of Congress in enacting the Medicare Modernization Act to reduce revenues to Indian health programs. The United States has a trust responsibility for Indian health, and this responsibility must assure that the Indian health system is not harmed by implementation of Part D.

We urge CMS to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely yours,

Phillip Martin, Chief

Attachment -- Part D Comments

COMMENTS REGARDING
PROPOSED REGULATIONS TO IMPLEMENT
THE MEDICARE PRESCRIPTION DRUG BENEFIT UNDER
THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT AND
MODERNIZATION ACT OF 2003
as published in
69 Fed. Reg. 46,632 et seq. (Aug. 3, 2004)
File Code CMS-4068-P

INTRODUCTORY STATEMENT REGARDING INDIAN HEALTH SYSTEM

These comments address the implications of the proposed rules on the Indian health care delivery system and the changes that must be made to prevent Part D's implementation from destabilizing the system responsible for providing health care to the approximately 1.3 million American Indians and Alaska Natives (AI/AN) served by the IHS system. In the form proposed by CMS, the rules will put in jeopardy significant revenues the Indian health system now collects from Medicaid for "dual eligibles" -- conservatively estimated at between $23 million to $53 million. Since the loss of revenue to Indian health was not Congress's objective in enacting the Part D benefit, the rules must be revised in several respects to protect the Indian health system from what would doubtless be substantial harm.

We ask that all CMS staff charged with reviewing comments and revising the proposed regulations be supplied with a copy of this introductory statement regarding the Indian health care system. Compliance with the dictates of notice and comment rulemaking requires that all relevant information supplied by commenters must be taken into account. Full consideration of the comments we offer on individual regulations can only be accomplished by a thorough understanding of the unique nature of the Indian health care system, and the responsibility of our steward, the Secretary of Health and Human Services, to assure that inauguration of Medicare Part D does not result in inadvertent and unintended harm to that system.

The regulations governing the Part D prescription drug benefit must be revised to achieve the following goals:

* Guarantee that AI/ANs have a meaningful opportunity to access the benefit through the pharmacies of the Indian health delivery system;

* Require private prescription drug plan sponsors (PDPs) and Medicare Advantage organizations offering prescription drug coverage (MA-PDs) to reimburse or contract with the pharmacies in the Indian health system -- those operated by the Indian Health Service, Indian tribes and tribal

organizations, and urban Indian organizations (collectively referred to as "I/T/Us");

* Order Indian-specific terms that must be included in those contracts to guarantee that I/T/U pharmacies can collect from PDPs, building on the experience gained from the Medicare Prescription Drug Discount Card program; and

* Develop a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. One idea for achieving this protection could be modeled on the "hold harmless" mechanism Congress established for FQHCs in Section 237 of the MMA. A less costly and less administratively cumbersome option is to keep AI/AN dual eligibles under State Medicaid plans for drug coverage, since the federal government has full economic responsibility for them under Medicaid (100% FMAP) and Medicare Part D.

In order to fully comprehend the potential adverse impact Part D implementation will have on the Indian health care system -- particularly with regard to the dual eligibles it serves -- one must have an understanding of the way health care services are delivered to AI/ANs and the current state of Indian health. These considerations must be kept in mind as CMS reviews these comments in order to promulgate regulations that assure the inauguration of the Part D program does not wreak havoc on the Indian health system by reducing the level of pharmacy reimbursements from Medicaid on which the system has come to rely.

Indian Health Care System and Indian Health Disparities

Overview. The Indian health care system does not operate simply as an extension of the mainstream health system in the United States. To the contrary, the Federal government has built a system that is designed specifically to serve American Indian and Alaska Native people in the context in which they live -- remote, sparsely-populated and, in many cases, poverty-stricken areas where the Indian health system is the only source of health care. Integral to that system are considerations of tribal cultures and traditions, and the need for culturally competent and sensitive care.

U.S. Trust Responsibility for Indian Health. The United States has a trust responsibility to provide health care to AI/ANs pursuant to federal laws and treaties with Indian tribes.1 Pursuant to statutory directive,2 this responsibility is carried out by the Secretary of Health and Human Services, primarily through the Indian Health Service (IHS) with annual appropriations supplied by Congress. The IHS-funded health system follows the public health model in that it addresses the need for both medical care and preventive care. In order to perform this broad mission, the IHS funds a wide variety of efforts including: direct medical care (through hospitals, clinics, and Alaska Native Village health stations); pharmacy operations; an extensive (but underfunded) contract health services program through which specialty care IHS cannot supply directly is purchased from public and private providers; health education and disease prevention programs; dental, mental health, community health and substance abuse prevention and treatment; operation and maintenance of hospital and clinic facilities in more than 30 states; and construction and maintenance of sanitation facilities in Indian communities.

Health Disparities. AI/ANs have a higher rate of disease and illness than the general population and consequently require more medications and incur higher prescription drug costs than most Americans. An examination of the health status data leads one to conclude that AI/ANs are the "Poster Children" of health disparities. A recent in-depth study of Indian health status performed by the staff of the U.S. Commission on Civil Rights3 reveals a number of alarming statistics such as:

* AI/ANs have the highest prevalence of Type II diabetes in the world, are 2.6 times more likely to be diagnosed with the disease than non-Hispanic whites, and are 420% more likely to die from the disease.
* The cardiovascular disease rate among AI/ANs is two times greater than the general population.
* AI/ANs are 770% more likely to die from alcoholism.
* Tuberculosis deaths are 650% higher among AI/ANs than the general population.
* AI/AN life expectancy is 71 years, five years less than the general U.S. population.
* The ratio of cancer deaths to new cancer cases is higher for Native Americans than the ratios for all other races, even though incidence rates are lower.
* The Indian suicide rate is 190 percent of the rate of the general population.

Composition of the Indian Health Care System. Operationally, health services to AI/ANs are delivered through the following entities:

* The Indian Health Service directly operates hospitals and clinics throughout Indian Country that are staffed by federal employees.
* Indian tribes and tribal organizations may elect to assume management and control over IHS programs at the local tribal level through authority of the Indian Self-Determination and Education Assistance Act. At present, over one-half of the IHS budget is distributed to ISDEAA tribal programs.
* In 34 cities, urban Indian organizations operate limited health programs (largely referral services) for Indian people living in urban areas through grants authorized by the Indian Health Care Improvement Act.

Funding Sources. Indian health programs are supported primarily from annual appropriations to the Indian Health Service. Regardless of the operational form, all Indian health programs are severely underfunded. In a 2003 report4, the U.S. Commission on Civil Rights found that the per-capita amount spent by the Indian Health Service for medical care was nearly 50% lower than spending for federal prisoner medical care and only slightly more than one-third of the average spending for the U.S. population as a whole. The Veterans Administration spends nearly three times as much for its medical programs as the Indian Health Service. Using the Federal Employee Benefit Package as a standard, in a 2002 study mandated by Congress the federal government has found that the Indian Health Service is funded at only 52 percent of the level of need.5

In an effort to improve the level of funding for Indian health programs, Congress, in 1976, made IHS/tribal hospitals eligible for Medicare Part A reimbursements, and enabled hospitals and clinics to collect Medicaid reimbursements, either as IHS facilities or as FQHCs. It was not until the 2000 BIPA that IHS facilities were authorized to collect for some Medicare Part B services. With enactment of the

MMA, Congress authorized these facilities to collect for remaining Part B services for a five-year period.

Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by IHS and tribes to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. When drug coverage for dual eligibles changes from Medicaid to Medicare, the Federal government must assure that reimbursement for drugs for Indian dual eligibles continues without interruption and without reduction.

Indian health programs have become critically reliant on the third-party revenues, especially those supplied by Medicare and Medicaid. According to the IHS, Medicare, Medicaid and other third party collections can represent up to 50% of operating budgets at some facilities.

Pharmacy Services for Dual Eligibles

Because most Indian health facilities are located in remote areas far distant from the mainstream health system, they must also operate pharmacies so their patients can access needed medications. IHS, tribes, and urban Indian organizations operate 235 pharmacies throughout Indian Country. IHS and tribes dispense pharmaceuticals to their Indian beneficiaries without charge, as is the case for all health services they offer.

A sizeable portion of the patient base for I/T/U pharmacies consists of dual eligibles. IHS estimates that there are between 25,9636 and 30,5447 individuals in the IHS patient database who are receiving both Medicare and Medicaid. Since this database does not include information from some tribally-operated facilities (those who do not use the IHS computerized data system) nor information about Indians served by urban Indian clinics, the number of dual eligibles system-wide is even greater than the IHS database reveals.

While there is no comprehensive data on the per-capita drug costs for dual eligibles in the Indian health system, we have been able to make some rough estimates by examining average state per-capita spending for this population. In 2002, the average per-capita spending for dual eligibles was $918. 8 We believe this is a very conservative figure for Indian Country, in view of the higher rates of illness that have expensive drugs associated with their treatment, including diabetes and mental illness. Furthermore, the IHS calculates that the cost of pharmaceuticals has increased by 17.6 percent per year between FY 2000 and FY 2003. This includes the cost of new drugs, increases in drug costs and population growth. Thus, if we trend the average out to the year 2006, the expected average per capita spending on drugs for dual eligibles would be $1,756.

Using these population and per-capita spending data, we estimate that the Medicaid recovery for dual eligible drug costs in the Indian health system ranges between $23.8 million9 and $53.6 million.10 It is vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid rolls for prescription drugs with the inauguration of Medicare Part D in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements.

Barriers to Part D access of Indian dual eligibles. There are several reasons why the intended conversion of dual eligibles from Medicaid to Medicare could be extremely problematic in the Indian health system:

* Switching payment sources from Medicaid to PDPs under Part D will hurt AI/AN consumers and Indian health providers because most tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. Dual eligibles in those areas will have difficulty accessing the Part D benefit unless they use an Indian health pharmacy admitted to PDP networks.

* Medicaid revenues have been an important source of income for Indian health facilities. As drug coverage for AI/AN dual eligibles is removed from Medicaid and placed under Medicare, the amount of revenue in jeopardy is estimated to be between $23.8 million and $53.6 million. Reductions in reimbursements for pharmaceuticals cannot be absorbed by raising rates for other services, as Indian patients are served without charge.

* The level of revenue an I/T/U would collect under Part D will very likely be less than it currently collects under Medicaid for dual eligible drug coverage. Therefore a “wrap around” payment from Medicare, consisting of the difference between the PDP/MA-PD contract amount and the amount the I/T/U would have received under Medicaid, must be utilized to “hold harmless” I/T/Us, if an I/T/U contracts with a PDP/MA-PD.

* If private prescription drug plans are not required to contract with I/T/U pharmacies, there will be little incentive for them to do so, as the service population of these pharmacies is comparatively small and the Indian population tends to be sicker. Without network status or payment for off plan services, an I/T/U pharmacy will not be able to collect for drugs dispensed to any AI/AN enrolled in a Part D plan. This would produce three negative results: (1) a loss of revenue to the I/T/U pharmacy; (2) no meaningful opportunity for the enrolled Indian to use his Part D benefit; and (3) a windfall for the PDP who collects premiums from CMS for a dual eligible, but pays no claims.

* Even if private plans are required to contract with I/T/U pharmacies, this command will be meaningless unless the regulations set out terms specifically drafted to address the unique circumstances of the IHS, tribal and urban Indian pharmacies.

* Even if an Indian beneficiary is enrolled in a Part D plan, the I/T/U pharmacy may not know what PDP or MA-PD to bill. Particularly with automatic enrollments, the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delay in accessing the benefit if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. This situation mirrors the disastrous consequences suffered by the I/T/Us when State mandatory Medicaid managed care enrollment programs were implemented.

* If delays in implementation occur, it is not clear how the I/T/U pharmacies will recoup payment for expenditures made during the period between when the AI/AN is switched from Medicaid to Medicare pharmacy benefits and when the I/T/U pharmacy is an established network provider or able to bill for out of network services. Even if the I/T/U pharmacy is allowed to bill for services provided from the beginning of 2006, they may not have the staff to deal with a backlog of billing. Confusion and lack of information could result in not billing for covered services.

The Part D program will also impact AI/AN Medicare beneficiaries who are not dual eligibles and must pay a premium for Part D participation. Since these individuals receive drugs at Indian Health Service and tribal health pharmacies without charge, there is no incentive for them to pay premiums to enroll in a Part D plan. In order to be able to collect reimbursements for drugs dispensed to those patients, CMS must facilitate group payer options for tribes who wish to pay premiums for these beneficiaries in order for their pharmacy to be reimbursed for drugs dispensed.

The Secretary of Health and Human Services, as the principal steward of Indian health, has a responsibility to assure that the MMA, which was intended to benefit all Medicare beneficiaries, does not produce the opposite result for Indian Medicare beneficiaries who use the Indian health care system. He can guard against such an outcome by exercising the broad authority granted to the Secretary by Section 1860D-4(b)(1)(C)(iv) of the MMA which authorizes him to establish standards to assure access to Part D for I/T/U pharmacies. By this provision, Congress recognized that access for Indian beneficiaries means the ability to utilize that benefit through I/T/U pharmacies.

ACCESS TO COVERED PART D DRUGS
Comments regarding: Section 423.120: Pharmacy Access Standards

We incorporate herein statements contained in the Introductory Statement of these comments regarding the Indian Health System.

Goal: To guarantee access to Part D prescription drug benefits for AI/AN beneficiaries by requiring private drug plans to contract with those pharmacies which serve the majority of this population -- I/T/U pharmacies.

Access Issue, Pages 46655-57: Should CMS use its authority under Section 1860D-4(b)(1)(C)(iv) of the Act (authorizing the Secretary to establish standards to provide access for I/T/U pharmacies to participate in the Part D program) to require or strongly encourage private drug plan sponsors (PDPs) and MA organizations offering MA-PD plans (MA-PDs) to contract with I/T/U pharmacies?

Comment: In order to realize its goals (as communicated on pages 46655 and 46633 of the Preamble) of ensuring convenient access to covered Part D drugs to plan enrollees and broad participation by Medicare beneficiaries in the new prescription drug benefit under Part D, CMS must use its authority under Section 1860D-4(b)(1)(iv) of the Act to require PDPs and MA-PDs to contract with I/T/U pharmacies. Without this requirement the private drug plans will have little or no incentive to contract

with I/T/U pharmacies.11 This is true because there is no financial incentive for private plans to contract with I/T/U pharmacies since these pharmacies and the AI/AN beneficiaries they serve are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks. If PDPs and MA-PDs are merely "strongly encouraged" to contract with I/T/Us12 they will not do so because of the uniqueness and remoteness of Indian health programs the comparatively small and sicker populations they serve, and the perceived cost and time it may take to enter into individual contracts with each I/T/U pharmacy. CMS acknowledges these concerns on page 46657 of the Preamble.13

Failure to include language in the rule requiring private plans to contract with I/T/U pharmacies will have the unintended consequence of denying access to the benefit for a majority of AI/AN beneficiaries. This would be contrary to the access requirements of the Act. If I/T/U pharmacies are not included in the PDP or MA-PD network, an estimated 26,000 AI/AN beneficiaries who obtain their drugs from I/T/U pharmacies will be unable to access the Part D drug benefit. CMS acknowledges this fact on page 46657 of the Preamble by stating that I/T/U pharmacies may be the only facilities available to AI/AN beneficiaries and recognizes that access to I/T/U pharmacies should be preserved because it "would greatly enhance Part D benefits" for AI/AN enrollees.

Access for I/T/U pharmacies to the Part D program is crucial for preserving current revenues. All AI/ANs dual eligibles will lose their Medicaid drug benefits and are required to enroll in a Part D or Part C plan. Those dual eligible who fail to enroll will be automatically enrolled in a private plan. Regardless of such a beneficiary's enrollment in the new prescription drug benefit, an AI/AN beneficiary will continue to utilize his/her I/T/U pharmacy. Absent an agreement with the private drug plans, these pharmacies will be unable to collect reimbursement for prescription dispensed to Medicare beneficiaries. In order for I/T/Us to collect reimbursement for prescription drugs provided to dual eligibles they must be included in the private plan network.

Therefore, it is vital that Section 423.120 be modified to include language requiring PDPs and MA-PDs to contract with I/T/U pharmacies, but required contracting is not enough. The unique status of tribes may become an issue in contract negotiations. The standard PDP/MA-PD contract could prove problematic for I/T/Us as CMS acknowledged in the Preamble on page 46657. In order to assist CMS, PDPs, and MA-PDs in resolving this difficulty, we urge that specific contract provisions, which are contained in the draft language below, be required provisions for agreements between PDPs/MA-PDs and I/T/U pharmacies.14

The following changes should be made to § 423.120:

Section 423.120 Access to covered Part D drugs.

§423.120 (a) Assuring pharmacy access.

Insert the following new paragraph and re-number all subsequent paragraphs:

"(2) Access to IHS, tribal and urban Indian pharmacies. In order to meet access standards under Section 1860D-4(b)(1)(C)(iv), a prescription drug plan or MA-PD plan must offer to contract with any I/T/U pharmacy in its plan service areas, and such contract must include the elements set out in §423.120(a)(4)."

§423.120(a)(4) Pharmacy network contracting requirements.

Insert the following new subparagraph (iv):

"(iv) Must incorporate in all contracts entered into with I/T/U pharmacies, within the text of the agreement or as an addendum, provisions that:
(A) Acknowledge the authority under which the I/T/U is providing services, the extent of available services and the limitation on charging co-pays or deductibles.
(B) State that the terms of the contract may not change, reduce, expand or alter the eligibility requirements for services at the I/T/U pharmacy as determined by the Medicare Modernization Act of 2003; Sec. 813 of the Indian Health Care Improvement Act, 25 U.S.C. §1680c; Part 136 of Title 42 of the Code of Federal Regulations; and the terms of the contract, compact or grant issued to the tribal or urban Indian organization's pharmacy by the IHS for operation of a health program.
(C) Incorporate federal law and federal regulations applicable to tribes and tribal organizations, including the Indian Self-Determination and Education Assistance Act, 25 U.S.C. §450 et seq. and the Federal Tort Claims Act, 28 U.S.C. §2671-2680.
(D) Recognize that I/T/Us are non-taxable entities.
(E) State that IHS, tribes and tribal organizations are not required to carry private malpractice insurance in light of the Federal Tort Claims Act coverage afforded them.
(F) State that a PDP may not impose state licensure requirements on IHS and tribal health programs that are not subject to such requirements.
(G) Include confidentiality, dispute resolution, conflict of law, billing, and payment rate provisions.
(H) State that an I/T/U pharmacy is not subject to the PDP formulary.
(I) State that the Agreement may not restrict access the I/T/U pharmacy otherwise has to purchase drugs from the Federal Supply Schedule or the Drug Pricing Program of Section 340B of the Public Health Service Act.
(J) State that the I/T/U shall not be required to impose co-payments or deductibles on its Indian beneficiaries.
(K) Authorize I/T/U pharmacies to establish their own hours of service."

REGULATIONS MUST PROVIDE A MECHANISM TO ASSURE NO REUDCTION IN REVENUES TO I/T/U PHARMACIES

Comments regarding: §423.120: Access to covered Part D drugs and §423.124: Special rules for access to covered Part D drugs at out-of-network pharmacies

We incorporate herein statements contained in the Introductory Statement of these comments regarding

the Indian Health System.

Goal: To include in the regulation a mechanism to prevent any reduction in the amount of revenue I/T/U pharmacies would have collected for drug coverage to dual eligibles under Medicaid when these individuals are required to move to Medicare Part D for drug coverage. We provide four options in our comments to achieve this goal:

Option 1: In-Network Status + Wrap-Around Payment. One mechanism for achieving this protection would be to require PDP to recognize I/T/U pharmacies as in-network providers and for CMS to provide "a wrap-around payment" modeled on the provision Congress established for FQHCs in Section 237 of the MMA. This payment would supplement the difference between the amount paid by the PDP/MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid.

Option 2: Out of Network Status + Wrap-Around Payment. In the event that I/T/U pharmacies are not treated as in-network pharmacies, they should be recognized as out-of-network pharmacies eligible for reimbursement from the private plan under §423.124 and receive a supplemental "wrap around" payment from the federal government which would include any increased differential in cost sharing related to use of out of network pharmacies. This supplemental payment would provide reimbursement for the difference between the out of network plan payment and the amount the I/T/U would have received as an in network provider.

Option 3: Special Endorsement PDP/MA-PD Plans. Specific PDPs could be designated to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Benefit Discount Card program.

Option 4: Exemption of AI/AN Dual Eligibles. Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid. This alternative would allow CMS to avoid the complicated issues of access and revenue loss that we discussed throughout these comments.

Comment: The regulations must contain a provision which protects the level of revenue I/T/U programs receive under the current Medicaid drug coverage for dual eligible individuals. Pursuant to Federal law, the cost of Medicaid-covered services, including pharmacy services, provided by I/T/Us to Indians enrolled in Medicaid are reimbursed to the States at 100% FMAP. Thus, the Federal government bears the full responsibility for these costs. Drug coverage for dual eligibles under Medicaid will cease January 2006, transferring these individuals to the Medicare Part D prescription drug coverage. This change in coverage will disproportionately and negatively impact Indian health facilities if I/T/Us are unable to secure the same level of reimbursement under Medicare as they currently receive under Medicaid for prescription drugs provided to dual eligibles. The MMA and its implementing regulations should not be used as a vehicle to reduce the amount of revenue I/T/U pharmacies currently receive under Medicaid for drug coverage to dual eligible beneficiaries.

As we discussed in the Introductory Statement to these comments we estimate that the Medicaid recovery for AI/AN dual eligibles drug costs ranges between $23.8 million15 and $53.6 million.16 It is

vital that these revenues, so critical to the Indian health system, not be interrupted or reduced when dual eligibles are removed from the Medicaid rolls when Medicare Part D becomes operative in 2006. In their present form, however, the proposed Part D rules would jeopardize the ability of I/T/U pharmacies to maintain this level of dual eligible reimbursements. Even if PDPs and MA-PDs are required to contract with I/T/U pharmacies, it is very likely that these contracts will not provide the level of reimbursement I/T/Us currently receive under Medicaid.

We propose that one of the four "hold harmless" provision options be included in the regulation to maintain the current level of revenue I/T/U pharmacies receive under Medicaid.

Option 1: In-Network Status with Wrap-Around Payment

While it would be the responsibility of CMS to establish ways to prevent loss of revenue at I/T/U pharmacies, we propose that CMS:

(a) Require all PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the appropriate rate17, and
(b) Provide a "wrap around" payment for drug coverage services similar to the special payment rules for medical services provided at federally qualified health centers (FQHCs) contained in Section 237 of the MMA.

Reimbursement as In-network Provider. We request that the regulations require PDPs and MA-PDs to recognize I/T/U pharmacies as in-network providers, even without a contract, and reimburse them at the Medicaid rates. This provision would prevent agreements in which the PDP/MA-PD agrees to pay an artificially low rate to the I/T/U pharmacy, with the knowledge that the I/T/U pharmacy will receive supplemental payments from CMS.

Wrap-Around Payment. We also propose that an I/T/U pharmacy which provides Part D drug benefits to AI/AN beneficiaries receive a "wrap-around payment" to supplement the difference between what the I/T/U pharmacy is paid from the private plan and the amount the pharmacy would have received for providing this benefit under Medicaid. This mechanism will allow an I/T/U pharmacy to receive payment from the federal government when the amount paid by the private plan is less than the Medicaid amount.

We suggest that the following provision or ones similar in nature be added to the Part D rules:

Section 423.120(a)(1): Convenient access to network pharmacies.

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"§423.120(a)(1)(iv). Any PDP or MA-PD plan with one or more I/T/U pharmacies within its service area shall recognize such I/T/U pharmacies as in-network providers for the purpose of paying claims for pharmaceuticals supplied to any American Indian or Alaska Native enrolled in such PDP or

MA-PD, regardless of whether the I/T/U pharmacy submitting a claim is a contracted network pharmacy."

The following language should be inserted into Part 423 at the appropriate place:

§423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 2: Out of Network Status with Wrap-Around Payment

In the even that I/T/U pharmacies are not recognized as in-network providers under Option 1, we propose that the regulations recognize these pharmacies as out of network providers under §423.124 and provide a wrap-around payment to supplement the difference between the out of network reimbursement rate and the Medicaid rate.

We suggest that the following sentence be added to Sec. 423.124(a):

Section 423.124(a) ***

"An I/T/U pharmacy that dispenses covered Part D drugs to an American Indian/Alaska Native beneficiary shall be considered an out of network pharmacy for payment of claims."

Additionally, the following provision should be included in Part 423:

§423.___. Special rules for payments to IHS, Tribal and Urban Indian Pharmacies.

"If an American Indian or Alaska Native enrollee in a PDP or MA-PD plan receives service from a I/T/U pharmacy, CMS will pay to the I/T/U pharmacy on a quarterly basis, the difference between the amount paid to the I/T/U pharmacy by the PDP or MA-PD plan and the amount the I/T/U pharmacy would have received under Medicaid."

Option 3: Special Endorsements with Wrap-Around Payment

Designating private plans to serve AI/AN beneficiaries through I/T/U pharmacies similar to the specially endorsed sponsors under the Temporary Prescription Drug Discount Card program is an alternative that could encourage PDP contracting with I/T/U pharmacies. Specifically identifying the PDP serving AI/AN will help I/T/Us to identify and bill the correct PDP or MA-PD. Additionally, designating specific PDPs and MA-PDs to contract with I/T/U pharmacies would allow an AI/AN beneficiary to easily identify which plan includes his/her I/T/U pharmacy, avoiding the need for the

individual to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider. Of course, to ensure that I/T/U revenues do not decrease under this option, the wrap-around payment provision discussed above would be necessary. Designation of specific PDPs would also facilitate development of specific I/T/U contract terms.

If CMS is unable to secure private plans to offer the benefit, then it could either subsidize the benefit or provide a "fall back" plan as authorized by Section 1860D-2(b) of the MMA. The Part D proposed regulations depend on the private market to drive the benefit; however, because of the unique characteristics of Indian health programs, private plans may not have incentive or interest in serving a predominately low-income population. Establishing specific PDPs and MA-PDs to serve the AI/AN population is entirely feasible since PDP and MA-PD regions have yet to be established.18

Option 4: Exemption of AI/AN Dual Eligible Individuals from Part D

We offer an alternative that would allow CMS to avoid the complicated issues of access in Section 423.120, revenue loss to I/T/Us and the "wrap around" mechanism discussed on page 11 of these comments -- Exempt AI/AN dual eligibles from Part D and allow them to continue prescription drug coverage under Medicaid.

We believe that exempting AI/AN dual eligibles from mandatory enrollment is an efficient and effective alternative for the following reasons:

> Exemption of AI/AN dual eligibles from mandatory enrollment will prevent any loss of revenue to I/T/U pharmacies that will result if drug coverage for dual eligibles is switched from Medicare to Medicaid.
> Exemption of AI/AN dual eligibles will eliminate the barriers dual eligibles, as well as AI/AN basic beneficiaries, will face in accessing the Part D benefit. For example, the MMA strategy to use private plans as a vehicle to provide prescription drug benefits severely restricts access for many AI/ANs because tribes are located in extremely rural areas where market forces do not make it advantageous for private plans to establish networks.
> Exemption of AI/AN dual eligibles from mandatory enrollment will eliminate the detrimental impact on reimbursement levels and the increase administrative costs that will occur when the I/T/U pharmacy does not know what PDP or MA-PD to bill. This is particularly true with regard to automatic enrollments because the AI/AN dual eligible may not know what PDP/MA-PD he or she has been enrolled in and it may be difficult for the I/T/U pharmacy to get this information. There may be additional delays if the individual has to disenroll and then enroll in a PDP/MA-PD for which the I/T/U pharmacy is a network provider.

It is important to recognize that exempting AI/AN dual eligibles from mandatory participation in Part D thereby allowing them to continue to receive prescription drug coverage through the State Medicaid Program will have no budget impact. This is so because prescription drug coverage costs will be paid by the federal government regardless of whether the benefit is provided under Medicaid at 100% FMAP or Medicare Part D subsidy for dual eligibles.

Exempting AI/AN from enrollment in Part D may be modeled on the existing statutory language exempting AI/AN from enrollment in mandatory Medicaid managed care plans. Section 1932(2)(C) of the Social Security Act, codified at 42 U.S.C. §1396u-2, provides for this exemption in recognition of the many difficulties (similar to the ones we have discussed throughout these comments) facing I/T/Us when dealing with private plans.

I/T/U PHARMACIES AND FEDERAL SUPPLY SCHEDULE (FSS)
Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems

Goal: To ensure that I/T/U pharmacies that participate in PDP pharmacy networks continue to have the option of purchasing prescription drugs for AI/AN Medicare beneficiaries at Federal Supply Schedule (FSS) prices or at the discounts available under the 340B program.

Terms and Conditions Issue, Page 46658: CMS notes that the proposed rule does not mandate a single set of terms and conditions for participation in a pharmacy network. CMS seeks comment on whether it should require that PDP sponsors and MA organizations offering an MA-PD plan make available to all pharmacies a standard contract for participation in their plans' networks.

Comment: As the Preamble recognizes, there are 201 I/T/U pharmacies serving 107,000 elderly and disabled AI/ANs in 27 states (page 46657). These pharmacies currently have access to Federal Supply Schedule (FSS) prices for the prescription drugs they dispense to AI/AN Medicare beneficiaries, or they are covered entities entitled to discounts under the 340B program, 42 U.S.C. 256b, or both. These discounted prices reflect the purchasing leverage of the Federal government and have enabled I/T/U pharmacies to meet the needs of AI/AN beneficiaries, whether or not enrolled in Medicare, in a cost-efficient manner.

We are concerned that PDP sponsors and MA organizations offering an MA-PD plan may require participating pharmacies to purchase drugs through the PDP sponsor or MA organization. This could have the effect of forcing I/T/U pharmacies to choose between participating in Medicare Part D and retaining their current access to FSS prices or 340B discounts, or both. We do not believe Congress intended that I/T/U pharmacies be forced into this choice. We therefore propose that the final rule prohibit PDP sponsors or MA organizations from requiring I/T/U pharmacies to purchase drugs through mechanisms other than FSS or the 340B program. This would not preclude an I/T/U pharmacy that wished to do so from purchasing its drugs through the PDP or MA-PD plan. The option, however, would be that of the I/T/U pharmacy, not the PDP or MA-PD plan.

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans should be

revised to read as follows (modifications are italicized):

"(4) Pharmacy network contracting requirements. In establishing its contracted pharmacy network, a PDP sponsor or MA organization offering qualified prescription drug coverage –
(i) Must contract with any pharmacy that meets the prescription drug plan's or MA-PD plan's terms and conditions;
(ii) May not require a pharmacy to accept insurance risk as a condition of participation in the PDP plan's or MA-PD plan's network; and
(iii) May not require an I/T/U pharmacy to purchase prescription drugs other than through the Federal Supply Schedule or prohibit an I/T/U pharmacy from receiving a discount as a covered entity under section 340B of the Public Health Service Act, 42 U.S.C. 256b. "

FORMULARY
Comments on Section 423.120(a)(4): Pharmacy Network Contracting Requirements.

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule.

Goal: I/T/Us should be exempt from formulary requirements and therefore able to utilize permissible substitutes. This exemption is needed to both accommodate the limited stock carried by many small I/T/U pharmacies and dispensaries and to allow I/T/Us to include in their formulary of drugs for which reimbursement will be paid those drugs available through FSS or 340b.

Comment: Section 423.120(b)(1) permits PDP and MA-PD plans to develop formularies so long as they meet the requirements of this section. We are concerned that plans that develop such formularies will make stocking the drugs in the formulary a requirement of its contracts with participating pharmacies. Many I/T/U pharmacies are small and cannot stock a full range of drugs, particularly if the condition the drug is used to treat is one beyond the scope of the I/T/U clinic and its providers. When establishing their formularies, I/T/U hospital and clinic pharmacies also consider aspects of treatment that may not be generally important, such as the extent of monitoring of the patient that may be required. Since many patients live far from the I/T/U pharmacy, this is an important therapeutic factor. Another factor in whether the I/T/U pharmacies will stock a particular drug is whether it is available from the Federal Supply Schedule or 340B program, which are the principle sources of drugs purchased by I/T/U pharmacies. See "I/T/U Pharmacies and Federal Supply Schedule (FSS)."

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans in Section 423.120(a)(4) should be further revised to add a new paragraph (iv) to read as follows (new language is italicized):

(v) May not require an I/T/U pharmacy to provide all the drugs in any formulary that may have been adopted by the PDP or MA-PD.

AI/AN beneficiaries often will have access only to an I/T/U pharmacy due to the remote locations where they live and where the I/T/U pharmacies are located. As noted in the Preamble, in the places where there are concentrations of Alaska Natives and American Indians, the I/T/U pharmacies are often the only pharmacy providers (page 46657). It is unfair to the AI/AN beneficiaries and to I/T/U providers to limit reimbursement or increase co-pays when a beneficiary is prescribed a drug that is not on the PDP or MA-PD formulary when that may be the only drug available from the I/T/U pharmacy that provides the same therapeutic effect as the formulary drug. In such cases, the PDP or MA-PD should be required to reimburse the I/T/U as if the drug were on its formulary in an amount equal to that the PDP or MA-PD would have paid for an equivalent drug on its formulary. In this way, neither the PDP or MA-PD or the I/T/U pharmacy is disadvantaged financially, and the patients are able to maintain access and continuity of care.

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (v) to read as follows (new language is italicized):

(vi) Must provide for reimbursement to I/T/U pharmacies for all covered Part D drugs whether or not they are on the PDP's or MA-PD's formulary at an amount not lower than the reimbursement that would have been made for an equivalent drug on the formulary.

BENEFITS AND BENEFICIARY PROTECTIONS
Comments on Section 423.100: DEFINITIONS
"Insurance or otherwise" for purposes of "Incurred costs"

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: To ensure that expenditures by I/T/Us on AI/AN beneficiaries (who do not qualify for the cost-sharing subsidy for low-income individuals) on prescription drugs count toward the annual out-of-pocket threshold ($3,600 in 2006).

Incurred Cost Issue, Pages 46649-46651: CMS notes that, under the proposed rule, AI/AN Medicare beneficiaries who are not eligible for low-income cost-sharing subsidies may receive drug coverage directly from I/T/U pharmacies or under CHS referrals. While these payments will count toward the AI/AN beneficiary's annual deductible, they will not count as incurred cost toward meeting the out-of-pocket threshold ($3,600 in 2006). The reason, in brief, is that "incurred costs" are defined by section 1860D-2(b)(4)(C)(ii) of the Social Security Act to exclude payments by "insurance or otherwise." But this statutory provision does not expressly include the I/T/U programs in this term. Rather, it is CMS, not the law that has defined what is encompassed by the term "insurance or otherwise". The agency has chosen to include I/T/U health programs as "insurance or otherwise," -- but has not explained the basis for that decision, nor analyzed the impacts of it on the IHS-funded system and affected Indian Medicare

beneficiaries, nor acknowledged that failing to count I/T/U pharmacy contributions toward "incurred costs" would be a windfall to the PDP in which an affected Indian is enrolled. Perhaps CMS recognized that this matter requires additional thought, as it asks for comments on "how … IHS beneficiaries will achieve maximized participation in Part D benefits."

Comment: The effect of CMS's decision to treat I/T/U programs as "insurance or otherwise" is to minimize, not maximize, participation of IHS beneficiaries in Part D benefits. As CMS itself acknowledges, "most IHS beneficiaries would almost never incur costs above the out-of-pocket limit." (69 FR at 46657). And, as CMS further recognizes, this policy "would likely provide plans with additional cost-savings." (69 FR at 46657). We do not believe that Congress intended Part D to be administered to minimize participation by AI/AN beneficiaries and to increase revenues for PDP and MA-PD plans at the expense of I/T/U programs. Yet that is precisely the result that the proposed rule achieves.

The proposed rule is not required by the statute. Section 1860D-2(b)(4)(C)(ii) does not expressly prohibit payments by I/T/U programs from being treated as "incurred costs." By using the phrase "not reimbursed by insurance or otherwise," Congress intended to give CMS discretion to fashion a sensible definition consistent with federal policy. AI/ANs are not "reimbursed" by their IHS or tribal health care providers or by any insurance. Rather in the case of AI/AN beneficiaries, that federal policy is the trust responsibility of the United States to provide health care to AI/ANs pursuant to laws and treaties. And, as CMS acknowledges in the Preamble at p. 46651, the I.H.S. "fulfills the Secretary's unique relationship to provide health services to AI/ANs based on the government-to-government relationship between the United States and tribes." In other words, AI/AN Medicare beneficiaries have a different legal standing than other Medicare beneficiaries.

The proposed rule, however, does not recognize this "unique" legal relationship. Instead, the proposed rule would require those AI/ANs who are Medicare beneficiaries but who are not eligible for the low-income subsidy program to pay substantial amounts out of pocket for their Medicare prescription drug coverage in order to meet the out-of-pocket threshold. In this way, the proposed rule violates the federal trust responsibility, under which AI/ANs are entitled to needed health care services, including prescription drugs, at the federal government's expense.

Section 1860D-2(b)(4)(C)(ii) specifies that costs shall be treated as incurred if they are paid "by another person, such as a family member, on behalf of the individual." (emphasis added). In the "unique relationship" between the federal government and AI/ANs, the I/T/Us are the functional equivalent of a "family member." Their mission, on behalf of the federal government, is to pay for prescription drugs and other health care services needed by AI/ANs. In terms of paying for prescription drugs, there is no functional difference between I/T/Us fulfilling their obligations to AI/ANs and family members fulfilling their obligations to one other. Again, there is nothing in the concept of family members paying incurred costs to suggest that Congress somehow intended that payments by I/T/Us on behalf of AI/ANs not be treated as incurred costs.

In the preamble, CMS explains that contributions made by charities would be considered "incurred

costs" and describes in detail the reasons for a desirable objectives achieved by this decision. Many of the considerations recited there apply to the I/T/U system, particularly the outcome that Medicare beneficiaries who are not eligible for the low-income subsidy would be able to qualify sooner for the catastrophic coverage level. In other words, these beneficiaries would have a better opportunity to fully utilize their Part D benefit.

The outcome is just the reverse with regard to an Indian not eligible for subsidy who is served by an I/T/U pharmacy. That Medicare beneficiary would have to pay the same premium for Part D coverage (or have it paid on his behalf by the I/T/U program as CMS suggests at p. 46651), but the benefit received for that premium would be only slightly more than $1000 -- far lower than that of a non-Indian beneficiary. This is so because this Indian patient would never get out of the "donut hole" and thus would never be able to utilize the catastrophic coverage feature of the Part D benefit.

The proposed rule has the effect of shifting from Medicare Part D and participating private plans to the Indian Health Service, tribes and tribal organizations, and urban Indian programs, the cost of Medicare prescription drug coverage for AI/AN Medicare beneficiaries who are not eligible for cost-sharing subsidies due to low income. This is because the I/T/Us will continue to use their limited appropriated funds to pay the prescription drug costs of these AI/AN beneficiaries – that is the I/T/U mission. As the preamble acknowledges, most of these beneficiaries will never reach the out-of-pocket limit as a result. The I/T/Us will then have to cover the drug costs above the out-of-pocket threshold, absorbing the costs that neither Medicare nor the Part D plans will cover. Given the poor health status of AI/ANs and the demonstrated underfunding of I/T/Us, it is inconceivable that Congress intended that CMS exercise its discretion to achieve this outcome. We therefore urge CMS to make the following revision to the rule:

Section 423.100-“Insurance or otherwise” for purposes of “Incurred Costs”

The definition of “insurance or otherwise” used to define “incurred costs” for purposes of meeting the out-of-pocket threshold should be revised to read as follows (modifications are italicized):

“Insurance or otherwise” means a plan (other than a group health plan) or program (other than a health program operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act , 25 U.S. C. 1603), that provides, or pays the cost of, medical care…, including any of the following: …(7) Any other government-funded program whose principal activity is the direct provision of health care to individuals (other than American Indians or Alaska Natives or urban Indians as those terms are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603).”

SUBMISSION OF BIDS AND MONTHLY BENEFICIARY PREMIUMS; PLAN APPROVAL
Comments regarding Section 423.286 Rules regarding premiums.

We incorporate herein statements contained in the Introductory Statement of these comments regarding

Indian health systems.

Goal: Tribes/Tribal Health Programs should be allowed to pay premiums on behalf of AI/AN (Group Payer) for AI/AN beneficiaries. Either rules or administrative policy should allow Tribes to add AI/AN beneficiaries to the group at any time.

Comment: We urge CMS to include I/T/U and/or tribes as permissible payment options and to remove barriers tribes have encountered in paying Part B premiums for AI/AN under current CMS group payer rules. Without these changes it is unlikely that AI/AN, who are entitled to health care without cost sharing, would elect to pay premiums themselves.

AI/ANs served in an I/T/U will most likely not elect to pay Part D premiums because these patients can access health care through the IHS based on the Federal Government's obligation to federally recognized Tribes. CMS recognizes this in the Preamble, page 46651, by stating that "the IHS may wish to pay for premiums to eliminate any barriers to Part D benefits". It is unlikely that AI/ANs, who are entitled to health care without cost sharing, would elect to pay premiums themselves, therefore, we request that language be included in the regulations recognizing the ability of I/T/Us to pay premiums if they so choose.

WAIVER OF COST SHARING
Comments on Background at 46651 and Section 423.120(a)(4)

We incorporate herein statements contained in the Introduction portion of these comments regarding Indian health systems and comments regarding I/T/U pharmacies and Federal Supply Schedule and Formulary.

Goal. Assure that I/T/U pharmacies are authorized to waive cost-sharing for AI/AN beneficiaries pursuant to Section 1128B (b)(3)(G) of the Social Security Act, as added by Section 101 of the MMA.

Comment: As discussed in the Preamble, the AI/AN beneficiaries receive health services under a unique government-to-government relationship between the United States and Tribes (page 46651). Under this relationship most care is provided directly by or through contract health services administered by I/T/U providers who provide the care without cost to the AI/AN beneficiary. The benefit plans provided under Medicare Part D contemplate patients sharing in the cost of the care they are provided. This is antithetical to the relationship between AI/AN beneficiaries and their I/T/U pharmacies.

* The pharmacy network contracting requirements applicable to PDPs and MA-PD plans, Section 423.120(a)(4) should be further revised to add an new paragraph (vi) to read as follows (new language is italicized):

(vii) Must authorize I/T/U pharmacies to waive all cost sharing obligations of AI/AN beneficiaries.

CREDITABLE COVERAGE
Comments Regarding Section 423.56: Procedures to Determine and Document Creditable Status of Prescription Drug Coverage

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: IHS coverage should be deemed "credible coverage" therefore making late enrollment penalties inapplicable to AI/AN beneficiaries.

Comment: The CMS TTAG strongly supports the decision of CMS to include in the definition of Creditable Prescription Drug Coverage a "medical care program of the Indian Health Service, Tribe or Tribal organization, or Urban Indian organization (I/T/U)" in the Medicare Prescription Drug Benefit Proposed Rule at § 423.56(a)(9). The Indian Health Service, Tribe or Tribal organizations, or Urban Indian organizations currently provide pharmaceuticals to AI/AN beneficiaries, either through direct care services or IHS Contract Health Services (CHS), at no cost to the beneficiary. For purposes of not being subject to late enrollment penalties, this Proposed Rule will protect those AI/AN beneficiaries who might not initially enroll in Medicare Part D because, for example, they receive their pharmaceuticals from an I/T/U pharmacy but later relocate off reservation and therefore need prescription drug coverage under Medicare Part D.

This definition is consistent with the definition of creditable coverage for purposes of continued health insurance coverage under the Employee Retirement Income Security Act (ERISA). See the Department of Labor regulations at 29 C.F.R. 2590.701-4 (a)(1)(vi). The DOL regulations include the I/T/U programs under their definition to ensure that when AI/AN beneficiaries relocate off reservation, where for example they had coverage from an IHS facility, that coverage counts as creditable coverage for group health plan coverage under the ERISA.

EXCLUDE CERTAIN INDIAN-SPECIFIC INCOME AND RESOURCES
FOR CONSIDERATION OF ELIGIBILITY OF AMERICAN INDIANS AND
ALASKA NATIVES FOR LOW-INCOME SUBSIDIES
Comments regarding Section 423.772: Premiums and Cost Sharing Subsidies for Low-Income Individuals-Definitions

Goal: To exclude from the income and resources tests for determination of an American Indian or Alaska Native (AI/AN) Medicare beneficiary's eligibility for a low-income subsidy under Part D certain income and assets that are excluded from consideration when determining eligibility for Medicaid.

Comment. CMS has recognized that certain Indian-specific income and assets are to be excluded when determining the eligibility of an AI/AN for Medicaid. See, e.g., CMS State Medicaid Manual Part 3 --

Eligibility, §3810. These same exclusions should apply to the determination of whether an AI/AN qualifies for a low-income subsidy under Part D. Since all dual eligibles will be moved from Medicaid to Part D for prescription drug coverage, it is appropriate that the same federally-established exclusions should apply to the affected AI/AN dual eligibles.

In Sec. 423.772, the definitions of "income" and "resources" should be revised to exclude income that derives from tribal lands and other resources currently held in trust status, from judgment funds awarded by the Indian Claims Commission and the U.S. Claims Court, and from other property held in a protected status, as specified in the Medicaid Manual. In addition, cultural objects, as specified in the Medicaid Manual, should also be exempted from the definitions of these terms.

ELIGIBILITY AND ENROLLMENT
Comments regarding Section 423.48: Information about Part D.

We incorporate herein statements contained in the Introductory Statement of these comments regarding Indian health systems.

Goal: Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to the I/T/U at no cost.

Comment: Without outreach, education and enrollment assistance from Indian health programs, AI/AN are unlikely to enroll in Medicare Part D or Part C. AI/AN are entitled to receive free health care at I/T/Us and through Contract Health Services, thus they have no incentive to enroll in programs requiring premiums and cost sharing. I/T/Us know who may be eligible for new Medicare programs and how to contact them. AI/ANs trust I/T/U health workers. Outreach and enrollment efforts specific to AI/AN should be implemented to address possible language and cultural barriers as well as the unique structure of Indian health programs. TTAG representatives should be included in the development of outreach and education materials, which should be provided to I/T/U at no cost. As CMS states on Page 46642 of the Preamble, “we would undertake special outreach efforts to disadvantaged and hard-to reach populations, including targeted efforts among historically underserved populations, and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. Materials and information would be made available in languages other than English, where appropriate.” In implementing this provision CMS must reach out to AI/AN beneficiaries.

Attachment 1.

INDIAN HEALTH ADDENDUM TO
SPECIAL ENDORSED PLAN AGREEMENT

1. Purpose of Indian Health Addendum; Supersession.

The purpose of this Indian Health Addendum is to apply special terms and conditions to the agreement by and between _____(herein "Plan" or Plan Sponsor") and _____ (herein "Provider") for administration of Transitional Assistance under the Prescription Drug Discount Card program authorized by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 at pharmacies and dispensaries of Provider. To the extent that any provision of the Special Endorsed Plan Master Agreement or any other addendum thereto is inconsistent with any provision of this Indian Health Addendum, the provisions of this Indian Health Addendum shall supercede all such other provisions.

2. Definitions.

For purposes of the Special Endorsed plan Master Agreement, any other addendum thereto, and this Indian Health Addendum, the following terms and definitions shall apply:

(a) The term "Plan Sponsor" means _____ which operates the Prescription Drug Discount Card Plan defined in subsection (b).

(b) The terms "Prescription Drug Discount Card Plan" and "Plan" means a Prescription Drug Discount Card Plan operated by Plan Sponsor that is approved by the Centers for Medicare and Medicaid Services (CMS) pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and holds a special endorsement from CMS to administer the Transitional Assistance feature of the Prescription Drug Discount Card program at pharmacies or dispensaries operated by the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations (hereafter "I/T/U endorsement").

(c) The term "Provider" means an Indian tribe, tribal organization or urban Indian organization which operates one or more pharmacies or dispensaries, and is identified by name in Section 1 of this Indian Health Addendum.

(d) The term "Centers for Medicare and Medicaid Services" means the agency of that name within the U.S. Department of Health and Human Services.

(e) The term "Indian Health Service" means the agency of that name within the U.S. Department of Health and Human Services established by Sec. 601 of the Indian Health Care Improvement Act, 25 USC §1661.

(f) The term "Indian tribe" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(g) The term "tribal organization" has the meaning given than term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(h) The term "urban Indian organization" has the meaning given that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

(i) The term "Indian" has the meaning given to that term in Sec. 4 of the Indian Health Care Improvement Act, 25 USC §1603.

3. Description of Provider.

The Provider identified in Section 1 of this Indian Health Addendum is (check appropriate box):

/_/ An Indian tribe that operates a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/_/ A tribal organization authorized by one or more Indian tribes to operate a health program, including one or more pharmacies or dispensaries, under a contract or compact with the Indian Health Service issued pursuant to the Indian Self-Determination and Education Assistance Act, 25 USC §450 et seq.

/_/ An urban Indian organization that operates a health program, including one or more pharmacies or dispensaries, under a grant from the Indian Health Service issued pursuant to Title V of the Indian Health Care Improvement Act.

4. Co-pays, deductibles.

The parties agree that the Provider may waive any co-payments for any Indian who is enrolled in the Plan when such Indian receives services pursuant to the Plan at any pharmacy or dispensary of Provider.

5. Persons eligible for services of Provider.

(a)The parties agree that the persons eligible for services of the Provider under the Special Endorsed Plan Master Agreement and all addenda thereto shall be governed by the following authorities:

(1) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and implementing regulations in Part 403 of Title 42, Code of Federal Regulations
(2) Sec. 813 of the Indian Health Care Improvement Act, 25 USC §1680c
(3) Part 136 of Title 42, Code of Federal Regulations
(4) The terms of the contract, compact or grant issued to Provider by the Indian Health Service for operation of a health program, including one or more pharmacies or dispensaries.

(b) No clause, term or condition of the Special Endorsed Plan Master Agreement or any addendum thereto shall be construed to change, reduce, expand or alter the eligibility of persons for services of the Provider under the Plan that is inconsistent with the authorities identified in subsection (a).

6. Applicability of other Federal laws.

The parties acknowledge that the following Federal laws and regulations apply to Provider as noted:

(a) A Provider who is an Indian tribe or a tribal organization:

(1) The Indian Self-Determination and Education Assistance Act,
25 USC §450 et seq.;
(2) The Indian Health Care Improvement Act, 25 USC §1601, et seq.;
(3) The Federal Tort Claims Act, 28 USC §2671-2680;
(4) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2; and
(5) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

(b) A Provider who is an urban Indian organization:

(1) The Indian Health Care Improvement Act, 25 USC §1601, et seq.;
(2) The Federal Privacy Act of 1974, 5 USC §552a and regulations at 42 CFR Part 2;
(3) The Federal Tort Claims Act, 28 USC §2671-2680 to the extent the urban Indian organization is a Federally Qualified Health Center;
(4) The Health Insurance Portability and Accountability Act of 1996, and regulations at 45 CFR parts 160 and 164.

7. Non-taxable entity.

Provider is a non-taxable entity and as such shall not be required by Plan or Plan Sponsor to collect or remit any Federal, State, or local tax.

8. Insurance and indemnification.

A Provider which is an Indian tribe or a tribal organization shall not be required to obtain or maintain general liability, professional liability or other insurance, as such Provider is covered by the Federal Tort Claims Act pursuant to Federal law (Pub.L. 101-512, Title III, §314, Nov. 5, 1990, 104 Stat. 1959, as amended by Pub. L. 103-138, Title III, §308, Nov. 11, 1993, 107 Stat. 1416 (codified at 25 USC §450f note); and regulations at 25 CFR Part 900, Subpt. M. A Provider which is an urban Indian organization which holds designation as a Federally Qualified Health Center shall not be required to obtain or maintain general liability, professional liability or other insurance as such Provider is covered by the Federal Tort Claims Act pursuant to such designation. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall be interpreted to authorize or obligate Provider or any employee of such Provider to operate outside of the scope of employment of such employee, and Provider shall not be required to indemnify Plan or Plan Sponsor.

9. Employee license.

Where a Federal employee is working within the scope of his or her employment and is assigned to a pharmacy or dispensary of Provider, such employee is not subject to regulation of qualifications by the State in which Provider is located, and shall be deemed qualified to provide services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided that such employee is currently licensed to practice pharmacy in any State. To the extent that any State exempts from state regulation a direct employee of Provider, such employee shall be deemed qualified to perform services under the Special Endorsed Plan Master Agreement and all addenda thereto, provided such employee is licensed to practice pharmacy in any State. This provision shall not be interpreted to alter the requirement that a pharmacy hold a license from the Drug Enforcement Agency.

10. Provider eligibility for payments.

To the extent that the Provider is exempt from State licensing requirements pursuant to 42 CFR §431.110, the Provider shall not be required to hold a State license to receive any payments under the Special Endorsed Plan Master Agreement and any addendum thereto.

11. Re-Enrollment Period.

The Centers for Medicare and Medicaid Services has established as a matter of policy that an enrollee eligible for services from an I/T/U pharmacy shall be permitted to disenroll from a prescription drug discount card plan that does not hold a special I/T/U endorsement and to re-enroll in a plan that has received such endorsement at any time during the life of the Medicare Drug Discount Drug Card Program. Nothing in the Special Endorsed Plan Master Agreement or any other addendum thereto shall be interpreted to impede this right of re-enrollment.

12. Dispute Resolution.

Any dispute arising under the Special Endorsed Plan Master Agreement or any other addendum thereto shall be resolved through negotiation rather than arbitration. The parties agree to meet and confer in good faith to resolve any such disputes.

13. Governing Law.

The Special Endorsed Plan Master Agreement and all addenda thereto shall be governed and construed in accordance with Federal law of the United States. In the event of a conflict between the Special Endorsed Plan Master Agreement and all addenda thereto and Federal law, Federal law shall prevail. Nothing in the Special Endorsed Plan Master Agreement or any addendum thereto shall subject Provider to State law to any greater extent than State law is already applicable.

14. Pharmacy/Dispensary Participation.

The Special Endorsed Plan Master Agreement and all addenda thereto apply to all pharmacies and dispensaries operated by the Provider, as listed on the Schedule B to this Indian Health Addendum.

15. Acquisition of Pharmaceuticals.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's acquisition of pharmaceuticals from any source, including the Federal Supply Schedule and participation in the Drug Pricing Program of Section 340B of the Public Health Service Act. Nor shall anything in the Special Endorsed Plan Master Agreement and all addenda thereto require the Provider to acquire drugs from the Plan Sponsor, the Plan or from any other source.

16. Formulary.

Nothing in the Special Endorsed Plan Master Agreement and all addenda thereto shall affect the Provider's formulary. The Provider is exempt from any provision of the Special Endorsed Plan Master Agreement and all addenda thereto requiring compliance or cooperation with the Plan Sponsor's or Plan's formulary, drug utilization review, generic equivalent substitution, and notification of price differentials.

17. Transitional Assistance Claims.

The Provider may submit claims to the Plan by telecommunication through an electronic billing system or by calling a toll-free number for non-electronic claims; in the case of the latter, Provider shall submit a confirmation paper claim. When the toll-free number is used for non-electronic claims, Plan will verify the balance of an enrollee's Transitional Assistance subsidy remaining as of that time and obligate funds from that subsidy for payment of the Provider's claim at the point of sale. Instructions for filing and adjudicating non-electronic claims are attached as Schedule C.

18. Payment Rate.

Claims from the Provider for Transitional Assistance benefits shall be paid at the same rates as the State Medicaid program fee-for-service in the State where the Provider's pharmacy or dispensary is located, pursuant to Schedule A of this Addendum.

19. Information, Outreach, and Enrollment Materials.

All materials for information, outreach, or enrollment prepared for the Plan shall be supplied by Plan to Provider in paper and electronic format at no cost to the Provider. Provider shall have the right to convert such materials as it deems necessary for language or cultural appropriateness.

20. Hours of Service.

The hours of service of the pharmacies or dispensaries of Provider shall be established by Provider. At

the request of the Plan, Provider shall provide written notification of its hours of service to the Plan.

1 See, e.g., 25 U.S.C. § 1601.
2 42 U.S.C. § 2001.
3 U.S. Commission on Civil Rights, Broken Promises: Evaluating the Native American Health Care System, July 2, 2004 (staff draft).
4 U.S. Commission on Civil Rights, A Quiet Crisis: Federal Funding and Unmet Needs in Indian Country, July 2003.
5 Federal Disparity Index Report for 2002, showing an expenditure of $1,384 per HIS user compared to a benchmark price of $2,687 per user.
6 This number represents 85 percent of the three-year total of active users.
7 This is the number of active users, defined as at least one visit in the past three years.
8 From Table 2, "Full" Dual Eligible Enrollment and Prescription Drug Spending, by State, 2002, in "The 'Clawback:' State Financing of Medicare Drug Coverage" by Andy Schneider, published by the Kaiser Commission on Medicaid and the Uninsured, June 2004.
9 This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.
10 This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.
11 Allowing the private plans to count I/T/U pharmacies toward access standards may provide incentive for private plans to contract with a few I/T/U pharmacies but only where the private plan needs the I/T/U pharmacy to meet the Tricare access standards. It will not be an incentive to contract with all I/T/U pharmacies.
12 CMS proposes this option in 69 FR at 46657.
13 One way to decrease administrative costs while at the same time assuring access for AI/AN beneficiaries who use I/T/U pharmacies is to create special endorsement PDPs and MA-PDs to serve AI/AN beneficiaries similar to the mechanism used in the Temporary Prescription Drug Discount Card Program. This matter is discussed further in our comments regarding §423.120(a)(1).

14 We submit as Attachment 1 a model tribal addendum prepared by the CMS Tribal Technical Advisory Group to be utilized by tribal and urban Indian pharmacies participating in the Temporary Prescription Drug Discount Card Program.
15 This low number was calculated using the 25,963 figure for dual eligibles in 2003 and the $918 per capita spending in 2002. It is probably unrealistically low for 2006 given the increase in aging population in Indian Country and the increase in drug prices.

16 This higher number uses the 30,544 number of dual eligibles in 2003 and the $1,756 estimated spending in 2006.
17 Washington State Administrative Code provides a precedent and contains sample language for this provision. WAC 284-43-200 Network adequacy. “(7) To provide adequate choice to covered persons who are American Indians, each health carrier shall maintain arrangements that ensure that American Indians who are covered persons have access to Indian health care services and facilities that are part of

the Indian health system. Carriers shall ensure that such covered persons may obtain covered services from the Indian health system at no greater cost to the covered person than if the service were obtained from network providers and facilities. Carriers are not responsible for credentialing providers and facilities that are part of the Indian health system. Nothing in this subsection prohibits a carrier from limiting coverage to those health services that meet carrier standards for medical necessity, care management, and claims administration or from limiting payment to that amount payable if the health service were obtained from a network provider or facility."

18 In creating special endorsements for AI/AN CMS could establish:
* A pool of Indian-specific PDP/MA-PD who would serve regions that mirror IHS Areas, or
* Nationwide PDPs/MA-PDs to serve AI/AN in all fifty states
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CMS-4068-P-543

Submitter : Jacalyn Lott **Date & Time:** 09/30/2004 07:09:32

Organization : The Arc of Union County

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-543-Attach-1.txt

CMS-4068-P

September 30, 2004

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

To Whom It May Concern:

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

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

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

Although the exact number of dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) receiving long-term care services due to mental retardation or a related developmental disability is unknown, Social Security Administration estimates suggest that they make up a significant proportion of the population (50 percent or more) served by Mental Retardation and/or Developmental Disabilities (MR/DD) state agencies. Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts
by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug

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

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

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

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

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

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

restrictions and they must have access to all medically necessary prescription drugs at a plan's preferred level of cost-sharing. We recommend that this treatment apply to the following overlapping special populations: people who are dually eligible for Medicare and Medicaid people who live in nursing homes, ICF-MRs and other residential facilities
people who have life threatening conditions
people who have pharmacologically complex condition such as epilepsy, Alzheimer's disease, multiple sclerosis, mental illness, HIV/AIDS.

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

exceptions process are made available at the preferred level of cost-sharing.

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

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

Thank you for your consideration of our views.

Sincerely,

Jacalyn Lott
Assistant Executive Director
The Arc of Union County

CMS-4068-P-544

Submitter : Mr. Phillip Martin **Date & Time:** 09/30/2004 07:09:50

Organization : Mississippi Band of Choctaw Indians

Category : Other Government

Issue Areas/Comments

GENERAL

GENERAL

See attached.

CMS-4068-P-544-Attach-1.pdf

MISSISSIPPI BAND OF CHOCTAW INDIANS

TRIBAL OFFICE BUILDING
P. O. BOX 6010
PHILADELPHIA, MISSISSIPPI 39350
TELEPHONE (601) 656-5251

September 30, 2004

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

address for electronic delivery: <http://www.cms.hhs.gov/regulations/ecomments>

RE: Comments on Proposed Rule -- Medicare Part D Permanent Prescription Drug Benefit pursuant to Notice in 69 Federal Register 46632 (August 3, 2004)
File Code CMS-4068-P

Dear Administrator:

On behalf of the Mississippi Band of Choctaw Indians, I hereby submit the attached comments on the proposed rules to implement the Permanent Prescription Drug Benefit under Part D of the Medicare program.

The attached comments address issues related to the impact implementation of the proposed rules will have on American Indian and Alaska Native beneficiaries who are served by pharmacies operated by the Indian Health Service, Indian tribes, tribal organizations or urban Indian organizations (I/T/U pharmacies). As proposed, the rules would have a devastating adverse impact on the revenue collected by the I/T/U pharmacies for their dual eligible Indian patients and must be revised to prevent this outcome. It clearly was not the intent of Congress in enacting the Medicare Modernization Act to reduce revenues to Indian health programs. The United States has a trust responsibility for Indian health, and this responsibility must assure that the Indian health system is not harmed by implementation of Part D.

We urge CMS to make revisions to the Part D regulations pursuant to recommendations set out in these comments.

Sincerely yours,

Phillip Martin/bjf
Phillip Martin, Chief

Attachment -- Part D Comments

CMS-4068-P-545

Submitter : Ms. Kathy Hoell **Date & Time:** 09/30/2004 07:09:29

Organization : Nebraska Statewide Independent Living Council

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-545-Attach-1.doc

Nebraska
Statewide Independent Living Council
SILC
215 Centennial Mall South
Suite 520
Lincoln, NE 68508
Voice-1-402-438-7979
Fax-1-402-438-7991
Nesilc@alltel.net or khoell@cox.net
supporting the right to independent living

September 30, 2004

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

To Whom It May Concern:

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

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

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, notwithstanding the best intentions or efforts by CMS, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. CMS and the private plans that will offer prescription drug coverage through the Part D program are faced with serious time constraints to implement a prescription drug benefit staring on January 1, 2006. This does not take into consideration the unique and complex set of issues raised by the dual eligible population. Given the sheer implausibility that it is possible to identify,

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

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

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

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

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

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

populations:

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

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:

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

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES:

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

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

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

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

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

Thank you for your consideration of our views.

Sincerely,

Kathy Hoell
Executive Director

CMS-4068-P-546

Submitter : **Date & Time:** 09/30/2004 07:09:17

Organization :

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-546-Attach-1.doc

September 30, 2004

I am writing today to express my concern regarding the proposed rule changes for the "Medicare Program: Medicare Prescription Drug Benefit." I feel that the proposed rule does not provide protections for 13 million Medicare beneficiaries with disabilities and chronic health conditions. I am especially concerned that the 7 million designated as dual eligible may lose all Medicaid prescription drug benefits currently available to them.

I would like to urge you to delay the implementation of Part D for dual eligibles. Dual eligibles are individuals who are both Medicare beneficiaries and also have Medicaid coverage. These individuals are in need of both as they typically have lower incomes than the general Medicare population and have wide-ranging needs forcing them to rely heavily on prescription drug coverage to maintain basic health needs. Additionally, these people are the poorest and most vulnerable of all Medicare beneficiaries and the proposed rule change will remove the present health safety net available to them through Medicaid. The result will be a decline in their health resulting in unwanted nursing facility placement or accessing mental institutions to obtain needed medications. This movement diverges from the independent living philosophy provided by Olmstead and the Freedom Initiative supported by the Centers for Medicine and Medicaid Services.

Another reason for delaying the implementation of Part D is to allow time to determine the potential for the proposed rule changes to affect the Ticket to Work/Work Incentives Improvement Act (TWWIIA), the Plan for Achieving Self Support (PASS) and other Social Security work incentives. Advocates and others have worked diligently over the last ten years to remove disincentives to work for beneficiaries. An overwhelming number of beneficiaries report the reason they did not aggressively seek employment was the loss of and/or reduced health care coverage. Another words, they stay home in order to obtain health coverage. If Part D is implemented, the same work disincentives so many worked so hard to eliminate will be reinstated. The final result will be that more of our citizens will choose to remain at home, disenfranchised from society, in order to get the medications they need.

Thank you for your consideration of my concerns.

Sincerely yours,

Judy Wright
26 Mary Street
Auburn, NY 13021
(315) 255-2508

Submitter : Holly Jones **Date & Time:** 09/30/2004 08:09:18

Organization : University of Wisconsin Hospital and Clinics

Category : Pharmacist

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 in an academic health system, I am deeply concerned with the rules as they are currently proposed.

First, I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I hope that my concerns and the concerns being expressed by 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,

Holly D. Jones, PharmD

Holly Jones, PharmD
University of Wisconsin Hospital and Clinics
Department of Pharmacy
F6/133 CSC, Mail Stop 1530
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Madison, WI 53792
(608) 263-1297
(608) 263-9424 - fax
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CMS-4068-P-547-Attach-1.doc

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 in an academic health system, I am deeply concerned with the rules as they are currently proposed.

First, I would like express my appreciation for this opportunity to offer the Centers for Medicare and Medicaid Services (CMS) my constructive opinion of the rules developed for the implementation of the Medicare Part D benefit. I hope that my concerns and the concerns being expressed by 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.

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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.

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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,

Holly D. Jones, PharmD

Holly Jones, PharmD
University of Wisconsin Hospital and Clinics
Department of Pharmacy
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CMS-4068-P-548

Submitter : **Date & Time:** 09/30/2004 08:09:41

Organization :

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

To whom it may concern,

My name is Janice and I have been on Xanax for the last 6 years, and am now in the process of slowly tapering myself off this medication. My doctor understands that you cannot just be taken off this type of medication abruptly, as there are severe withdrawals.

When my mother was alive she also was on Xanax for several years. My mother died 2 years ago, and I know for a fact, had my mother been taken off her medication abruptly, it would have made her last years of living totally unbearable. To her, as well to myself, this medication has been a life saver, and to take this medication off the market would be an extreme disservice to everyone on benzodiazepines, and would literally I believe kill some people. The only way to get off the medication, is a slow tapering of the drug, over the course of years. Switching a patient to another medication, would cause more harm as withdrawal symptons would adversely affect not only the patient, but the people around them.

I am sorry I was ever put on this medication, but am glad I have found a doctor who understands that the only method of treatment is a slow tapering of the medication, not an abrupt stopping, or switching to another medication. This will hurt the patients on this medication. as withdrawal from benzodiazepines in not like a withdrawal from heroine. You don't go through just a 3 day withdrawal, like in detox centers, but a far deadly withdrawal, that gets worse in time, and not better.

I hope that you will not pass this legislation, as the people affected by this decision, are the ones who need it the most, the people on Medicare/Medicaid, can't afford both the mental and physical anguish of abrupt withdrawal.

I wonder how many of you on this panel have every been on a benzodiazepine and then abruptly been taken off. I strongly urge you all to stop this legislation. It is hard enough to find good physicians that understand the process involved in getting off benzodiazepines, and removing them from the people who need them most, would both be a disservice to you as a physician, but to those, who you put on this medication to begin with.

Sincerely,
Janice from Boston

CMS-4068-P-549

Submitter : Ms. Laura Williams **Date & Time:** 09/30/2004 08:09:20

Organization : Californians for Disability Rights

Category : Individual

Issue Areas/Comments

Issues 1-10

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

The Dual Eligible regulations will mean the most vulnerable Americans will lose access to medications and services now fully covered by the dual coverage. The very health and welfare of millions of Americans will be jeopardized by inserting these regulations that will impose out of pocket costs. You will be taking the food from their mouths or making them chose between eating and medical care.

CMS-4068-P-550

Submitter : Ms. Barbara Linn **Date & Time:** 09/30/2004 08:09:42

Organization : Ms. Barbara Linn

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Please see the attached letter from the disabled community:

September 30, 2004

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

To Whom It May Concern:

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

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

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

Being familiar with the work of the National Council on Disability in 1994 ? 1996 to develop the Ticket to Work/Work Incentives Improvement Act, and having advocated for its passage through Congress, I am personally appalled that the Part D Program, touted as a benefit, could, as it is written, negate our ten years of hard work.

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

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

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

Thank you for your consideration of my views.

Yours sincerely,

Barbara Linn
3970 Hillman Ave. Apt 8-B
Bronx, New York 10463
(718) 796-9673
bblin@AOL.com

Submitter : Mrs. Tracy Sault **Date & Time:** 09/30/2004 08:09:52

Organization : Finger Lakes Independence Center

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

September 30, 2004

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

To Whom It May Concern:

The Finger Lakes Independence Center welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Finger Lakes Independence Center assists all people with disabilities, their families and friends to promote independence and make informed decisions in pursuit of their goals. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

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

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

DESIGNATE SPECIAL POPULATIONS WHO WILL RECEIVE AFFORDABLE ACCESS TO AN ALTERNATIVE, FLEXIBLE FORMULARY:
For people with serious and complex medical conditions, access to the right medications can make the difference between living in the community, being employed and leading a healthy and productive life on the one hand; and facing bed rest, unnecessary hospitalizations and even death, on the other. Often, people with disabilities need access to the newest medications, because they have fewer side effects and may represent a better treatment option than older less expensive drugs. Many individuals have multiple disabilities and health conditions making drug interactions a common problem. Frequently, extended release versions of medications are needed to effectively manage these serious and complex medical conditions. In other cases, specific drugs are needed to support adherence to a treatment regimen. Individuals with cognitive impairments may be less able to articulate problems with side effects making it more important for t

CMS-4068-P-552

Submitter : Ms. Cristine Marchand **Date & Time:** 09/30/2004 08:09:09

Organization : The Arc of Maryland

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the disability community.

CMS-4068-P-552-Attach-1.txt

CMS-4068-P

September 30, 2004
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
Baltimore, MD 21244-8014

To Whom It May Concern:

The Arc of Maryland welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Arc of Maryland is a state chapter of The Arc, the largest statewide advocacy organization for persons with mental retardation and related developmental disabilities. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

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

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

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

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

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

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

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

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

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

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

populations:

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of our views. Sincerely, Cristine Marchand Executive Director

CMS-4068-P-553

Submitter : Dr. Debra Wentz **Date & Time:** 09/30/2004 08:09:30

Organization : New Jersey Association of Mental Health Agencies

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the NJ Association of Mental Health Agencies, Inc, a statewide mental health provider association.

CMS-4068-P-553-Attach-1.doc

September 30, 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: Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)
File Code CMS-4068-P

Dear Colleagues at CMS:

The New Jersey Association of Mental Health Agencies, Inc. (NJAMHA) is statewide association comprised of mental health provider organizations, both hospitals and independent clinics, serving persons with mental illnesses in the community. Many beneficiaries who will be enrolled in the drug prescription benefit of the MMA will become eligible for the program by virtue of having a psychiatric disability, regardless of age, through the Social Security Disability Insurance (SSDI) Program, and many of these individuals will be both indigent and have a mental illness. In fact, the Bazelon Center for Mental Health Law reports that "Medicare is the primary health coverage for some five million non-elderly adults who receive SSDI—more than one fourth disabled by a mental illness."

A significant portion of the public served by our member providers are poor, coping with serious mental illness, have experienced psychiatric hospitalizations and, at one time or another, have been prescribed psychotropic medications to help manage their symptomatology. They are frequently socially isolated due to the associated stigma of mental illness, and far too many do not adhere to their medication regimen due to various factors such as bothersome side effects. For many, due to disability, age or poverty status, they have qualified for Medicare or both Medicare and Medicaid benefits.

It is from this perspective that NJAMHA submits the following comments on the proposed rule specifying most of the requirements for the implementation of the prescription drug program regulations of the Medicare Prescription Drug Benefit (Medicare Part D) of the Medicare Modernization Act of 2003 published in the August 3, 2004 Federal Register. The complexity and sheer length of the proposed rule have challenged a thorough review, but we have noted our concerns in regard to those areas expected to present major impediments to the individuals served by our member agencies and organizations.

1) Formularies: Under the new Medicare drug benefit, prescription drug coverage for dual eligibles,

now provided under the New Jersey Medicaid program, will terminate as of January 1, 2006, when the MMA prescription drug benefit becomes effective; however, eligibility for all other state Medicaid services will continue for this group of beneficiaries.

For dual eligibles in New Jersey, the vast benefits of the New Jersey Medicaid program's relative open access to prescription drugs with no formulary will be sacrificed. Clearly, as a result of the anticipated restrictive formularies under the new drug benefit plan, these vulnerable individuals will have less access to medically necessary medications essential to their recovery. The draft formulary guidelines severely limit access to the array of "newer" atypical antipsychotic medications that have directly contributed to increased rates of recovery and symptom reduction. An even more immediate concern is that when the new law becomes effective in 2006, dual eligibles may have to stop taking their medications if their medications are not on the formulary or be switched to medications that are not effective. The affect of antipsychotic and atypical medications vary significantly in their impact from individual to individual, to a much greater extent than medications prescribed for physical illnesses, based on their dissimilar effects on different receptors in the brain, specific diagnoses, coexisting medical conditions, genetics, cultural influences, differences in individuals' pharmacological response and tolerance and factors associated with age. (William M. Glazer, MD, Glazer Medical Solutions, 2000; Richard Levy, Ph.D., National Pharmaceutical Council, 2004)

Restrictive formularies do not recognize the idiosyncratic nature of mental illnesses and the subtleties associated with prescribing of psychotropic medications. This includes the necessity of myriad combinations of drugs that are required in the treatment of mental illnesses. The proposed formulary guidelines radically reduce the number of distinct drug classes and categories from Medicare's current 209 to 146 under the private plan providers of drugs under Medicare Plan D. Private plans are required to cover at least two drugs under each category and class. The newer atypicals, of which there are presently six, will likely be reduced or omitted due to their cost. These drugs are not substitutable for one another, and restricting these drugs to only one or two to a formulary (if not left out entirely) is a recipe for disaster. The indications dictating their use are unique across the six. Further, their use has increased compliance rates and consequently reduced the rates of hospitalization and emergency room utilization at a cost savings much more significant than the cost of the medication itself, especially for persons with histories of psychiatric hospitalizations.

Drugs for the treatment of mental illnesses are not interchangeable and can require periods of six weeks or longer to determine efficacy, often after harrowing trial-and-error. The fact that health plans would be allowed to severely restrict classes and categories and routinely change formularies without regard to the effect on enrollees causes concern for the safety and welfare of this vulnerable population. Formularies must be expansive and flexible in order to enable beneficiaries to find and remain on any drug or drug combination that will help them sustain their symptom relief and their tenure in their home communities. Individuals of low income living with serious mental illnesses, who frequently also have complex medical conditions, will have difficulty traversing the system due to lower levels of functioning resulting from their highly compromised situations. As such, they would be at imminent risk of decompensation and destabilization if their access to medications were reduced.

Research has shown that many states have exempted mental health medications from formularies or preferred drug lists. Numerous states that did not exempt psychotropic medications, found costs grew significantly due to increased emergency room visits, specialty visits and hospitalizations. In fact, a number of states, such as New Hampshire, Michigan and Maine, have moved away from their restrictive policies limiting access to psychiatric drugs.

Health plans providing Medicare Part D coverage must have flexible and extensive formularies for persons with mental illnesses or else the enormous scientific and societal gains made in regard to the treatment of persons with mental illnesses will be jeopardized.

We are also calling for safeguards to protect enrollees whose prescription plan decides to eliminate the medications they are currently prescribed during the period they are locked into a particular plan.

2) Co-Payments: Vulnerable, low-income persons with psychiatric illnesses must be protected from co-payments they cannot afford. A majority of these individuals have complex medical conditions concomitant with their mental illnesses that require multiple medications making even modest co-payments excessive. Furthermore, there will be no assurances that dual eligibles who are unable to afford the co-payments, will be able to have their prescriptions filled.

3) Continuity of Care: As referenced above under formularies, NJAMHA recommends the adoption of language that provides special protections for low-income beneficiaries with mental illnesses. This will also mean that many beneficiaries presently on medications that will not be included under the new Medicare prescription benefit will have to be taken off the medication and placed on those included in the formulary for which, frequently, there is no therapeutic equivalent. Recurrence of symptoms and increased institutional costs will undoubtedly diminish or obviate all intended benefits of this component of the MMA.

4) Appeals Process: An appeals process, by an independent authority, that is clearly understood, and easy to navigate is absolutely essential for persons whose levels of functioning may be compromised by mental illness or for persons who are poor and of low income who do not have the internal and financial resources to navigate difficult appeals processes. NJAMHA understands that under the Medicare Part D benefit, physicians/psychiatrists will not be allowed to file an appeal. NJAMHA strongly advocates for opening appeals to providers as well. NJAMHA also understands that notification to enrollees of their ability to appeal is not required if their medication is removed from the formulary or if the co-payment for their medication is increased during the enrollment period. Enrollees must receive this notification in clear, concise and straightforward language. While under appeal, access to clinically/medically necessary drugs must be granted with no financial penalty to enrollees if the appeal is lost.

Closing Comments:
For persons now covered by both Medicare and Medicaid, the specter of restricted access imposed by formularies to medically and clinically necessary medications and the levy of co-payments proposed under the Medicare Part D benefit will undoubtedly directly contribute to increased visits to emergency rooms and costly hospitalizations. This untoward outcome is decidedly counter to the intent of the

MMA. In that a major stated goal of this undertaking is to assure beneficiaries access to medically necessary drugs, NJAMHA finds limiting access through restrictive formularies and imposing co-payments for lower income persons with psychiatric disabilities is totally inconsistent with the open access essential to treating individuals with mental illnesses.

Enormous strides have been made over the past decades to close state psychiatric facilities and to increasingly shift the locus of care to the community. A major factor in reducing the rate of new and repeated hospitalizations, family disruption, homelessness, inappropriate incarceration and costly emergency room visits is open access to medications and compliance with medication regimens, which often becomes a barrier when first generation drugs are prescribed due to their significant side effects such as sedation, confusion, as well as extra-pyramidal symptoms. Especially for persons who are mentally ill and indigent, the lack of access to medications that "work", frequently found after many years of trial and tribulation, is a surefire way to increase the expenditure of public funds, not to mention the associated human cost.

NJAMHA urges you to consider safeguards for beneficiaries who are poor and living with mental illnesses such as: 1) exemptions in formularies for persons with mental health diagnoses (at a minimum, no disruptions of medication regimens during the plan year for persons stabilized); 2) the elimination of co-payments for poor and low income enrollees; 3) the expansion of parties who may file an appeal to include providers; 4) clear, easy-to-understand appeals processes with the ability to continue access to medication throughout appeal process.

NJAMHA thanks you for the opportunity to provide comments on the MMA. If you have any questions regarding this response, please do not hesitate to contact me at (609) 838-5488, extension 292.

Very truly yours,

Debra L. Wentz, Ph.D.
Chief Executive Officer

Cc: President George W. Bush
Senator Charles E. Grassley, R-Iowa, Chair, Senate Finance Committee
Mark B. McClellan, Administrator, Centers for Medicare and Medicaid Services (CMS)
New Jersey Congressional Delegation
Myra Eskin, President, NJAMHA Board of Directors
Robert Davison, Chair, NJAMHA Public Policy Committee

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CMS-4068-P-554

Submitter : **Date & Time:** 09/30/2004 08:09:12

Organization :

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

COORDINATION WITH PLANS AND PROGRAMS THAT PROVIDE PRESCRIPTION DRUG COVERAGE

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

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

Multiple Dispensing Fees Needed
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.?

ORGANIZATION COMPLIANCE WITH STATE LAW AND PREEMPTION BY FEDERAL LAW

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.

PAYMENTS TO PDP AND MA-PD PLANS

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Submitter : Ms. Amy Braglia **Date & Time:** 09/30/2004 08:09:06

Organization : Harbor-UCLA DaVita Dialysis Center

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

Issues 1-10: Please strongly consider addition of renal multi-vitamins to prescription benefit coverage for repletion of vitamins lost during peritoneal and hemodialysis treatments. Chronic kidney patients on dialysis are at high risk for B-vitamin and Vitamin C deficiencies that may precipitate other medical conditions, including anemia and malnutrition. Thanks, Amy Braglia, RD

CMS-4068-P-556

Submitter : Mrs. Ann Balogh **Date & Time:** 09/30/2004 09:09:34

Organization : Arc of Norht Carolina

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the developmental disability community.

CMS-4068-P-556-Attach-1.doc

September 30, 2004

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

To Whom It May Concern:

The Arc of North Carolina welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Arc of North Carolina is an advocacy organization for people with developmental and other mental handicaps . We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

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

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

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

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

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

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

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

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

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

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

* people who are dually eligible for Medicare and Medicaid

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

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

Thank you for your consideration of our views.

CMS-4068-P-557

Submitter : Ms. Janice Hufnagle **Date & Time:** 09/30/2004 09:09:20

Organization : York Hospital

Category : Pharmacist

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.

Controlling HIV Viral Loads is a public health issue. Since adequate treatment of individuals who are HIV positive is one way to limit the spread of HIV, in the long run, it will be far less expensive to keep these individuals as healthy as possible. Also, adequate treatment allows thousands of U.S. citizens a chance to stay well enough to be employed and to take care of their children. The medications used to control the virus currently cost $12,000 to $15,000 a year. Only with adequate help from the government, will most people with HIV be able to start or continue appropriate medication.

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

Sincerely, Jan Hufnagle, RPh

CMS-4068-P-558

Submitter : Roberta Downey **Date & Time:** 09/30/2004 09:09:28

Organization : Eastern Agency on Aging

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

We are gravely concerned about the impact of excluding coverage for benzodiazepines. The consequences of this exclusion affecting 41.2 million Medicare recipients were inadequately assessed by Congress and the Administration. The Medicare benzodiazepine exclusion is an ill-considered and harmful approach to health care and should be revisited.

Roberta Downey, Executive Director, Eastern Agency on Aging, redowney@eaaa.org or Phone: (207)941-2865 or FAX: (207) 941-2869.

CMS-4068-P-559

Submitter : Ms. cynde soto **Date & Time:** 09/30/2004 09:09:12

Organization : CALIF

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

see attached file from the disability communitee.

CMS-4068-P-559-Attach-2.doc

CMS-4068-P-559-Attach-1.doc

CALIF
Communities Actively Living Independent & Free
634 S. Spring St. 2nd Floor Los Angeles, CA 90014

September 30, 2004

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

To Whom It May Concern:

As an Independent Living Center for people with disabilities, we are commenting on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. We are concerned that the proposed rule does not provide sufficient protections for beneficiaries with disabilities.

Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. Given the sheer implausibility to enroll 6.4 million dual-eligibles in six weeks, we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. This may require a legislative change and we hope that you will support legislation in the current session of Congress.

For people with serious and complex medical conditions, access to appropriate medications can make the difference between living independently, being employed, leading a healthy and productive life and death; both physical and emotional. Often, people with disabilities need access to the newest medications because they have fewer side effects and may represent a better treatment option. The consequences of denying the appropriate medication for an individual with a disability are serious and can result in injury, ongoing debilitating side effects, even hospitalization or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have timely and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and have access to all medically necessary prescriptions. We recommend that this treatment apply to the following overlapping special populations:

* people who are dually eligible for Medicare and Medicaid
* people who live in nursing homes, ICF-MRs and other residential facilities

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

In addition to providing for special treatment for special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug as this will cause an undo financial burden to people on fixed incomes.

We are also concerned that the appeals processes, as outlined in the proposed rule, are overly complex and inaccessible to beneficiaries with disabilities. We strongly recommend CMS to establish a less complicated process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors. This includes a truly expedited exceptions process for individuals with immediate needs.

MMA that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. We recommend that CMS revamp the exceptions process to establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

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

We encourage you to take our comments into consideration as you continue to evaluate this issue. Your decision impacts many millions of lives.

Thank you,

Cynde Soto
Systems Change Coordinator

M. Jamie Watson
Systems Change Coordinator

CALIF
Communities Actively Living Independent & Free
634 S. Spring St. 2nd Floor Los Angeles, CA 90014

September 30, 2004

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

To Whom It May Concern:

As an Independent Living Center for people with disabilities, we are commenting on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. We are concerned that the proposed rule does not provide sufficient protections for beneficiaries with disabilities.

Dual eligibles have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We are very concerned that, there is not enough time to adequately address how drug coverage for these beneficiaries will be transferred to Medicare on Jan. 1, 2006. Given the sheer implausibility to enroll 6.4 million dual-eligibles in six weeks, we recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. This may require a legislative change and we hope that you will support legislation in the current session of Congress.

For people with serious and complex medical conditions, access to appropriate medications can make the difference between living independently, being employed, leading a healthy and productive life and death; both physical and emotional. Often, people with disabilities need access to the newest medications because they have fewer side effects and may represent a better treatment option. The consequences of denying the appropriate medication for an individual with a disability are serious and can result in injury, ongoing debilitating side effects, even hospitalization or other types of costly medical interventions.

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs. We believe that to ensure that these special populations have timely and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions and have access to all medically necessary prescriptions. We recommend that this treatment apply to the following overlapping special populations:

* people who are dually eligible for Medicare and Medicaid
* people who live in nursing homes, ICF-MRs and other residential facilities

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

In addition to providing for special treatment for special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require. For example we strongly oppose allowing any prescription drug plan to impose a 100% cost sharing for any drug as this will cause an undo financial burden to people on fixed incomes.

We are also concerned that the appeals processes, as outlined in the proposed rule, are overly complex and inaccessible to beneficiaries with disabilities. We strongly recommend CMS to establish a less complicated process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors. This includes a truly expedited exceptions process for individuals with immediate needs.

MMA that call for the creation of an exceptions process are a critical consumer protection that, if properly crafted through enforceable regulations, could ensure that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs. We recommend that CMS revamp the exceptions process to establish clear standards by which prescription drug plans must evaluate all exceptions requests; to minimize the time and evidence burdens on treating physicians; and to ensure that all drugs provided through the exceptions process are made available at the preferred level of cost-sharing.

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

We encourage you to take our comments into consideration as you continue to evaluate this issue. Your decision impacts many millions of lives.

Thank you,

Cynde Soto
Systems Change Coordinator

M. Jamie Watson
Systems Change Coordinator

CMS-4068-P-560

Submitter : Kimberly Lewis **Date & Time:** 09/30/2004 09:09:52

Organization : Kimberly Lewis

Category : Health Care Professional or Association

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

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

I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

GENERAL PROVISIONS

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.'

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.

CMS-4068-P-561

Submitter : Mr. Kris Scarborough **Date & Time:** 09/30/2004 09:09:36

Organization : Moody Drug Co. , Retail Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam: Thank you for allowing me to comment on the Medicare prescription drug benefit program.As an independent pharmacist for 33 years I have seen the phamacy profession go through some drastice changes,few which have been adavantagous to the pharmacist. In any proposed regulations, will you please consider the roll that a pharmacist has played in the delivery of health care to patients. In the world of the independent pharmacist these patients become friends and trusting bonds are built. Any proposals should consider the patient's care first,their convenience and their comfort in obtaining medications. Many patients are unable to travel and must be cared for by the pharmacy. They need someone to discuss their medicine problems with and it needs to be someone that they know. Develope a plan that brings patient, doctor and pharmacist closer together and you will have a plan that better serves the patient.

CMS-4068-P-562

Submitter : Mr. Philip Curtis **Date & Time:** 09/30/2004 09:09:55

Organization : AIDS Project Los Angeles

Category : Other Health Care Professional

Issue Areas/Comments

GENERAL

GENERAL

Please see attached comments from AIDS Project Los Angeles

CMS-4068-P-562-Attach-1.pdf

APLA
AIDS Project Los Angeles

THE DAVID GEFFEN CENTER
APLA DENTAL CLINIC
NECESSITIES OF LIFE PROGRAM
Long Beach *South Los Angeles*
San Fernando Valley *Wilshire Center*

ADMINISTRATION
The David Geffen Center
611 South Kingsley Drive
Los Angeles, California 90005
Telephone **213.201.1600**
Fax **213.201.1595**
Website **www.apla.org**

September 30, 2004

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

Re: Comments on the implementation of the Medicare Modernizations Act (MMA)

AIDS Project Los Angeles welcomes the opportunity to submit comments regarding the implementation of the Medicare Modernization Act (MMA) and its likely consequences for people living with HIV/AIDS.

APLA, one of the nation's largest AIDS service organizations, provides direct, bilingual services to more than 7,500 men, women and children living with HIV/AIDS in Los Angeles County each year. Services include prevention education, food banks and nutrition education, professional dental care, mental health counseling, housing and transportation assistance, information and referral services, case management and home health care. APLA is a leader in the development of HIV prevention programs, and helps shape fair and effective HIV/AIDS-related policy and legislation in response to the local, national and international epidemics. For more information, please visit www.apla.org.

Antiretroviral therapy (HAART) for the treatment of HIV disease has led to dramatic declines in HIV/AIDS morbidity and mortality over the past ten years. HAART involves strict adherence to very complicated, and sometimes changeable, drug regimens. APLA is very concerned that provisions in MMA may limit access to these critical prescription drug regimens for Medicare beneficiaries with AIDS.

We are particularly concerned about the effect implementation will have on dually eligible individuals who are disabled with HIV/AIDS. These individuals – often the poorest, sickest and most vulnerable of Medicare populations -- currently have access to all drugs approved by the Food and Drug Administration through Medicaid (Medi-Cal in California).

Beginning in 2006, prescription drug coverage for individuals who are dually eligible for Medicaid and Medicare will be transferred to Medicare, which does not have the same level of critical beneficiary protections as Medicaid. Additionally,

MA's reliance on private plans creates new risks for beneficiary populations with intensive prescription drug needs, such as people living with HIV/AIDS.

In view of past, and anticipated, complications in implementing the MMA, we suggest that you consider designating people living with AIDS a "special population," with exemptions from formulary restrictions and special protections from cost-sharing and other cost containment measures that may inhibit their access to life-saving medications. We also recommend that you pursue the requisite legislative approval to delay coverage for the dually eligible population, in order to facilitate the transition to MMA without endangering this population's need for uninterrupted drug coverage.

Our other concerns are listed below, along with some recommendations for resolving potential problems involved with the implementation of MMA. Our comments closely follow more a more detailed letter submitted to you by the HIV Medicaid & Medicare Working Group.

- Drug Plan Information: People with HIV/AIDS must have detailed information regarding their drug benefit before they commit to a plan for a full year. HIV/AIDS medications are exacting medications. This population cannot afford to miss doses or switch to drug regimens at the plans' convenience. They will require complete information on drug prices, formularies, dosage levels, etc.

- Formularies: HHS should develop regulations that require plans offering drug coverage to include all FDA-approved medications to treat HIV disease, in all approved formulations, as reflected in federal HIV-related guidelines. Regulations also should require plans to cover medications to treat conditions that are frequently related to HIV disease. As the FDA approves new drug therapies for HIV/AIDS, they should be immediately added to all Medicare/plan formularies. The MMA is vague about off-label uses of medications. Off-label prescribing is a common practice in HIV medicine, where individual HIV specialists, through informed trial and error, have developed new and more effective treatment regimens and have developed off-label applications that have become central to the treatment of HIV/AIDS and part of the standard of care. We request that MMA regulations restrict the ability of prescription drug plans to limit physician prescribing for off-label purposes unless there is objective medical evidence that such prescribing is inefficacious or harmful to the individual patient.

- Appeal Processes: As per the recommendations of the HIV Medicaid & Medicare Work Group, we encourage you to clarify the rights of beneficiaries to authorize physicians and family members to appeal plan decisions on their behalf. This is especially important for dually diagnosed individuals with, for instance, both mental health and HIV/AIDS disabilities. We also recommend that HHS state clearly in regulations that individuals have a right to expedited coverage determination and reconsideration of denials of non-formulary drugs in cases of emergency. The regulations should also state that treatment interruptions for HIV-related therapies constitute an emergency. We also follow the Work Group in recommending regulations giving individuals a right to request an exception for a drug denial for off-formulary drugs and that such drugs be made available at the cost sharing designated for preferred drugs if the appeal is unsuccessful.

Beneficiaries existing drug regimens should also be grandfathered in when the benefits begins in 2006, regardless of a plan's formulary. Dollar thresholds for appeal rights should be waived in the case of essential medications, such as those treating HIV/AIDS. This is especially important for the dually eligible.

- Cost Sharing: Even minimal levels of cost sharing may limit access to necessary medical care for low-income individuals. We urge you to make sure that this does not happen, particularly with the dually eligible, who must maintain the same level of coverage available under Medicaid. Also, non-formulary drugs should count toward a beneficiary's out of pocket limits and be designated as out of pocket costs.

- ADAP: The state AIDS Drug Assistance Programs should be recognized as state pharmacy assistance programs and allowed to wrap around the Medicare drug benefit, in order to maximize access to care and treatment. ADAP expenditures should also be counted as out of pocket costs.

I would like to emphasize our concern for the dually eligible who may find (in California as well as many other states) that Medicare Part D drug benefit provides them less coverage than they had under Medi-Cal.

Besides seeking a delay in implementation for this population, we also recommend that you seek a change in the law allowing state Medicaid programs to get federal matching funds if they wrap-around the Medicare prescription drug benefit. Also, the dually eligible should have access to the full range of plans in their area and not be limited to plans with the lowest or average premiums. This population should not be charged premiums in any event, if their medical care requires a higher premium plan.

Thank you again for the opportunity to submit these comments prior to implementation of the drug plan. We hope these suggestions will help eliminate some of the difficulties anticipated in the implementation of this important new Medicare benefit.

Sincerely,

Craig E. Thompson

Craig E. Thompson
Executive Director

CMS-4068-P-563

Submitter : Mr. Christian Fuentes **Date & Time:** 09/30/2004 10:09:08

Organization : None

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

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

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

CMS-4068-P-564

Submitter : Genie Polower **Date & Time:** 09/30/2004 10:09:38

Organization : Benzo@yahoogroups.com and Benzo.org.uk

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

September 30, 2004

September 30, 2004

Re: Docket #CMS-4068P, Medicare Program, Medicare Prescription Drug Benefit, Issue #3, Benefits and Beneficiary Protection

It has recently come to my attention that Benzodiazepines, a class of drugs prescribed to millions of older adults, will not be covered by the new Medicare prescription drug benefit. The consequence of this exclusion will affect 41.2 million Medicare recipients. In January 2006, doctors will expect older adults who have been taking Benzodiazepine tranquilizers to be switched to another covered drug.

If Medicare will no longer cover Benzodiazepine tranquilizers for senior citizens who have been taking them, this action could have serious consequences for the elderly and the disabled. Benzodiazepine tranquilizers belong to a particular class of drugs which cannot be stopped abruptly. They are highly addictive and stopping them rapidly often will result in horrific withdrawal symptoms such as seizures and cardiac arrest. This could potentially lead to lawsuits and hospitalizations.

Switching elderly people who are taking Benzodiazepine tranquilizers to other medications, such as SSRIs, simply won't work because SSRIs affect different receptors in the brain from Benzodiazepines. The only safe method of withdrawing people from Benzodiazepine tranquilizers is by means of a slow, steady tapering process.

If you do nothing else, I implore you to log onto the website, benzo.org.uk, where you can download a copy of The Ashton Manual. The manual will tell you everything you need to know about this class of drugs and how to withdraw from them.

How do I know so much about Benzodiazepine tranquilizers? I know a lot about them because I was one of the unfortunate people who did not have the option of tapering slowly off these drugs. When the Ativan I was taking for my hyperactive thyroid no longer worked, my former doctor sent me to a detox clinic where they took me off a fairly high dose of the drug in two weeks. I was 55 at the time and quite unprepared for the aftermath of detox, which included seizures, hypertension, dehydration and kidney malfunction. I had to be hospitalized four times for withdrawal related problems. After I spent months without any sleep and lost 30 pounds from dehydration, I found a doctor who told me to go back on Valium, a longer-acting Benzodiazepine tranquilizer, for the purpose of tapering properly. Had I not found this doctor, I probably would not be alive today to tell my story.

Now, two years later, I am down to a fraction of my Valium dose and I'm getting my life back again. Please don't let millions of senior citizens experience what I did.

Sincerely,

Genie E. Polower, Ph.D.
P.O. Box 234
Salt Point, NY 12578

CMS-4068-P-565

Submitter : Suzanne Fornaro **Date & Time:** 09/30/2004 10:09:19

Organization : Learning Disabilities Association of America

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-565-Attach-1.doc

Learning Disabilities Association of America
4156 Library Road, Suite 1
Pittsburgh, Pennsylvania 15234-1349

September 30, 2004

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

To Whom It May Concern:

The Learning Disabilities Association of America (LDA) welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. LDA is a grassroots, voluntary membership organization of parents, individuals with learning disabilities and professionals in the field. LDA is dedicated to a world in which all individuals with learning disabilities are provided the opportunity to succeed in school, at work, in relationships and within the community. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

Dual eligibles (i.e. Medicare beneficiaries who also have Medicaid coverage) have more extensive needs and lower incomes than the rest of the Medicare population. They also rely extensively on prescription drug coverage to maintain basic health needs and are the poorest and most vulnerable of all Medicare beneficiaries. We recommend that transfer of drug coverage from Medicaid to Medicare for dual eligibles be delayed by at least six months. We view this as critical to the successful implementation of the Part D program and absolutely essential to protect the health and safety of the sickest and most vulnerable group of Medicare beneficiaries. We recognize that this may require a legislative change and hope that CMS will actively support such legislation in the current session of Congress.

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

We strongly urge CMS to develop a specific plan for facilitating enrollment of beneficiaries with disabilities in each region that incorporates collaborative partnerships with state and local agencies and disability advocacy organizations.

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

We strongly support the suggestion in the proposed rule that certain populations require special treatment due to their unique medical needs, and the enormous potential for serious harm (including death) if they are subjected to formulary restrictions and cost management strategies envisioned for the Part D program. We believe that to ensure that these special populations have adequate, timely, and appropriate access to medically necessary medications, they must be exempt from all formulary restrictions We recommend that this treatment apply people who are dually eligible for Medicare and Medicaid and who have pharmacologically complex condition such as mental illness.

Impose new limits on cost management tools:
In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that individuals can access the medications they require.

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

We are also concerned that the appeals processes outlined in the proposed rule are overly complex, drawn-out, and inaccessible to beneficiaries with disabilities. We strongly recommend CMS establish a simpler process that puts a priority on ensuring ease of access and rapid results for beneficiaries and their doctors, includes a truly expedited exceptions process for individuals with immediate needs, and ensures that the unique and complex needs of people with disabilities receive a quick and individualized coverage determination for on-formulary and off-formulary drugs

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

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

Thank you for your consideration of our views.

Suzanne Fornaro,
President

CMS-4068-P-566

Submitter : Mr. Toby Cook **Date & Time:** 09/30/2004 10:09:40

Organization : Mr. Toby Cook

Category : Individual

Issue Areas/Comments

Issues 1-10

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

I am very concerned about family member being able to obtain necessary medications for mental illness. My experience is that these particular medications have to be tried to find one that works for the individual. When you find one that works for you, they need to be able to obtain it, and they need to be able to try others without a big hassle. I don't believe a formulary can be successfully implemented for mental problems.

CMS-4068-P-567

Submitter : Miss. Andrea Brown **Date & Time:** 09/30/2004 11:09:19

Organization : UT Health and Science Center

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:
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.?

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

Thank you for considering my comments.

Sincerely,

Andrea L. Brown
UT College of Pharmacy Student
& Future Pharmacist

Issues 1-10

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

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.

Andrea L Brown

CMS-4068-P-568

Submitter : Ms. Marge Pelletier **Date & Time:** 09/30/2004 11:09:55

Organization : UTHSC Pharmacy Student

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BACKGROUND

September 30, 2004
Centers for Medicare & Medicare Services
Department of Health and Human Services
Attention: CMS-4068-P
Baltimore, MD 21244-8014

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.

As a student pharmacist I already realize the importance of this upcoming decision and I urge CMS to make the needed revisions to the Medicare prescription drug benefit regulations to better serve Medicare beneficiaries.

Thank you for considering my comments.

Sincerely,

Marge Pelletier
Pharmacy Student Year 3

BENEFITS AND BENEFICIARY PROTECTIONS

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

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

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.
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utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
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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.
-Marge Pelletier

ELIGIBILITY, ELECTION, AND ENROLLMENT

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

PAYMENTS TO PDP AND MA-PD PLANS

Medication Therapy Management Program:
I appreciate that CMS recognizes that different beneficiaries will require different Medication Therapy Management (MTM) services such as health assessments, medication treatment plans, monitoring and evaluating responses to therapy, etc. However, the proposed regulations give plans significant discretion in designing their MTM programs. The regulations do not define a standard package of MTM services that a plan has to offer and a beneficiary should expect to receive. This means there could be wide variations in the types of MTM services that will be offered, even within plans in the same region. I recommend CMS define a minimum standard package of MTM services that a plan has to offer.

In addition, the proposed regulation does not include specific eligibility criteria for MTM services. Each plan can define his differently, resulting in beneficiaries having unequal access to MTM services. The law permits CMS to define the eligibility criteria and I believe CMS should exercise its authority in this area. In my opinion, patients with two or more diseases and taking two or more medications should qualify. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs.
- Marge Pelletier

Submitter : Mr. INDER RAKALLA **Date & Time:** 09/30/2004 11:09:31

Organization : POLYCLINIC PHARMACY

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

WHEN YOU ARE FIGURING OUT APPROPRIATE REIMBURSEMENT, PLEASE REMEMBER, THAT BESIDES OUR COST OF THE MEDICINE WE HAVE SHIPPING, DELIVERY , STORAGE, WASTAGE,BILLING EXPENSES, STAFF EXPENSE,AND ON TOP OF ALL THIS WE WOULD LIKE A REASONABLE AMOUNT OF PROFIT TO MAKE IT WORTH OUR WHILE TO DO THE BUSINESS, BECAUSE JUST LIKE YOU GET PAID FOR WORKING FOR THE GOVERNMENT WE ALSO HAVE OUR FAMILIES TO TAKE CARE OF AND IT WOULD BE NICE TO GET PAID FOR OUR WORK. YOU KEEP MENTIONING WHAT THE VA PAYS FOR THEIR DRUGS AND SUPPLIES, DO YOU EVER INCLUDE THE COST OF THE BUILDINGS, UTILITIES, PERSONNEL, COMPUTERS ETC TO THE INITIAL COST, BECAUSE WHEN YOU PAY US TO DO THE JOB ALL THESE COSTS ARE INCLUDED IN THE REIMBURSEMENT. tO REALLY COMPARE APPLES TO APPLES YOU HAVE ADD ALL THE ADDITIONAL COSTS(ACCOUNTING DEPT PAYROLL DEPT ETC) TO

CMS-4068-P-570

Submitter : Mr. Stacy Beasley **Date & Time:** 09/30/2004 11:09:04

Organization : Mr. Stacy Beasley

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 a 36 year old man living in Waco, Texas and I am HIV+. I am on Disability and make $904 "A MONTH" to live on. I am subject to student physicians at a small clinic. The physician I see now for my HIV has never had an HIV+ patient. I also have other problems from renal failure, gout, high blood pressure, high cholesterol and bleeding ulcers. Needless to say, my prescription bill is outrageous every month not to mention the clinic fees not covered by medicare.

I truly DO NOT understand how the United States can send millions and millions of dollars to other countries for the AIDS epidemic, yet they let Americans/Tay Payers suffer like we do. Maybe if someone in President Bush's family was to contact AIDS something more would be done.

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

Sincerely,

Stacy Beasley
1609 Clater Powell Rd
Waco, TX 76705

254-829-3176

[Your name]

CMS-4068-P-571

Submitter : Mr. Glen Allen **Date & Time:** 10/01/2004 12:10:55

Organization : Mr. Glen Allen

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

To Whom It May Concern:

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

CMS must designate people living with HIV/AIDS as a "special population" and ensure that they have access to an open formulary of prescription drugs and access to all medications at the preferred level of cost-sharing.

This would ensure that HIV-positive individuals would have affordable access to all FDA-approved antiretrovirals, in all approved formulations, as is recommended by the Public Health Service HIV treatment guidelines.

As an individual on Medicare and Medicaid,and as a person living with AIDS, my prescriptions are now fully covered by Medicaid. I must have full access to all treatments available, regardless of ability to pay.
I would be unable to afford medications that would not be covered by Medicare. My income is fixed, as I receive Social Security Disability. If I were forced to discontinue any of my medications, my disease would progress and I would die.

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

Sincerely,

Glen Allen
5146 Cologne Ave.
St. Louis, MO 63116

CMS-4068-P-572

Submitter : Dr. James Stevenson **Date & Time:** 10/01/2004 12:10:17

Organization : University of Michigan

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I write today to offer comments regarding the proposed Medicare Part D rules. As the Director of Pharmacy Services at the University of Michigan Health System, I am deeply concerned with the rules as they are currently proposed and the negative impact they could have on the services provided to Medicare beneficiaries.

MTM Services

1. CMS rules must allow for pharmacists to be included not precluded. This is critical in order to ensure the appropriate and cost-effective use of these valuable resources. Providing a benefit without appropriate management provisions is a poor use of these funds. Pharmacists at the University of Michigan are an integral part of the health care team, helping to manage the care of Medicare patients with chronic diseases on a daily basis. These services not only improve the quality of patient outcomes, they also dramatically lower total medical costs. A specific example is the pharmacy benefit management program that we have been running at the University of Michigan with our faculty physician group. Pharmacists provide management support and education to physicians in order to assure the best use of the pharmacy benefit. The results have shown high compliance with preferred medication use and quality indicators, while costs that have been less than the regional benchmarks.

2. CMS should promulgate rules that assure that adequate indicators for quality of medication therapy are incorporated into every sponsor?s plan.

3. MTM service payment must be sufficient to warrant provision of the necessary services by a pharmacist. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers for MTM services.

4. MTM services should be able to be provided in conjunction with and outside of product dispensing.

5. An efficient electronic MTM claims process should be established for pharmacist submission of MTM service claims, similar to the electronic system for submitting prescriptions claims.

6. Plan sponsors should be required to establish a CMS-specified set of MTM services. The specified set of services should be a minimum set while additional services should be encouraged.

7. CMS should consider developing a program to accredit plans that agree to meet the above stated conditions that add value to and lower the cost of care.

Access to Pharmaceuticals ? Drug Product Provisions within Part-D

1. Co-payment reductions should not be provided to coerce beneficiaries into using "preferred" pharmacy providers solely on the basis of pricing or cost. This practice could result in pharmacies that specialize in accepting the lowest reimbursement formula but develop ?schemes? to shift patients to high-profit margin regimens that ultimately increase costs to the plan.

2. Plan sponsors should be prohibited from requiring to recipients to use mail order pharmacies. There are safety and medication management concerns when beneficiaries are required to use mail order pharmacies. If mail service is offered as an incentive to lower costs, all pharmacies should be offered standard contract language and allowed to participate as a mail service provider. Beneficiaries should not be required to use mail service pharmacies.

3. To prevent conflict of interest, plan sponsors should be prohibited from promoting or requiring the use of pharmacies in which they have an ownership interest.

In closing, pharmacists must be an integral component of the new Medicare benefit. It is essential that pharmacists? expertise is used in making this new benefit successful. Medicare must make specific requirements of the plan sponsors otherwise many of the nation?s foremost pharmacy practices may not even be included in the various plan programs. And finally, pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

CMS-4068-P-573

Submitter : Mr. Sae-Hong Lee **Date & Time:** 10/01/2004 12:10:36

Organization : University of Toledo

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I appreciate that CMS are doing something to benefit general public.
However, it is important that a professional who knows about a medication(drug) the most should involve regarding this matter.
So, if you review the curriculum in the U.S. medical schools, Nursing schools Dental schools and pharamcy schools, it is quiet obvious that pharmacy shools teach the most and the vast amount of information on drugs and drug related matters. NO other professionals school come close to this aspect!!! Thus, I think pharmacist should be the primary providers of the Medication Therapy Management Services.
Thus, I support the Medication Therapy Management Services Definition and program Criteria developed and adapted by 11 national pharmacy organizations in July 2004.

CMS-4068-P-574

Submitter : Christina Marsh **Date & Time:** 10/01/2004 12:10:07

Organization : Life Foundation

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

Christina Marsh
250 Kapili St, #10
Honolulu, HI 96815

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

To Whom It May Concern:

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

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

The need of people living with HIV and AIDs must have FULL access to all medical and prescriptions without any barriers to ensure a quality of life that would not be avaiable to them otherwise.

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

Sincerely,

Christina Marsh

cc: rclary@projectinform.org

CMS-4068-P-575

Submitter : Jennifer Schumann **Date & Time:** 10/01/2004 01:10:19

Organization : Coalition for Safe Community Needle Disposal

Category : Other Association

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 the 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 and community. This issue is supported by members of the House and Senate and several state governments. The Coalition for Safe Community Needle Disposal, including such organizations as The American Medical Association, the American Pharmacists 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 be taken into serious consideration. I urge the CMS to include safe disposal in its coverage for the millions of patients injection medication in their homes daily.

CMS-4068-P-576

Submitter : Mr. Elroy Siegler **Date & Time:** 10/01/2004 01:10:57

Organization : UW Hospital & Clinics

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

To Whom it May Concern:
Re: CMS-4068-P

I am writing to offer comments regarding the proposed Medicare Part D rules. As a Senior Clinical Pharmacist, I am deeply concerned with the rules as they are currently proposed. Thank you for the opportunity to offer 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 do 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 pharmacises to be included, not precluded. Plan sponsors should be required to establis CMS specified MTM services.

CMS should require all plan 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. MTM services should be able to be provided in conjunction with and outside of product dispensing. At a minimum, each plan should be required to pay for MTM services ordered by a prescriber. Plans should be required to pay pharmacists for MTM services at the same rate and under the same terms in which they pay other providers of MTM services. They should not be allowed to discriminate and leave pharmacists out of the loop.

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 payments must be sufficient to warrent provision of the necessary services by a pharmacist. All pharmacists practicing within a region should be afforded the opportunity to provide MTM services. Plans should offer standard contract language to all pharmacies willing to participate in the program as a prescription and MTM services provider. They should not be able to limit the number of pharmacy providers. All pharmacies should be able to dispense prescription medications for beneficiaries who receive care in their facilities. It is essential the Univeristy of Wisconsin Hospital and Clinics pharmacies are able to participate as a pharmacy provider for Medicare patients who receive care in our facilities. Co-payment reductions should not be provided to beneficiaries who use "preferred" pharmacy providers. This will only provide incentives for beneficiaries to use low cost, low quality providers and ultimately increase the cost of patient care and produce a chasm. It will disrupt existing pharmacist-patient relationships which will ultimately result in diminished drug therapy outcomes.

Pharmacist are a "corps" of professionals who actively and cooperatively contribute to the Nations Public Health Initiatives. They are currently actively supporting the goals of "Healthy People 2010" by working toward successes in leading health indicators such as tobacco use, substance abuse, overweight and obesity, immunization, diabetes, heart disease and stroke.

Pharmacies and pharmacists 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. 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. Pharmacy providers must receive adequate payment for the services they provide to recipients of the program.

Thank you.

Submitter : Mr. Thomas Hanson **Date & Time:** 10/01/2004 02:10:36

Organization : Mr. Thomas Hanson

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

Subpart C: 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 their local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

Subpart D: COST CONTROL AND QUALITY IMPROVEMENT REQUIREMENTS FOR PRESCRIPTION DRUG PLANS:
I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely 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 these MTM services. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I am currently managing my patients drug therapy by making sure they are compliant taking their medications and that they do not refill any of their medications late. We know that when people take their medications correctly, they are more healthy and experience a better quality of life. Plans should be encouraged to use my services--- let me help my patients make the best use of all their medications.

I would urge CMS to revise the regulation to include all of my recommendations. Thank you for considering my view.

Sincerly,
Thomas Hanson, Pharmacist
321 S. Western Ave.
Bartlett, Illinois 60103
e-mail address is rphth@msn.com

CMS-4068-P-578

Submitter : Ms. LaCresha Skillern **Date & Time:** 10/01/2004 02:10:33

Organization : Ms. LaCresha Skillern

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

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

Dear Sir or Madam:

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

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

Multiple Dispensing Fees Needed
The proposed regulation offers three options for dispensing fees. Rather than adopting one dispensing fee, CMS should allow for the establishment of multiple dispensing fees in order to differentiate between the activities associated with dispensing services provided in various pharmacy environments such as home infusion.
I recommend that one option cover the routine dispensing of an established commercially available product to a patient. It is important that the definition of mixing be clarified to indicate this term does not apply to compounded prescriptions.
A second dispensing fee should be defined for a compounded prescription where a product entity does not exist and is prepared by the pharmacist according to a specific prescription order for an individual patient.
A third dispensing fee should be established for home infusion products. The National Home Infusion Association, with the approval of CMS, developed a standardized coding format for home infusion products and services in response to the HIPAA requirements. This approach should be utilized in establishing the third dispensing fee and home infusion reimbursement methodology.
Dispensing fee option 3 as described in the proposed regulation discusses ongoing monitoring by a ?clinical pharmacist.? I recommend changing ?clinical pharmacist? to ?pharmacist.? CMS should not limit monitoring to ?clinical pharmacists,? as all pharmacists are qualified by virtue of their education and licensure to provide monitoring services as described in option 3. Also, there is only one state that defines a ?Clinical Pharmacist? in its rules and regulations. Nationally, there is no clear definition of a ?clinical pharmacist.?

Proposed Regulation Creates Networks Smaller than TRICARE:
The proposed regulation also allows plans to create ?preferred? pharmacies and ?non-preferred? pharmacies, with no requirements on the number of preferred pharmacies a plan must have in its network. Plans could identify only one ?preferred? pharmacy and drive patients to use it through lower co-payments, negating the intended benefit of the access standards. Only ?preferred? pharmacies should count when evaluating whether a plan has met the required TRICARE access standards. The Department of Defense network of pharmacies meets the TRICARE access standards and has uniform cost sharing for all these network pharmacies. CMS should require plans to offer a standard contract to all pharmacies. Any pharmacy willing to meet the plan?s standards terms should be allowed to provide the same copays to the patient population.

Equal Access to Retail a

CMS-4068-P-579

Submitter : Mr. Thomas Hanson **Date & Time:** 10/01/2004 02:10:22

Organization : Mr. Thomas Hanson

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Dear Sir or Madam:

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

Subpart C: 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 their local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

Subpart D: Cost Control and Quality Improvement Requirements for Prescription Drug Plans
I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as a health assessment, a medication treatment plan, monitoring and evaluating response to therapy, etc. I also appreciate CMS' recognition that pharmacists will likely 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 these MTM services. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I am currently managing my patients drug therapy by making sure they are compliant taking their medications and that they do not refill any of their medications late. We know that when people take their medications correctly, they are more healthy and experience a better quality of life. Plans should be encouraged to use my services--- let me help my patients make the best use of all their medications.

I would urge CMS to revise the regulation to include all of my recommendations. Thank you for considering my view.

Sincerly,
Thomas Hanson, Pharmacist
321 S. Western Ave.
Bartlett, Illinois 60103
e-mail address is rphth@msn.com

Submitter : Dr. Christopher Green **Date & Time:** 10/01/2004 02:10:03

Organization : University Health Connection (Ohio State Univ.)

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

September 30, 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:

Wanted to thank you for all of your hard work in revising and updating Medicare regarding the prescription drug benefit. I would like to take this opportunity to offer some comments for CMS to consider as you develop the final regulations.

Regarding Subpart C: Benefits and Beneficiary Protections:

I would like to suggest that you revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local, and not the plan?s overall, service level. If plans meet the standard on the local level, that is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and would allow my patients to continue to use the pharmacies near their home or work.

Additionally, 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 may identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Further, plans should not be allowed to count their non-preferred pharmacies when evaluated as to whether they meet the access standards. Congress seems to have intended that patients have fair access to their local pharmacy. As the regulation is currently written, it could lead to a restriction of access for many of my patients and Americans in general. I would ask that CMS require plans to offer a standard contract to all pharmacies.

Regarding 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 am also excited to see that CMS has recognized that pharmacists will likely be the primary providers of MTM services. However, I am concerned that leaving the decision to the plans to choose their provider may lead to the choice of less qualified providers, or worse, providers that they pay to perform these services?a conflict of interest to say the least.

Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I currently work in a physician?s office practice and offer medication management services for diabetes, hypertension, depression, and smoking cessation to highlight a few. Plans should be encouraged to use not only my services but the services of all pharmacists helping patients each and every day. I believe that I speak for my profession when I say that our primary goal is to help patients gain the best benefit from their medications, with the highest level of safety, and at the lowest possible cost to both the patient and the system.

In conclusion, I would like to thank you for allowing me the opportunity to express my views and applaud you for all of your hard work.

Thanks so much,

Christopher G. Green, R.Ph., Pharm.D.

Ambulatory Care Pharmacist
University Health Connection

The Ohio State University
500 West 12th Ave., Room 100
Columbus, OH 43210
(614)688-0713
green-18@medctr.ohio-state.edu

CMS-4068-P-580-Attach-1.doc

September 30, 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:

Wanted to thank you for all of your hard work in revising and updating Medicare regarding the prescription drug benefit. I would like to take this opportunity to offer some comments for CMS to consider as you develop the final regulations.

Regarding Subpart C: Benefits and Beneficiary Protections:

I would like to suggest that you revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local, and not the plan's overall, service level. If plans meet the standard on the local level, that is the only way to ensure that all beneficiaries have convenient access to a local pharmacy and would allow my patients to continue to use the pharmacies near their home or work.

Additionally, 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 may identify one preferred pharmacy and coerce patients to use it through lower co-payments, negating the benefit of the access standards. Further, plans should not be allowed to count their non-preferred pharmacies when evaluated as to whether they meet the access standards. Congress seems to have intended that patients have fair access to their local pharmacy. As the regulation is currently written, it could lead to a restriction of access for many of my patients and Americans in general. I would ask that CMS require plans to offer a standard contract to all pharmacies.

Regarding 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 am also excited to see that CMS has recognized that pharmacists will likely be the primary providers of MTM services. However, I am concerned that leaving the decision to the plans to choose their provider may lead to the choice of less qualified providers, or worse, providers that they pay to perform these services…a conflict of interest to say the least.

Pharmacists are the ideal health care professionals to provide MTM services and determine which

services each beneficiary needs. I currently work in a physician's office practice and offer medication management services for diabetes, hypertension, depression, and smoking cessation to highlight a few. Plans should be encouraged to use my services and the services of all pharmacists helping patients each and every day. I believe that I speak for my profession when I say that our primary goal is to help patients gain the best benefit from their medications, with the highest level of safety, and at the lowest possible cost to both the patient and the system.

In conclusion, I would like to thank you for allowing me the opportunity to express my views and applaud you for all of your hard work.

Thanks so much,

Christopher G. Green, R.Ph., Pharm.D.
Ambulatory Care Pharmacist
University Health Connection

The Ohio State University
500 West 12th Ave., Room 100
Columbus, OH 43210
(614)688-0713
green-18@medctr.ohio-state.edu

CMS-4068-P-581

Submitter : Dr. John Franklin, Pharm.D. **Date & Time:** 10/01/2004 03:10:01

Organization : Dr. John Franklin, Pharm.D.

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

I have concerns over the Medicare part D regulation and I wish to comment.

State Medicaid has mandated rebates that the manufacturers must pay the State. Why doesn't this law mandate manditory minimum rebates which must be passed directly to the patient at 100%?????? Right now a PBM could negotiate rebates and keep 99% of it.

This law allows these scumbag PBM's (i.e. Medco hellth) to manipulate and force patients into mail order by charging patients higher copays at retail pharmacies vs. mail order pharmacies. They also could mandate 21 day supplies at retail pharmacies while there mail order pharmacy is allowed to do 3 month supplies. These plans need to be forced to accept any willing pharmacy provider will be allowed to dispense equally to any other provider.

Why are you shuting out pharmacy providers? PDP's and Medicare advantage can use preferred and non-preferred contracts to set there pharmacy network. I am in Ogallala Nebraska. I live in the definition of "rural". How far are you going to make patients travel to get a preferred pharmacy? Patients need allowed access to local community pharmacies 100% of the time, not the recommended 70%. We already have healthcare access problems out here. We don't need another law to worsen that.

Medco Hellth is the dirtiest PBM out there. Why are they being allowed to even participate in the Medicare Drug program? They just settled a huge lawsuit to pay for thier ilegal behaviors. They own there own mail order pharmacy and they force patients to use it by limiting the days supply of medication they can get at the local pharmacy and forcing huge copays at local pharmacies. I don't want any of my patients using these scumbags.

Dispensing fees need to be fair. I serve ambulatory and nursing home patients. It is 6 times more expensive for me to sent unit dose medications to a nursing home patient than an ambulatory patient. The packaging is much more expensive and its a very labor intensive process to put pills into unit dose cassettes 1 by 1. I need a bigger dispensing fee to do this. My fear is that you will loose pharmacy providers for nursing home if you allow only 1 dispensing fee. This needs to be mandated or the PBM's won't do it because they could care less about people getting medicine.

Price differential for generic vs. brand should be told to patients prior to dispensing. Why are mail order pharmacies allowed to tell patients after the fact? They have phones.

Medication treatment management has been tried by insurance companies and for the most part large failures because to make the program cheaper they higher nurses who call patients. If you want this to work, you should mandate this management be done by pharmacists at local pharmacies.

Medicare/Medicaid dual eligible patients usually are the most disabled of my patients. I wish you would reconsider moving them from State Medicaid to the scumbag PBM's. The State does a great job managing them and there care is good. Our State also has excellent cost saving and formulary management at higher negotiated rebates. This saves more money than PBM's every will. PBM's are untested with this vulnerable and needy group. They will fail and failure in this group means patients will die.

I doubt anything I have said in here will get much changed. As I read this law it sounded like a drug company, a PBM and a mail order pharmacy wrote it.

John Franklin, Pharm.D., RP.
114 Hidden Canyon Estates
Brule, NE. 69127

CMS-4068-P-582

Submitter : Mr. Kevin Mays **Date & Time:** 10/01/2004 03:10:45

Organization : American Pharmacists Association Academy of Studen

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

CMS-4068-P-582-Attach-1.doc

September 29, 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. Student pharmacists are trained to provide cognitive services for patients. The PharmD curriculum includes courses in communication and overcoming patient barriers. In addition to these courses we are instructed on the proper use of medications and how to make the most cost effective therapeutic decisions. Pharmacists play a vital role in the health care system and can help to reduce healthcare costs by making sure that patients are using medications properly and by

designing cost effective therapies to benefit our patients. Cost containment will benefit insurance providers, patients and our nation's healthcare budget.

In conclusion, I urge CMS to revise the regulation to ensure that patients have the ability to use the pharmacy provider of their choice. By meeting the TRICARE pharmacy access requirements on a local level patients would be ensured access to healthcare within their respective communities and pharmacies would be able to expand upon the services that they currently provide. Offering the same contracts to all pharmacies would provide for equal opportunities for community pharmacies and would create a competitive environment that would benefit our patients in the long run. Pharmacists impact patient's lives on a daily basis and are in a position to help patients use their medications properly. Pharmacists are trained to offer various different services and can recognize patients individual needs to develop a personal therapeutic plan.

* Thank you for providing me with an opportunity to express my views related to this topic.

Sincerely,
Kevin M. Mays
PharmD Candidate 2005
Nova Southeastern University College of Pharmacy
9600 NW 7th Circle
Apt# 1423
Plantation, FL 33324
(954)370-6728
kmaysrx@bellsouth.net

CMS-4068-P-583

Submitter : Mr. Kevin Mays **Date & Time:** 10/01/2004 03:10:01

Organization : Mr. Kevin Mays

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

? Subpart C: Benefits & Beneficiary Protections
? Please revise the pharmacy access standard to require plans to meet the TRICARE pharmacy access requirements on a local level, not on the plan?s overall service level. 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

? 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. Student pharmacists are trained to provide cognitive services for patients. The PharmD curriculum includes courses in communication and overcoming patient barriers. In addition to these courses we are instructed on the proper use of medications and how to make the most cost effective therapeutic decisions. Pharmacists play a vital role in the health care system and can help to reduce healthcare costs by making sure that patients are using medications properly and by designing cost effective therapies to benefit our patients. Cost containment will benefit insurance providers, patients and our nation?s healthcare budget.

In conclusion, I urge CMS to revise the regulation to ensure that patients have the ability to use the pharmacy provider of their choice. By meeting the TRICARE pharmacy access requirements on a local level patients would be ensured access to healthcare within their respective communities and pharmacies would be able to expand upon the services that they currently provide. Offering the same contracts to all pharmacies would provide for equal opportunities for community pharmacies and would create a competitive environment that would benefit our patients in the long run. Pharmacists impact patient?s lives on a daily basis and are in a position to help patients use their medications properly. Pharmacists are trained to offer various different services and can recognize patients individual needs to develop a personal therapeutic plan.

CMS-4068-P-584

Submitter : Mrs. Marilyn Eland **Date & Time:** 10/01/2004 04:10:49

Organization : Benzodiazepine Awareness Network

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

September 30, 2004

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

To Whom It May Concern:

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

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

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

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

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

Sincerely,

Marilyn Eland

CMS-4068-P-585

Submitter : **Date & Time:** **10/01/2004 04:10:03**

Organization :

Category : **Other Health Care Professional**

Issue Areas/Comments

GENERAL

GENERAL

September 30, 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. As a pharmacy student in a Pharm-D program, I am being thoroughly trained to care for my patients in many care settings. Upon graduation, I will be able to determine what medications my patients should be using, how best to avoid any duplpication or interaction, and help them to discover how their medications can best work in concert with lifestyle changes to control their disease and have the best quality of life possible, just to name a few skills.
Plans should be encouraged to use my services - to let me help my patients make the best use of their medications. As one of the most accessible health care providers, (can you get your doctor on a phone on Sunday afternoon?) I feel that I will be in a position to support my patients best by my ability to provide these services.
Thank you for considering my view.
Sincerely,
~Nicole Peterson~
Member, APhA-ASP
University of Wisconsin School of Pharmacy
Madison, Wisconsin

Submitter : Dr. Mark Boesen **Date & Time:** 10/01/2004 06:10:16

Organization : Health Policy Associates, LLC

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

Comment: PDPs must allow beneficiaries to obtain the same benefits at a community pharmacy that they can access at a mail order pharmacy.

The private sector programs run by today?s PDPs have provided participants with tremendous incentives for accessing medications through the mail. Participants are often steered to mail order facilities through reduced co-payments and the ability to obtain a 90-day supply of a maintenance medication. In return for rock bottom deals, the mail order recipients are left to ?figure it out on their own.? Mail order customers often suffer from medication misadventures due to the complicated nature of today?s medication and their delivery systems. Without a pharmacist to interact with them in person, medication mishaps are inevitable.

If certain services are offered through the mail, Medicare beneficiaries should also have access to the exact same benefits when visiting the local drugstore. Seniors are the population with the most significant need for direct pharmacist-patient interaction. Mail order only provides the patient with a product. However, if the product is used wrong, and the patient does not have the benefit of pharmacist monitoring in between physician office visits, complications usually result.

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

Comment: Ensure that Medicare Quality Improvement Organizations have access to pharmacy claims data collected by the PDPs.

A Medicare outpatient prescription drug benefit presents an opportunity to improve the quality of life for our nation?s seniors, but also brings the real risk of increased morbidity and mortality associated with an increase in the use of medications. It is reasonable to predict that with an outpatient prescription drug benefit, more seniors will receive more drugs. Expanding access to and availability of drugs, without a complementary investment in quality improvement, will exacerbate the unacceptable cost and incidence of hospital and long-term care admissions associated with medication use. A 2002 meta-analysis of 11 different studies, published in the Journal of the American Pharmacists Association, reviewed drug use in the elderly population. The authors found ?[t]he reported prevalence of elderly patients using at least one inappropriately prescribed drug ranged from a high of 40% for a population of nursing home patients to 21.3% for community-dwelling patients over age 65.?

When the United States? Congress included Section 109 in the Medicare Modernization Act (MMA), Congress directed the QIOs to expand their work to quality improvement resulting from pharmacy generated claims data.

For years community pharmacists have struggled when providing pharmaceutical care services because the pharmacist lacked certain data elements from the medical record necessary to fully evaluate prescribers? medication orders. On the other hand, QIOs have collected some of these basic data elements abstracted from medical records for many years.

In addition, physicians (and other licensed prescribers) have struggled to make fully informed prescribing decisions because the physician lacked a complete and accurate medication history. On the other hand, pharmacy benefit management companies have been collecting this data for many years.

By utilizing the HIPAA-exempt status of the Medicare QIOs to integrate the existing medical and pharmacy data systems, CMS has an opportunity to provide its health care practitioners with a world class data delivery system. That system could lead to an electronic medical record skeleton accessible by pharmacists, physicians, and QIOs dramatically improving the pharmacotherapy quality outcomes and patient safety.

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

Comment: Ensure that ?any willing? pharmacy has the ability to write contracts with the regional and national PDPs.

HPA is concerned that the proposed regulation limits the ability for pharmacies to participate in certain PDP sponsored programs by allowing the PDPs to establish their own exclusive pharmacy networks. In addition, the regulation does not describe the requirements about how many pharmacies a plan must have in its preferred pharmacy network.

Today?s very best community-based pharmacy services are usually not delivered in the PDP ?preferred? pharmacy networks. Mail order facilities and high volume national chain drugstores usually make up ?preferred? provider lists in most PDP plans. These facilities serve some patients very well. Routine and non-complicated cases are handled adequately by high-volume pharmacy providers. However, most seniors? drug therapy regimens require a more specialized approach. Many seniors are drawn to community-pharmacy specialty facilities because the clinical services and medication inventory required for their care can only be accessed at community pharmacy specialty stores.

Allowing any willing pharmacy to accept the PDP payment terms in return for inclusion in the PDP?s network is critical to providing the nation?s seniors with access to high quality community pharmacy services.

Furthermore, if PDPs are free to set up ?preferred? and ?non-preferred? networks, pharmacies should be allowed to accept payment terms in either contract category and participate in any plan best meeting the pharmacies should be allowed to accept payment terms in either contract category and participate in any plan best meeting the pharmacy provider?s business model.

CMS-4068-P-587

Submitter : Mrs. Calista Chukwu **Date & Time:** 10/01/2004 06:10:15

Organization : Student, UNC School of Pharmacy NC

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

September 29th 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
I would like you to revise the pharmacy access standard that requires plans to meet the TRICARE pharmacy access on overall service level. I suggest requiring the plan to meet the standard on a local level to ensure that all beneficiaries have convenient access to local pharmacy and that the patients that I will have when I graduate will be able to continue to use my pharmacy.

I also suggest a revision of the preferred and non preferred pharmacy requirement. Your proposal has no requirement on the number of preferred pharmacies a plan must have. Thus, plans could identify one preferred pharmacy and coerce patients to use it in through lower co-payments, negating the benefit of access standards. Also in your proposal, only preferred pharmacies should count when evaluating whether a plan has met the pharmacy access standards. I am also concerned that allowing plans to count their non-preferred pharmacies conflicts with the congress? intent to provide patients fair access to local pharmacies. CMS should require plans to offer a standard contract to all pharmacies.

SubpartD: Cost Control & Quality improvement Requirements for Prescription Drug Plans:

I appreciate that CMS recognizes that different beneficiaries will require different MTM services such as health assessment, a mediation 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. Since pharmacists specialize in drug science, they are the ideal health care professionals to provide MTM services and determine each beneficiary's needs. I am currently a student hoping to be a CPP and /or a pharmacy specialist. Plans should be encouraged to use my services- to let me help my patients to make the best use of their medications. Reimbursement should also be such that other pharmacists would be willing to participate in MTM services.

In conclusions I urge CMS to revise the regulations to require pharmacies access on a local level rather than on overall service level. I also urge you not to allow Plans decide who the MTM service provider should be.
Thanks for considering my view

Sincerely
Calista Chukwu
UNC School of Pharmacy
Chapel Hill North Carolina
Email- Chukwu@email.unc.edu

CMS-4068-P-589

Submitter : Dr. James Begley **Date & Time:** 10/01/2004 11:10:10

Organization : TN Pharmacist Association

Category : Pharmacist

Issue Areas/Comments

Issues 1-10

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

Pharmacists have always been and remain the patient's most accessible member of the healthcare team, and our experience talking with patients make us the obvious choice for all MTM needs. This could be a valuable addition to any healthcare program. MTM by pharmacists could elevate the US's overall health to a new level.

CMS-4068-P-590

Submitter : Jeff Lurey **Date & Time:** 10/01/2004 12:10:48

Organization : Georgia Pharmacy Association

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

I would like to offer the following comments for consideration:
1. 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. This would allow all beneficiaries to have convenient access to a local pharmacy and would allow patients to continie to use their existing pharmacies.
2. CMS should require plans to offer a standard contract to all pharmacies.
3. Pharmacists are the ideal health care professionals to provide MTM services and determine which services each beneficiary needs. I hope plans are not allowed to choose less qualified providers to provide MTM services.

The pharmacists of this country are the most qualified and most accessible health care provider with regards to MTM. I hope you will allow us to provide the services that we are best trained to do.

Thank you for allowing me to express my views.

Sincerely,

Jeff Lurey, RPh
Georgia Pharmacy Association
50 Lenox Pointe
Atlanta, GA. 30324

CMS-4068-P-591

Submitter : Mr. Thomas Broderick **Date & Time:** 10/01/2004 12:10:36

Organization : The Goodyear Tire & Rubber Company

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

Attached are comments to the Medicare Modernization Act for the Goodyeare Tire & Rubber Company

CMS-4068-P-591-Attach-1.doc

The GoodYear Tire & Rubber Company
Medicare Modernization Act
Regulation Comments
Reference File Code CMS-4068-P

1. Introduction

First, on behalf of Goodyear I would like to express the company's appreciation for the timely, thoughtful and comprehensive nature of the regulations and comments provided by CMS. It is obvious that CMS has done its homework by developing an in depth knowledge of the issues facing employers.

The Goodyear Tire & Rubber Company (NYSE:GT) is a Fortune 500 company headquartered in Akron, Ohio. Founded there in 1898, the company today manufactures tires, engineered rubber products and chemicals in about 85 plants located in 28 countries. Goodyear sells its products to auto and agricultural equipment manufacturers, home appliance producers, mining operations and industrial businesses, among others, and in the huge replacement tire market. In addition to overseas rubber plantations in Indonesia, Goodyear has sales and marketing operations in almost every nation of the world, and currently employs about 86,000 people, globally.

Goodyear has about 35,000 employees and 35,000 retirees (25,000 Medicare eligible) in North America. The company spends about $500 million annually for all active and retiree healthcare benefits.

There are many areas where Goodyear could provide feedback on the proposed regulations, however, I will comment on behalf of the company only on the major areas that are crucial to Goodyear's ability to provide financial support for Medicare prescription drugs. We will rely on organizations, like ERIC, to provide feedback on the numerous technical issues that challenge the whole employer community.

2. Actuarial equivalence – Preferred approach
Reference Subpart R “Payments to Sponsors of Retiree Prescription Drug Plans”

We agree with CMS that the intent of the Medicare Modernization Act (MMA) is to maximize the number of retirees receiving generous employer sponsored retiree drug coverage. Further, we also understand that the MMA was crafted in an effort to limit the federal budgetary outlays for Medicare prescription drugs.

The single most important area in the regulations that can either make or break the intent of the MMA is the method(s) for determining actuarial equivalence. Clearly the intent of the MMA was to provide incentives for employers to continue their existing or even enhance their coverage for retirees. The ability for employers to maintain their current plans, without requiring companies to renegotiate or change their plans in order to receive financial support, is paramount in reaching this goal.

Goodyear agrees that no employer should receive a "windfall" and that the 2-prong approach (gross test on plan design and net value test) is an appropriate structure to prevent an employer from receiving more than they paid into a plan.

Further, to make the 2-prong approach work CMS must set a reasonable threshold for employers to qualify for subsidies. This is especially true for employers, such as Goodyear, who have placed some form of cap on their contribution toward retiree health care. Without a reasonable threshold, employers will be forced into either walking away from sponsoring retiree coverage or, at best, change their current plans to coordinate with Medicare through an admittedly complex and potentially costly process (Troop and other administrative issues).

Goodyear strongly believes the yearly average subsidy (estimated to be $611 per individual in 2006) that is provided to each employer should be the maximum threshold level. We do not believe the $900 amount, at which CMS valued the employer "wrap" coverage would be appropriate since it does not take into consideration the Part D premiums that would be required or the additional administrative expenses. If these items are factored into the equation, an estimate of the threshold would be below $480.

Further, using a value of $1,200, which represents the average value an individual receives if they enroll in Medicare Part D, is totally inappropriate. Employers and retirees are not receiving the full value of the drug benefit from Medicare and no beneficiary will be penalized since they can always opt out of the employer's plan, without penalty (assuming gross test is met for creditable coverage), and enroll in Medicare Part D. While we agree that Part D may be the appropriate plan for some retirees, it should remain the individual's choice to decide based upon his or her own unique needs and circumstances.

CMS also asked for comments regarding setting the appropriate threshold to encourage employers to increase the generosity of their coverage. CMS stated, "adopting a lower value for the net test might qualify more plan sponsors to participate in the retiree drug subsidy, but it might also discourage some employers and unions from increasing their contributions to reach the higher level." We believe reality is 180 degrees from the above assertion.

Employers who provide retiree benefits do so voluntarily, to the extent they can, while maintaining their global competitiveness. If CMS sets the threshold too high it will merely force employers toward one of the alternatives, up to and including walking away from their support of retiree healthcare coverage. There is clear evidence of this based on the decrease of employer sponsored retiree healthcare coverage over time. The 2004 Kaiser Survey of Employer-Sponsored Health Benefits noted, the percentage of large firms offering retiree health benefits has fallen from 66% in 1988 to 36% in 2004. Raising the threshold is tantamount to increasing costs, which is the reason for the precipitous decline in employer sponsored coverage. Based on the above facts, we believe the logic for arguing the merits of higher thresholds is flawed and inconsistent with the legislative intent to encourage employers to sponsor voluntary retiree healthcare programs.

Clearly, Congress wanted to provide employers financial incentives to maintain coverage through the

subsidy. However, placing arbitrary thresholds above the subsidy level, in effect, limits the duration of the subsidy intended by the legislation. We believe the legislative history supports the prevention of windfalls to employers. However, we find no basis in "raising the bar" above the minimum requirements necessary to prevent an employer windfall. Any provisions in the regulations that attempt to increase the already voluntary financial support of employers could have catastrophic implications on employer based retiree healthcare coverage.

CMS has also expressed concern with employers lowering their contribution support level if the qualifying threshold is set low. This concern can only be for employer programs where the employer has the unilateral right to change. Clearly, under collective bargaining and other contractual arrangements, unilateral action is not an option to employers. We firmly believe that large employers, where they have the unilateral right to change support levels, want to continue their current level of commitment and plans without disruption to their retirees. Receiving the subsidy will help accomplish this goal.

In fact, there is no logical basis to conclude that a lower qualifying threshold will lower the level of employer support. The financial benefit to employers from the actual subsidy payment is defined by the statute and does not change - whatever the amount of the qualifying threshold. In deciding the level of employer support, factors such as the impact of higher premiums on retirees as well as the employer's competitive position are given consideration. If employers have not already voluntarily chosen to lower their support and increase retiree contributions before the MMA, what has changed to make employers take this action under any scenario after MMA? There is no further incentive for employers to lower their support than that which already exists within our businesses. If anything, an argument can be made to the opposite effect. By qualifying more employers for the subsidy, employers will have more financial resources than prior to the MMA and therefore have the ability to sustain or possibly increase their level of support. The only logical threshold, that is consistent with legislative intent, is to establish the level at a point no higher than necessary to prevent employer windfalls.

CMS's own data clearly indicates that establishing an inappropriate subsidy level threshold would be devastating to the intent of the MMA. The Office of the Actuary for CMS has demonstrated this fact in a letter dated September 2004 to Mark McClellan, Administrator for CMS. This study showed that the number of employers being able to choose the subsidy decreases as the qualifying threshold increases. Based on the CMS actuary's estimates for employer subsidy payments versus the value of Medicare Part D for 2006, retirees and their dependents who are forced out of their employer's coverage will increase the federal government's spending by about $600 per individual.

Any misstep by CMS in establishing the threshold will result in many retirees involuntarily losing the ability to choose their employers' coverage causing a severe retiree backlash against the MMA. In particular, this is a major problem for retirees whose employer has placed a cap on their financial contribution toward retiree healthcare. In today's environment this is more the rule than the exception. Severely limiting the number of employers eligible to receive the subsidy would preclude any offset of a retiree's cost or premium (see Attachment 1). In addition, the only real options remaining for many employers will be coordinating with Medicare (clearly not as an attractive option financially or

administratively) or handing over the responsibility of providing drug coverage for our retirees to Medicare. The risk to the MMA is great because once an employer eliminates retiree benefits, the likelihood of recommencing their financial support is infinitesimal.

We agree that the two-prong approach (gross value and net value test) to determine actuarial equivalence is appropriate. We urge CMS to seriously consider establishing the net value threshold at the expected average subsidy payment for each employer.

3. Allocation of employer contributions toward subsidy payment eligibility
Reference Subpart R "Payments to Sponsors of Retiree Prescription Drug Plans"

Based upon the information received from the CMS "open house" conference calls and other written material, CMS appears to be indicating that it is the employer's choice as to how to allocate retiree caps for the purposes of qualifying for the MMA employer subsidy. Clearly, allowing employers the flexibility in the methods of allocating the caps is consistent with legislative intent by allowing employers to qualify for subsidy payment for a longer period of time. We agree with the CMS position, but we would want to have something explicitly written in the regulations to assure that we can design our benefit plans with confidence of being in compliance with the law. This would also help clarify the accounting options available to our organization.

4. Definition of "Gross Covered Cost"
Reference Subpart R "Payments to Sponsors of Retiree Prescription Drug Plans"

For the benefit of its employees and retirees located in the area of four of its U.S. facilities, Goodyear operates pharmacies in conjunction with primary care medical centers also located in these areas. The centers currently allow Goodyear to provide an enhanced drug benefit to Medicare eligible retirees at a lower total cost to Goodyear. It is crucial to the viability of these Goodyear-run facilities that the total direct cost allocable to Medicare retirees be included in any calculation for subsidy purposes. These costs should be included in the definition of "gross covered cost" because they are in lieu of a dispensing fee. As already stated, we estimate that the total cost of these facilities is lower than our other contractual prescription drug arrangements and therefore would also lower the federal government's subsidy payments. We ask that CMS clearly include these direct costs of company pharmacy operations as eligible expenses for reimbursement under the subsidy calculation.

5. Medicare Coordination
Reference Subpart J "Coordination Under Part D Plans with Other Prescription Drug Coverage"

It is Goodyear's desire to maintain its current plans and submit for the employer subsidy. However, this will only be possible if our issues stated above are positively addressed in the regulations. The total value of "wrapping" our plans with Medicare Part D appears to be lower than receiving the employer subsidy. Wrapping our coverage with Medicare Part D would be a last resort due to the complexities. This includes plan changes, potential required union negotiations, retiree communications and education and the major administrative issues and cost of coordination. Below are our comments and concerns

surrounding Medicare coordination.

Even though the MMA provides CMS with the ability to charge user fees for coordination, we respectfully ask that CMS not exercise this authority. Employers coordinating with Part D are already financially disadvantaged when compared to employer's that qualify for subsidies or an individual that enrolls into Part D without employer supplemental coverage. It is unwise to increase employer cost any further as it will have the effect of increasing the number of employers that choose to "walk away" from their existing levels of coverage.

Also, we would like to request that CMS establish a central clearinghouse entity for coordination of Troop much like it does for Medicare Part A and B.

Goodyear respectfully asks that CMS give careful consideration to its comments and we offer to meet with CMS staff and administration to clarify and discuss these comments. Please contact Thomas Broderick, Director – Compensation and Benefits, at (330)-796-5537, or email – thomas.broderick@goodyear.com for any assistance with this matter.

Thomas J. Broderick
Director Compensation and Benefits
The GoodYear Tire & Rubber Company

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Comment

The chart below illustrates how a typical employer retiree cap operates. If the threshold is set too high, the employer will not qualify for the subsidy payments, precluding any use of funds to offset retiree premiums. The result will be more retirees being financially forced into the Medicare prescription drug program.

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TJB Goodyear MMA Reg Comments 10012004

CMS-4068-P-592

Submitter : Mrs. Sheila Cobb **Date & Time:** 10/01/2004 12:10:56

Organization : School of Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

Sheila A. Bizune
209 Walnut Woods Drive
Morrisville, NC 27560
PharmD. candidate-University of North Carolina at Chapel Hill

To whom it may concern,

My name is Sheila Bizune and I would like to make a few comments regarding the Medicare Prescription Drug Benefit. It is in my opinion a posititve step especially for future pharmacists such as myself.

I truly believe if this plan is implemented pharmacists will have a great impact on quality of life for senior citizens. Medication therapy provided via the pharmacist is crucial especially to this set of population. The elderly use more prescription medications that any other group. Often times they are on more than one medication and don't have a clear understanding of the adverse effects of some of these drugs. Many times they have drug-drug interactions occur and end up in the hospital leading to more expensive treatment that probably could otherwise have been avoided with proper counseling.

That's where pharmacists come in. If pharmacists are reimbursed for their services it will positively impact the senior community as well as the healthcare field as a whole. I strongly support this plan and hope to see it implemented in the future.

CMS-4068-P-593

Submitter : Ms. Rebecca Artman **Date & Time:** 10/01/2004 12:10:51

Organization : P.A.N.D.O.R.A.

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

CMS-4068-P-593-Attach-1.doc

CMS-4068-P-593-Attach-2.doc

October 1, 2004

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

To Whom It May Concern:

P.A.N.D.O.R.A., Inc. (Patient Alliance for Neuroendocrineimmune Disorders Organization for Research and Advocacy) welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The name of organization is standard description of your
organization. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

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

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

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

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

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

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

IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:

In addition to providing for special treatment for certain special populations, we urge CMS to make significant improvements to the consumer protection provisions in the regulations in order to ensure that

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

STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND APPEALS PROCESSES:

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

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

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

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

DECLINE MEDICARE PRESCIPTION COVERAGE

Many people have purchased private insurance to cover their prescription medications. There is no provision to allow people to decline this coverage, which is sometimes not wanted. These people will soon be billed for Medicare Prescription Coverage which is unwanted.

Thank you for your consideration of our views.

Rebecca Artman
Chairperson -Legislative and Advocacy Affairs Committee- P.A.N.D.O.R.A., Inc.
Patient Alliance for Neuroendocrineimmune Disorders Organization for Research and Advocacy
http://www.pandoranet.info/

October 1, 2004

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-4068-P
P.O. Box 8014
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Chairperson -Legislative and Advocacy Affairs Committee- P.A.N.D.O.R.A., Inc.
Patient Alliance for Neuroendocrineimmune Disorders Organization for Research and Advocacy
http://www.pandoranet.info/

CMS-4068-P-594

Submitter : Dr. iraj lou **Date & Time:** 10/01/2004 01:10:46

Organization : health department

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

tha current language is highly ambiguous .i like to see in the regulation that CMS might consider that people with HIV/AIDS may have extenuating circumstances that coul;d necessitate exempting them as a special population under the regulation

CMS-4068-P-595

Submitter : Mrs. Barbara Phillips **Date & Time:** 10/01/2004 01:10:51

Organization : Council on Renal Nutrition

Category : Dietitian/Nutritionist

Issue Areas/Comments

GENERAL

GENERAL

As a Registered Dietitian and Certified Diabetes Educator working with patients with End Stage Renal Disease (requiring 4 hr. dialysis treatements 3 times per week), I encourage the coverage of prescription vitamins under the Medicare Prescription Drug Program. The dialysis procedure removes toxins as well as large amounts of vitamins that cannot be replaced by their diet. The B-vitamins in a presctiption renal vitamin are found in larger amounts than a typical over the counter vitamin. And the prescription vitamins do not have the vitamins A, D and E which can be harmful to dialysis patients if taken in regularly over a long period of time. Please include at least some of these prescription vitamins. I realize cost is an issue and some of these vitamins are quite expensive. But Nephplex-RX is one of the prescription vitamins that I have found to be well tolerated and less expensive than the others ($13.00-$14.00 per month vs $20.00 - $55.00 per month) I do encourage you to include these important prescription vitamins in the benefit. Thank you.

CMS-4068-P-596

Submitter : CHARLES STONE **Date & Time:** 10/01/2004 02:10:52

Organization : SANTA CRUZ COMMISSION ON DISABILITY

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

I AM A DUAL ELIGIBLE AND I SEE ONLY A MORASS OF CONFUSION WHEN IT COMES TO 'REFORMING' MY PERSCRIPTION BENEFITS WHICH ARE FINE AS THEY ARE NOW.I HAVE BEEN TO SEVERAL PUBLIC MEETINGS AND ALL SEEM TO INDICATE A POSSIBLE CO PAY IN THE FUTURE.I AM A PERMANENTLY DIABLED BABY BOOMER WITH DIABETES,SPINAL ARTHRITIS,DEGENRATIVE DISC AND JOINT DISEASE AND A HOST OF OTHER MALADIES.I LIVE IN CALIFORNIA WHICH HAS AN EXTREMELY HIGH COST OF LIVING AND I AM BARELY SCRAPING BY AS IT IS.PLAN D SOUNDS LIKE A NIGHTMARE TO ME AND OTHERS OF MY ILK LESS COMPUTER SAVVY.I URGE YOU TO WORK ALL THE BUGS OUT OF THIS OVERLONG CONSUMER UNFRIENDLY FORMULATION BEFORE YOU INFLICT IT UPON US,THE ALREADY OVERBURDENED.THANK YOU.

CMS-4068-P-597

Submitter : Mr. Chris Aycock **Date & Time:** 10/01/2004 02:10:00

Organization : NAMI North Carolina, Inc.

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4068-P-597-Attach-1.doc

October 1, 2004

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

Attention: CMS-4086-P

On behalf of the 1,300 members of NAMI North Carolina, Inc., I am pleased to submit the following comments on Notice of Proposed Rulemaking (NPRM) implementing the Medicare Prescription Drug Improvement and Modernization Act (MMA, P.L. 108-173).

Unique Needs of Medicare Beneficiaries Living with Mental Illness
During Congressional consideration of the MMA last year, NAMI raised concerns to Congress regarding how the new drug benefit would impact beneficiaries with severe mental illnesses, particularly those disabled and currently receiving their drug coverage through state Medicaid programs. Specifically, NAMI supported the inclusion of appropriate safeguards to protect these beneficiaries and ensure open access to critically important medications. Congress recognized the unique needs of this population and attempted to begin to address this situation by adding the following language to the final House-Senate Conference Report on P.L. 108-173.

"It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Centers for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention disorder/ attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes.

The conferees anticipate that disabled individuals will enroll in one of the many private sector prescription drug plans or MA-PD plans. Competition will necessitate plans offering the full complements of medicines including atypical antipsychotics, to treat the severely mentally ill. If a plan chooses not to offer or to restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to chose 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."1

In NAMI's view, it is extremely important that Medicare enrollees with severe mental illness, such as schizophrenia, bipolar disorder and major depression have sufficient protections to ensure access to the full range of treatments currently available to them. Without such protections, beneficiaries could suffer substantial irreversible clinical harm resulting in significantly higher overall Medicare costs, if their

access to psychotropic pharmaceuticals is compromised. In moving forward in developing the final regulations, NAMI would like to remind CMS that:

Psychiatric medications are unique, different from other classes and each other
* Individual responses to psychotropic medicines vary as a result of many factors, including race, ethnicity, gender, severity of illness, and other illnesses or medicines.
* It can take weeks or even months to determine whether mental health medicines are having their intended effect. Delaying access to appropriate medicines may leave some patients without effective treatment for months.
* Psychiatric medications in the same class can work on different areas or chemicals in the brain, so they may be effective for one consumer, but not another.
* Psychotropic medications differ in their side effects, dosing and interactions with other medicines or health conditions. Minimizing side effects and interactions is critical to encourage patients to take their medicines and control their illness.
* Newer psychotropic medications generally offer improvements in effectiveness and have fewer and more tolerable side effects. Older anti-psychotics in particular have debilitating side effects that make compliance extremely difficult.

Restrictions on access harm vulnerable individuals living with mental illness
* A recent study of 47 Medicaid programs found that restrictive formularies decreased drug spending by 13.4%. However, these savings were more than offset by a 28.7% increase in physician spending and a 39.1% increase in mental health hospital spending.
* Adding short-sighted bureaucratic hurdles makes it even more difficult and more costly to treat complex brain disorders.
* Treatment failures usually mean a further spiraling down for the individual, leading to more intensive, and more costly medical treatment than would previously have been required.
* The personal and social costs of getting it wrong can be too high to calculate when dealing with individuals with mental illness. It does not mean a lost work day or simple inconvenience or discomfort. Psychotic breaks put vulnerable beneficiaries and their families at risk. These treatment failures have enormous costs for states and communities including incarceration, homelessness and even suicide.

NAMI would therefore make the following recommendations with respect to the final regulations implementing the MMA.

1) Continuity of Care for Dual Eligible Beneficiaries: NAMI urges CMS to include in the Final Rules a requirement to ensure “continuity of care” for dual eligibles with mental illnesses by requiring prescription drug plans and Medicare Advantage plans to continue coverage for medications that are already effective in maintaining stability for individual beneficiaries.

2) Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses: NAMI urges the inclusion of a requirement for prescription drug plans and Medicare Advantage plans to put in place alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies like

prior authorization, fail first, step therapy, and therapeutic substitution.

3) Pharmacy and Therapeutic Committees: NAMI urges greater clarity to ensure that P&T Committee operations are more transparent and reflect an independent assessment of all coverage restrictions.

4) Therapeutic Substitution: NAMI recommends that the Final Rules incorporate protections for therapeutic substitution and, in particular, a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician.

5) Changes in a Plan Formulary: NAMI urges CMS to expand beneficiary protections in cases where a prescription drug plan enacts a change in the plan formulary in the midst of a plan year.

6) Appeals and Grievance Procedures: NAMI urges CMS to simplify the grievance and appeals procedures detailed in the Notice of Proposed Rulemaking (NPRM) by easing access, ensuring rapid results for beneficiaries and their doctors, and providing greater clarity for the expedited process for individuals with immediate needs.

7) Outreach and Enrollment: NAMI urges CMS to partner with, and provide support to, community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.

8) Involuntary Disenrollment for Disruptive Behavior: NAMI urges CMS to establish greater protections for beneficiaries with mental illnesses threatened with and subjected to involuntary disenrollment by prescription drug plans and Medicare Advantage plans for “disruptive behavior.”

Attached is a more detailed analysis of the summary recommendations included above. NAMI North Carolina, Inc. appreciates the opportunity to submit comments on these important regulations.

Sincerely,

Chris Aycock
Executive Director, NAMI North Carolina, Inc.

1 H.Rpt. 108-391, p. 769.

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CMS-4068-P-598

Submitter : Andrea Sinclair **Date & Time:** 10/01/2004 02:10:30

Organization : Avesta Housing

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

please see attached file from the disability community

CMS-4068-P-598-Attach-1.txt

LIGIBLES AT RISK
>
10/01/04

>
> Centers for Medicare and Medicaid Services
> Department of Health and Human Services
> Attention: CMS-4068-P
> P.O. Box 8014
> Baltimore, MD 21244-8014
>
> To Whom It May Concern:
>
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> even death, on the other. Often, people with disabilities need access
> to the newest medications, because they have fewer side
> effects and may represent a better treatment option than
> older less expensive drugs. Many individuals have multiple
> disabilities and health conditions making drug interactions
> a common problem. Frequently, extended release versions of
> medications are needed to effectively manage these serious
> and complex medical conditions. In other cases, specific
> drugs are needed to support adherence to a treatment
> regimen. Individuals with cognitive impairments may be less
> able to articulate problems with side effects making it

> more important for the doctor to be able to prescribe the
> best medication for the individual. Often that process
> takes time since many people with significant disabilities
> must try multiple medications and only after much
> experimentation find the medication that is most effective
> for their circumstance. The consequences of denying the
> appropriate medication for an individual with a disability
> or chronic health condition are serious and can include
> injury or debilitating side effects, even hospitalization
> or other types of costly medical interventions.
>
> We strongly support the suggestion in the proposed rule
> that certain populations require special treatment due to
> their unique medical needs, and the enormous potential for
> serious harm (including death) if they are subjected to
> formulary restrictions and cost management strategies
> envisioned for the Part D program. We believe that to
> ensure that these special populations have adequate,
> timely, and appropriate access to medically necessary
> medications, they must be exempt from all formulary
> restrictions and they must have access to all medically
> necessary prescription drugs at a plan's preferred level of
> cost-sharing. We recommend that this treatment apply to the
> following overlapping special populations:
>
> * people who are dually eligible for Medicare and Medicaid
> * people who live in nursing homes, ICF-MRs and other
> residential facilities
> * people who have life threatening conditions
> * people who have pharmacologically complex condition such
> as epilepsy, Alzheimer's disease, multiple sclerosis,
> mental illness, HIV/AIDS.
>
> IMPOSE NEW LIMITS ON COST MANAGEMENT TOOLS:
>
> In addition to providing for special treatment for certain special
> populations, we urge CMS to make significant improvements to the
> consumer protection provisions in the regulations in order to ensure
> that individuals can access the medications they require. For example
> we strongly oppose allowing any prescription drug plan to impose a
> 100% cost sharing for any drug. We urge CMS to prohibit or place
> limits on the use of certain cost containment policies,
> such as unlimited tiered cost sharing, dispensing limits,

> therapeutic substitution, mandatory generic substitution
> for narrow therapeutic index drugs, or prior authorization.
> We are also concerned that regulations will create barriers
> to having the doctor prescribe the best medication for the
> individual including off-label uses of medications which
> are common for many conditions. We strongly recommend that
> the final rule prohibit plans from placing limits on the
> amount, duration and scope of coverage for covered part D
> drugs.
>
> STRENGTHEN AND IMPROVE INADEQUATE AND UNWORKABLE EXCEPTIONS AND
> APPEALS PROCESSES:
>
> We are also concerned that the appeals processes outlined
> in the proposed rule are overly complex, drawn-out, and
> inaccessible to beneficiaries with disabilities. We
> strongly recommend CMS establish a simpler process that
> puts a priority on ensuring ease of access and rapid
> results for beneficiaries and their doctors and includes a
> truly expedited exceptions process for individuals with
> immediate needs. We believe that the proposed rule fails to
> meet Constitutional due process requirements and fails to
> satisfy the requirements of the statute. Under the
> proposed rule, there are too many levels of internal appeal
> that a beneficiary must request from the drug plan before
> receiving a truly independent review by an administrative
> law judge (ALJ) and the timeframes for plan decisions are
> unreasonably long.
>
> The provisions in the Medicare Prescription Drug,
> Improvement and Modernization Act of 2003 (MMA) that call
> for the creation of an exceptions process are a critical
> consumer protection that, if properly crafted through
> enforceable regulations, could ensure that the unique and
> complex needs of people with disabilities receive a quick
> and individualized coverage determination for on-formulary
> and off-formulary drugs. As structured in the proposed
> rule, however, the exceptions process would not serve a
> positive role for ensuring access to medically necessary
> covered Part D drugs. Rather, the exceptions process only
> adds to the burden on beneficiaries and physicians by
> creating an ineffectual and unfair process before an
> individual can access an already inadequate grievance and

> appeals process. We recommend that CMS revamp the
> exceptions process to: establish clear standards by which
> prescription drug plans must evaluate all exceptions
> requests; to minimize the time and evidence burdens on
> treating physicians; and to ensure that all drugs provided
> through the exceptions process are made available at the
> preferred level of cost-sharing.
>
> REQUIRE PLANS TO DISPENSE A TEMPORARY SUPPLY OF DRUGS IN
> EMERGENCIES:
>
> The proposed system does not ensure that beneficiaries' rights are
> protected and does not guarantee beneficiaries have access to needed
> medications. For many individuals with disabilities such as epilepsy,
> mental illness or HIV, treatment interruptions can lead to serious
> short-term and long-term problems. For this reasons the final rule
> must provide for dispensing an emergency supply of drugs pending
> the resolution of an exception request or pending
> resolution of an appeal.
>
> Thank you for your consideration of our views.
>
> # # #
> :
> --
> ---
>

CMS-4068-P-599

Submitter : Mr. Dennis Micai **Date & Time:** 10/01/2004 02:10:34

Organization : The Arc Mercer, Inc.

Category : Consumer Group

Issue Areas/Comments

GENERAL

GENERAL

please see the attched file from the disability community

CMS-4068-P-599-Attach-1.doc

CMS-4068-P-599-Attach-2.doc

October, 1, 2004

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

To Whom It May Concern:

The Arc of Mercer, Inc. welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Arc of Mercer, Inc is organization that serves more than 1000 developmentally disabled persons. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions.

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

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

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

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

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

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

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

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

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

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

* people who are dually eligible for Medicare and Medicaid

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

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

Strengthen and improve inadequate and unworkable exceptions and appeals processes:

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

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

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

Thank you for your consideration of our views.

Very truly yours,

DENNIS C. MICAI
Executive Director

October, 1, 2004

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

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Thank you for your consideration of our views.

Very truly yours,

DENNIS C. MICAI
Executive Director

CMS-4068-P-600

Submitter : **Date & Time:** **10/01/2004 02:10:29**

Organization : **KY-IN Chapter Paralyzed Veterans of America**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

Please see attached file from the Kentucky-Indiana Chapter of the Paralyzed Veterans of America.

CMS-4068-P-600-Attach-1.doc

October 1, 2004

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

To Whom It May Concern:

The Kentucky-Indiana Chapter of the Paralyzed Veterans of America welcomes the opportunity to provide comments on the proposed rule "Medicare Program; Medicare Prescription Drug Benefit," 69 FR 46632. The Kentucky-Indiana Chapter of the Paralyzed Veterans of America is a veteran's service organization made up of veterans with spinal cord dysfunction. We are concerned that the proposed rule does not provide sufficient protections for the 13 million Medicare beneficiaries with disabilities and chronic health conditions. The following are critical recommendations:

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

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

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Thank you for your consideration of our views.

Sincerely,

James Meyer
President

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

Organization : Mr. Ron Hogan

Category : Individual

Issue Areas/Comments

Issues 1-10

BENEFITS AND BENEFICIARY PROTECTIONS

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