National Mental Health Association

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Cynthia Wainscott, Chair of the Board • **Michael M. Faenza**, President and CEO

October 4, 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:

On behalf of the National Mental Health Association (NMHA), I am submitting the attached comments on the proposed regulations regarding the Medicare Part D prescription drug benefit published by the Centers for Medicare and Medicaid Services (CMS) on August 3, 2004. This drug benefit is long overdue as prescription medications have become, over the years, some of the most efficacious treatments for many illnesses and conditions, including mental illness. We strongly believe that Medicare beneficiaries deserve and need comprehensive drug coverage that will ensure them access to all necessary medications, and we appreciate this opportunity to provide input on how this critical benefit must be implemented.

The National Mental Health Association is the country's oldest and largest non-profit organization addressing all aspects of mental health and mental illness. Our members are consumers of mental health services, family members of consumers, providers of mental health services, and other concerned citizens – all advocates for improving care for individuals with mental illness. NMHA was established in 1909 by a former psychiatric patient who, during his stays in public and private institutions, witnessed and was subjected to horrible abuse. Out of this experience, he founded the NMHA and set in motion a mental health reform movement that has greatly contributed to improving treatment for individuals with mental illness with a particular focus on increasing access to community-based care. Access to psychiatric medications is a critical component of community-based care, and thus ensuring implementation a Medicare drug benefit that provides coverage for all medically necessary mental health medications is one of our primary goals.

Many Medicare beneficiaries face mental illness, often alone and without medications that have proven widely effective and that would likely ease their symptoms and lead to recovery. Research has shown that some 37% of older adults show signs of depression when they visit their primary care physician,[1] but we know that most are not receiving the care they need. In

[1] U.S. Department of Health and Human Services, Administration on Aging. *Older Adults and Mental Health: Issues and Opportunities*, January, 2001, p. 9.

fact, older adults have the highest rate of suicide of any age group in the country.[2] 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.[3] Beneficiaries who qualify for Medicare based on their disability status also frequently experience mental illness, and studies have shown that over half of all under-65 beneficiaries with disabilities have problems with mental functioning.[4] We are particularly concerned about 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.[5] We must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new Medicare drug benefit and are not made worse off when their drug coverage is switched from Medicaid to Medicare at the end of 2005.

Thus, we are extremely concerned that the proposed regulations implementing the Part D drug benefit would likely cause harmful disruptions in care for dual eligibles as well as result in 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 have grave concerns regarding the lack of adequate safeguards against the overzealous use of utilization management techniques by private drug plan and Medicare Advantage drug plan to restrict access to medications. However, we do appreciate recognition by CMS of the need for special exemptions from these techniques for certain beneficiaries, including those with mental illness. Provisions to grant drug plans flexibility to implement cost constraints must be limited by the primary goal of providing Medicare beneficiaries with desperately needed coverage for prescription medications. The proposed rules allowing involuntary disenrollment of beneficiaries for disruptive behavior will undoubtedly invite discrimination against individuals with mental illness. In addition, the grievance and appeals processes outlined in the proposed regulations are overly complex, drawn-out, and inaccessible to beneficiaries. Furthermore, 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 disadvantaged populations. These and other concerns are discussed in detail in the attached comments.

We urge CMS to incorporate the following changes, addressing our primary areas of concern, into the final rule:

- 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;
- For Medicare beneficiaries with mental health needs, and particularly dual eligibles, require plans to use alternative, flexible formularies for beneficiaries with mental illnesses that

[2] Id., p. 3.
[3] Id., p. 11.
[4] The Henry J. Kaiser Family Foundation, *The Faces of Medicare: Medicare and the Under-65 Disabled*, July 1999.
[5] Medpac, *Report to Congress: New Approaches in Medicare*, June 2004, p. 72.

provide access to the full array of mental health medications without restrictive policies like prior authorization, fail first, step therapy, and therapeutic substitution;
- Establish greater protections for beneficiaries threatened with and subjected to involuntary disenrollment by their drug plans for disruptive behavior;
- 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; and
- 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.

We strongly believe that these concerns must be addressed in order 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.

Thank you for your consideration of our comments. If you have any questions, please contact Kirsten Beronio at (202) 675-8413.

Sincerely,

Michael M. Faenza, MSSW
President and CEO

Attachment

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National Mental Health Association
Comments on the Centers for Medicare and Medicaid Services' Notice of Proposed Rulemaking (August 3, 2004) Medicare Part D Prescription Drug Benefit

Contents

Part D Enrollment Process (§423.34)

We are very concerned that the provisions in the notice of proposed rulemaking (NPRM) addressing enrollment of beneficiaries into private drug plans (PDPs) or Medicare Advantage prescription drug plans (MA-PDPs) do not adequately address the need for targeted and hands-on outreach, particularly outreach to low-income beneficiaries and beneficiaries with mental illness.

Officials at the Centers for Medicare and Medicaid Services (CMS) have indicated that they will rely heavily on State Health Insurance Assistance Programs (SHIPs) to assist with enrollment, but these organizations are staffed primarily by volunteers who are already overburdened. Moreover, SHIPs are primarily focused on assisting seniors and generally do not have the capacity to address the special needs of individuals with disabilities. More attention must be given to developing materials and education and enrollment campaigns focused on informing beneficiaries with disabilities, including mental illness, about the new drug benefit and helping them to enroll in the best plan available.

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, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention deficit/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes." [Report No. 108-391, pp. 769-770] Experience implementing Medicaid managed care programs over the past 10 years shows that to successfully enroll individuals with mental illness, outreach, education, and enrollment opportunities must be incorporated at multiple points within the mental health community.

The proposed rule does not provide the appropriate steps for effective enrollment of this vulnerable population that Congress demanded in the conference report. 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. It is to these organizations, which beneficiaries with disabilities know and trust, that they will likely turn 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 disabilities about the new benefit. CMS has indicated it plans to disseminate information through community organizations in the discussion regarding Part D information that CMS provides to beneficiaries (§423.48). But providing community-based organizations with pamphlets and brochures alone is not adequate to enable these organizations to take on the complex, labor-intensive work required to help this population to make informed decisions about enrollment.

To answer the many difficult, detailed, time-consuming questions that beneficiaries will have about the new program, extensive face-to-face counseling services will be critical. Community-

based organizations can gear up to provide the kind of detailed and personalized help needed, but they will require additional resources to do so.

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

Enrollment for Dual Eligibles

The NPRM fails to adequately address how drug coverage for the 6.4 million Medicare beneficiaries with full Medicaid coverage (i.e., the dual eligibles) will be transferred to Medicare on January 1, 2006. The NPRM states that dual eligibles will be automatically enrolled in a PDP or MA-PDP, if they do not enroll themselves, by the end of the initial enrollment period. However, that enrollment period would end on May 15th and therefore **there could be a four and a half month gap when these individuals have no drug coverage at all**. Moreover, it is hard to see how over six million people will be educated about and enrolled in a drug plan by January 1, 2006 given that the enrollment period will not begin until November 15th. The unique circumstances and needs of dual eligibles makes it critical that CMS 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 prescription drug coverage to which they are entitled.

CMS requests comments on whether CMS or the states should perform automatic enrollment of dual eligibles. State officials have more readily available data identifying the dual eligibles in their state and they will also be involved in the enrollment process because they are already required to perform low-income subsidy enrollment. In addition, there is an incentive for them to enroll these individuals in a Medicare drug plans because without drug coverage they will increase utilization of other Medicaid services. However, there is also a disincentive in that the "clawback" payment states will have to make to CMS, to cover part of the cost of transferring drug coverage for the duals to Medicare, will be based on the number of dual eligibles enrolled in the new Part D benefit.

In either case, the states or CMS must also involve community-based organizations and providers that serve and work with dual eligibles in this enrollment process. In addition, the states or CMS must devote resources to helping these organizations and providers inform dual eligibles of their choices and what they need to do to sign up. These organizations can help duals find the best plan available to them and let them know that they can switch plans if they have been automatically enrolled in a plan that is not the best through the special enrollment provision in § 423.36 of the regulations.

Continuity of Care for Dual Eligibles

We are extremely concerned with ensuring continuity of care for dual eligibles. A disproportionate number of dual eligibles struggle with mental illness and need access to a wide variety of medications. According to Medpac, 38% of all dual eligibles have cognitive or mental impairments.[1]

As proposed in the NPRM, duals would 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, or through automatic enrollment they would be required to be placed in these low-cost plans. The formularies for these plans will not be as comprehensive as the drug coverage these individuals currently have through Medicaid. Even in states that have restricted access to drugs in Medicaid programs with preferred drug lists and prior authorization requirements, most of these states have exempted mental health medications from these restrictions.

Adverse health effects: Without access to the coverage they need, dual eligibles will be forced to switch medications. In a June 10, 2004 letter to Dr. Mark McClellan, Michael Hogan, former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, advises that "[a]ppropriate continuity of care provisions for psychiatric medications for dual eligibles are critical and needs to be considered in the development of this program. It has been shown that once a patient has evidence of successful response to a particular medication or treatment regimen, switching the treatment without clear clinical indication is deleterious."

Changing psychiatric medications is very difficult and dangerous. It can take as much as six to twelve weeks to determine if a medication works, and almost as long to wash a medication out of a consumer's system. Abrupt changes in psychiatric medications bring the risk of serious adverse drug interactions. Moreover, each failed trial results in suffering and possible worsening of a person's condition. People who switch from one SSRI to another, for example, tend to remain in treatment 50 percent longer than those who don't, and their treatment typically costs about 50 percent more than it would have if they'd been allowed to continue taking a medication that has already been deemed appropriate.[2]

Cost impact: Not ensuring continuity of care for dual eligibles will greatly increase costs. In his June 10, 2004 letter to Dr. McClellan, Dr. Hogan states that "[p]atients who are not adequately treated, or treated with the wrong therapeutic agent, tend to utilize more costly crisis intervention, inpatient hospital, and intensive case management services. They also will tend to be less adherent to prescribed medications from that point forward, even when a more clinically appropriate treatment regimen has been prescribed." A study of the overall medical costs and use of services among people who had mental illnesses and were uninsured revealed that continuity of medication therapy resulted in a 65 percent reduction in inpatient costs, a 55 percent reduction in emergency costs, a 23 percent increase in outpatient care and an overall

[1] Medpac (June, 2004), *Report to Congress: New Approaches in Medicare*, p. 72.
[2] Hensely, PL and Nurnberg, H.G. (2001), *Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls*, Pharmacoeconomics, Vol. 19, No. 10, pp. 973-982.

mean cost savings of $166 per patient per month.[3] Fewer prescriptions are needed when access to medications is not limited, but increased restrictions are associated with more physician and emergency room visits, hospitalizations and prescriptions which become increasingly costly each year.[4]

Moreover, it is clear that **Congress was concerned with ensuring access to psychotropic medications under the new Part D benefit.** The conference report states 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." [5]

The NPRM does not, however, adequately provide the protection for people with mental illness that Congress called for in the conference report. Certainly the NPRM provides a special enrollment period for dual eligibles to use "at any time" (§ 423.36). However, this provision will not adequately address the needs of dual eligibles. It is unlikely that there will be much choice of low-cost drug plans in each region, particularly in rural areas which have not had much luck attracting Medicare+Choice plans in the past. In addition, these individuals will not have the resources to pay more in premiums for more comprehensive coverage. Moreover, the special enrollment provisions do not specify that dual eligibles would not be subject to a late enrollment fee if this complex process of disenrollment and reenrollment resulted in a gap in coverage of over 63 days.

In the preamble to the proposed regulations, CMS points to the exceptions process as a means of securing coverage of off-formulary medications. But the process proposed would be completely ineffective for this population. It is extremely complex and impossible to navigate for people experiencing psychiatric crises or facing cognitive impairments. Moreover, the timelines established are extremely drawn out; for example, an "expedited determination" could take as long as two weeks. Drug plans are not required to provide an emergency supply of medications until at least two weeks following a request. As Michael Hogan, former chair of the President's New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department, has pointed out in a letter dated June 10, 2004, to Dr. 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." Dr. Hogan also urges CMS not to rely on grievance and appeal processes as a substitute for open formulary access to mental health medications.

Congress and the Administration have promised that dual eligible beneficiaries would be better off with this new Part D drug benefit than they were receiving drug coverage through Medicaid. To honor this promise, **coverage of mental health medications for dual eligibles must be**

[3] Del Paggio, D., Finley, P., and Cavano, J. (2002), Clinical and economic outcomes associated with Olanzapine for the treatment of psychotic symptoms in a county mental health population, *Clinical Therapeutics*, 24.5, pp. 803-817.
[4] Horn, W, Unintended Costs and outcomes: The Fiscal Case for Open Access, Drug Benefit Trends, Vol. 15, Supplement 1.
[5] Conference Report No. 108-391, pp. 769-770.

grandfathered into the new Part D benefit just as a number of states (e.g., Wisconsin, Oregon, Kentucky, Texas and California) have done in implementing preferred drug lists for their Medicaid programs. Drug plans must be required to cover these medications, or at least for current dual eligibles the mental health medications they are already taking, with higher reimbursement for this coverage based on "allowable and allocable costs" as CMS has proposed to pay fallback plans. Increased federal payments are warranted as coverage of the full array of mental health medications by these drug plans will prevent increased utilization of more costly inpatient and outpatient services and resulting increases in Medicare Part A and B costs.

In addition, **CMS must require plans to establish an alternative flexible formulary for dual eligibles and other Medicare beneficiaries with mental health disorders** as suggested in the preamble to the proposed regulations. This flexible formulary should incorporate utilization management techniques that focus on improving inefficient and ineffective provider prescribing practices but do not restrict access to medications through prior authorization, fail first, step therapy, or therapeutic substitution requirements. Again, increased payments for drug plans based on "allowable and allocable costs" as proposed for fallback plans is warranted to account for the savings to Medicare Parts A and B that will result from ensuring access to needed mental health medications. A more detailed discussion of this alternative flexible formulary proposal can be found in our comments on section 423.120, "Access to Covered Part D Drugs."

Disenrollment by the PDP (§ 423.44)

We have a number of very serious concerns regarding provisions in the proposed regulations to allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is "disruptive, unruly, abusive, uncooperative, or threatening" (§ 423.44). These provisions create enormous opportunities for discrimination against individuals with mental illnesses. 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.

Moreover, CMS lacks statutory authority to authorize PDPs to involuntarily disenroll beneficiaries. Under the MMA, section 1860D-1(b) directs the Secretary to establish a disenrollment process for PDPs using rules similar to a specific list of rules for the Medicare Advantage program. This list does not include reference to section 1851(g)(3)(B) of the Social Security Act which authorizes MA plans to disenroll beneficiaries for disruptive behavior. Thus, these proposed regulations must not be included in the final rule.

Furthermore, CMS has proposed to lower the standard for involuntary disenrollment in these Part D regulations (as well as the proposed regulations for the new Medicare Advantage (MA) program) from that included in the Medicare+Choice (M+C) program regulations after which these regulations were clearly modeled. The preexisting M+C regulation allowing for disenrollment for disruptive behavior states that M+C plans may not disenroll an individual if the behavior at issue is "related to the use of medical services or diminished mental capacity." The

proposed regulation for Part D plans (and the new requirements for MA plans) would lessen the degree of protection for beneficiaries against involuntary disenrollment for disruptive behavior. The proposed regulations state that "disruptive behavior may not be based on noncompliance with medical advice." This standard would unfairly deny protection for beneficiaries who complied with medical advice, for example, by trying an on-formulary drug instead of the drug needed, and as a result experienced a bad reaction causing their disruptive behavior.

Although the proposed regulations would also require that the behavior be committed by someone with "decision making capacity," this standard is not as broad as protections for people with diminished mental capacity as previously provided under the M+C program. It is patently unfair and discriminatory to deny protections for those whose allegedly disruptive behavior is a result of diminished mental capacity. Moreover, this lower standard would impose unacceptable risks to the health and well-being of these beneficiaries many of whom are likely to have very low incomes with no way to access needed medications during the extended period when they would have no drug coverage as a result of being involuntarily disenrolled.

The proposed regulations also add "threatening" to the list of behaviors that could merit disenrollment under the M+C program, in addition to disruptive, abusive, unruly, and uncooperative. Under the preexisting regulations, a beneficiary had to have at least taken some action to merit disenrollment. Moreover, the highly subjective term of "threatening" is not defined.

CMS must not include this lower standard for involuntary disenrollment for disruptive behavior that it has proposed in the NPRM in the final regulation.

We are alarmed by CMS's proposal to establish an expedited disenrollment process for disruptive or threatening behavior. The proposed expedited disenrollment process is itself undefined, and provides no standards, requirements, or safeguards. Moreover, the NPRM allows plans to employ this mechanism on the basis of behaviors described in the broadest of terms – terms which could easily be mis-applied or applied capriciously or punitively. Thus, it would undermine all the minimal protections that would otherwise apply. This expedited disenrollment process must not be included in the final rule.

In the preamble, CMS appears to be asking for comments on whether a PDP should be allowed to refuse reenrollment of an individual who has been involuntarily disenrolled if there is no other PDP in the area. Obviously, these plans must be required to allow reenrollment. Those individuals most likely to be subject to involuntary disenrollment will not have the resources to pay for their medications out-of-pocket. Moreover, these individuals are entitled to this benefit. Disruptive behavior does not disqualify one from Medicare coverage. Congress clearly intended for all Medicare beneficiaries to have access to this benefit as evidenced by the fact that the Medicare Modernization Act requires that there be fallback plans available in areas where there are not at least two private drug plans.

The stigma that continues to surround mental illness all but assures that where these regulations open the door, such discrimination will occur. Congress' clear concern in the conference report for assuring access to needed medications for individuals with mental illness argues for exercise

of the greatest care in the development of these regulations to ensure that avenues for potential discrimination are barred. Absent such steps here, the disenrollment processes proposed in the NPRM will have a disproportionate impact on individuals with disabilities particularly, those with mental illness. Such processes lend themselves to discrimination against such individuals either through purposeful efforts or as an indirect consequence of plans not making adequate accommodations for individuals with disabilities, e.g., by training plan personnel on the special needs of these individuals and providing simplified processes for them to use to access the medications they need.

In the preamble, CMS states that PDPs must apply policies for involuntary disenrollment consistently among beneficiaries enrolled in their plans, "unless we permit otherwise" and must comply with laws against discrimination based on disability. We question under what circumstances would CMS permit plans not to apply these policies in a consistent manner. There is already a significant and highly troubling risk that these provisions will be used to discriminate against certain individuals, and we urge CMS to review plans' requests for approval with the utmost scrutiny and to strictly require consistency in the applications of these provisions.

Individuals that are involuntarily disenrolled would not have the opportunity to reenroll in a plan until the next annual enrollment period and may therefore be subject to a late penalty and increased premium as a result. This result is patently unfair in light of the fact that the disruptive behavior may have resulted from denial of access to needed medications in the first place, and given the high risk of discrimination presented by these provisions. Thus, at the very least, 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.

In addition, the following protections must be included in the regulations implementing the Part D benefit and the Medicare Advantage program to lessen the grave risks inherent in authorizing sanctions on "disruptive behavior:"

- PDPs and MA-PDPs must be prohibited from disenrolling a member 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.
- PDPs and MA-PDPs may not disenroll a member for "disruptive" behavior if such behavior results from failure to provide access to needed medications or failure to provide timely and responsive appeals processes.
- PDPs and MA-PDPs may not disenroll a member because he/she chooses not to comply with any treatment regimen developed by the plan or any health care professionals associated with the plan.
- Documentation provided to CMS arguing for approval of a plan's proposal to involuntarily disenroll an individual must include:
    - documentation of the plan's effort to provide reasonable accommodations for individuals with disabilities, where applicable, in accordance with the Americans with Disabilities Act; and
    - documentation that the plan provided the member with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment.

- PDPs and MA-PDPs must provide beneficiaries subject to involuntary disenrollment with the following notices:
    - Advance written and verbal notice to inform the individual that the consequences of continued disruptive behavior will be disenrollment;
    - Notice of intent to request CMS' permission to disenroll the individual; and
    - A planned action notice advising that CMS has approved the plan's request for approval of involuntary disenrollment.

Late Enrollment Penalty (§ 423.46)

The procedures for applying late enrollment fees provided in the proposed regulations also raise several issues. Late penalties apply when an individual has not maintained "creditable" drug coverage for 63 days following the last day of an individual's initial enrollment period. The regulations provide no opportunity to appeal these penalties, but some recourse must be provided to enable beneficiaries to challenge late fees that have been incorrectly applied.

As discussed above, for involuntarily disenrolled individuals, special enrollment periods should be provided with late fee exceptions.

Individuals that face special challenges, including individuals with mental illnesses, may need additional time to determine which plan is best and to enroll and they should be given a grace period or extension as needed without the application of late fees.

Finally, individuals who take advantage of the special enrollment periods must not be subject to late enrollment penalties as long as any delay between disenrollment and enrollment in a new plan beyond 63 days could not reasonably have been avoided.

Part D Information that CMS Provides to Beneficiaries (§ 423.48)

The regulation itself merely states that CMS will provide beneficiaries "information they need to make informed decisions among the available choices for Part D coverage." In the preamble, CMS states that this information will include information regarding benefits and prescription drug formularies. We urge that the comparative information provided to beneficiaries include specific information regarding which drugs are covered by each plan and the relevant co-pays. Mental health medications are not generally interchangeable and the effectiveness of certain medications varies widely from individual to individual. Thus, it is critical that beneficiaries with mental illness be well-informed about the specific medications covered by a plan and the amount of any required copayments. This information is an essential element of the information beneficiaries will need to make an informed decision among available plans – as described in the regulation. CMS has taken a positive step in this direction by proposing to extend the price comparison web site established for the Medicare drug discount card. However, many beneficiaries do not have access to the internet and thus this information also must be provided in written form and mailed directly to beneficiaries in each region. In addition, CMS must undertake strict oversight of the website to ensure the accuracy of the prices listed there.

CMS also indicates that it will undertake special outreach efforts to disadvantaged and hard-to-reach populations and coordinate with a broad array of public, voluntary, and private community organizations serving Medicare beneficiaries. These outreach efforts must involve community-based groups on a collaborative basis and not just use these groups as conduits for distributing written materials produced by CMS regarding the new benefit. As discussed earlier, resources must be provided to enable these groups to educate beneficiaries about their choices and help enroll them. This collaboration with community groups must begin as soon as possible to establish the infrastructure needed once the drug benefit goes into effect.

Approval of Marketing Materials and Enrollment Forms (§ 423.50)

CMS requests comments on whether to allow plans to offer financial services. This proposal will only further complicate an already overly complex process. Allowing these additional services would not be in the best interests of beneficiaries. This proposal raises concerns regarding the misuse of medical information by plans that also offer financial services.

Information Provided to PDP Sponsors and MA Organizations

In the preamble, CMS poses the following significant questions regarding how and what information they should provide to drug plans. Should beneficiaries be given the ability to choose not to have their information shared with drug plans? CMS should only inform plans of a beneficiary's eligibility for Part D coverage and relevant contact information for that beneficiary. No information regarding diseases or conditions that individual may have should be disclosed in light of medical privacy concerns and particularly the stigma attached to mental illness. CMS also asks whether plans should only be allowed to contact beneficiaries through written communications. Medicare beneficiaries are, for the most part, a very vulnerable population who face advanced age and disabilities. In light of on-going and widespread abuse in telemarketing, telephone contact must be prohibited unless a beneficiary's coverage is at stake. Following any telephone contact, written documentation of the conversation must be sent to the beneficiary as soon as possible. CMS also asks whether beneficiary information should be provided to plans upon request or only at certain times, e.g. just before annual enrollment. As this information is intended to help "facilitate marketing and enrollment," there is no need for plans to receive this information other than just before annual enrollment. In the case of special enrollment periods, plans could verify the eligibility of beneficiaries applying for enrollment on a case by case basis. Finally, CMS asks whether plans should be permitted to market directly to beneficiaries, bypassing CMS. As mentioned earlier, Medicare beneficiaries face many challenges including old age, chronic illness, and disabilities. The enrollment process will be enormously complex and difficult for them. CMS must provide strict oversight over marketing and enrollment to ensure that the populations they serve are not misled by plans and that they are enrolled in plans that best meet their needs. For these reasons, CMS also must not establish the streamlined approval process for marketing materials proposed in section 423.50 and referred to as "File and Use."

Definition of Covered Part D Drug – Excluding Benzodiazepines (§ 423.100)

We are concerned that the exclusion of benzodiazepines from coverage under the new Part D drug benefit will harm many beneficiaries with mental health disorders. Benzodiazepines, including Xanax, Ativan, Restoril, and Valium, are used often in combination with mood stabilizers to treat mania.[6] They are also used to treat insomnia in older adults. The loss of coverage for these medications could cause many beneficiaries, particularly those with low incomes, to switch to other medications but these alternatives are likely to be more costly for the Part D program because all benzodiazepines are available in generic form. Moreover, abrupt switching could result in severe withdrawal symptoms and adverse drug interactions and as a result, greater utilization of higher cost inpatient and emergency services.

In the preamble, CMS states they intend to "ensure that the Part D benefit 'wraps around' Part B drug benefits to the greatest extent possible" and requests comments regarding any gaps in combined Part D and B coverage.[7] The lack of coverage for benzodiazepines is a significant gap in coverage that will harm beneficiaries who need these medications. We urge CMS to extend coverage for these medications, or at the very least, strongly encourage states that are already covering benzodiazepines in their Medicaid programs to continue providing this coverage for dual eligibles after their drug coverage is transferred to Medicare Part D in 2006.

Access to Covered Part D Drugs (§ 423.120)

The proposed regulations do not establish any limits on, or safeguards to protect against overzealous use of utilitization management techniques by drug plans to restrict access to needed medications. This grave omission is inconsistent with public comments made by CMS. In written answers for the record to a question from Senator Baucus on his nomination to be Administrator of CMS, Dr. Mark McClellan stated that "[b]eneficiaries who elect to enroll in this new open-ended drug benefit will have no limits on the number of prescriptions filled, no limits on the maximum daily dosage, and no limits on the frequency of dispensing a drug." To ensure that the primary purpose of the new drug benefit – to provide Medicare beneficiaries with access to the prescription drugs they need -- is not compromised by the latitude health plans are given to implement cost-constraints, regulatory limits and safeguards must be established. At the very least, the prohibitions Dr. McClellan described in the above-quoted statement must be included in the final regulations for the Part D benefit. Research indicates that any program that permits fewer than six mental health medications per month seriously risks patient health.[8]

Moreover, in the preamble CMS actually encourages plans to utilize other restrictive policies like prior authorization, fail first and step therapy requirements. These requirements must not be applied to mental health medications which are generally not interchangeable, including those

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[6] U.S. Department of Health and Human Services (1999), *Mental Health: A Report of the Surgeon General*, p. 268.
[7] *Federal Register*, Vol. 69, No. 148 (August 3, 2004), p. 46647.
[8] Harrington, C., Scallet, L., Goplerud, E., Robinson, G.K., Gregorian, R.S., Hughes, C., Treciak, K. (1998), *Health Plan Benefit Barriers to Access to Pharmaceutical Therapies for Behavioral Health.* SAMHSA Managed Care Tracking System. Prepared by the Lewin Group.

with the same mechanism of action, and differ fundamentally in how they affect brain chemistry. For example, while the different types of selective serotonin reuptake inhibitors (SSRIs) may be similar, they have been shown to have significantly different clinical effects, side effects, and adverse effects in different individuals.[9] As noted by the American Psychiatric Association, "[a]ll SSRIs may block the reuptake of serotonin by binding to and inhibiting the serotonin transporter, but each individual medication is structurally different, and therefore binds to a potentially different set of individual receptors, proteins, and enzymes associated with nerve cells that use serotonin."[10] In addition, each SSRI has a distinct profile of its own particular side effects, and these medications vary widely in how long they last in the body. Furthermore, research shows that different antipsychotic medications (including atypicals) affect separate portions of the brain and affect the brain in very different ways.[11] There are two or more distinct types of atypical anti-psychotics that each has different chemical structures, mechanisms of action, and clinical outcomes. As a result, these medications have varied clinical and side effects.[12] In a June 10, 2004 letter to Dr. McClellan, Michael Hogan, former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health states that "most psychotropic medications, even if classified within the same therapeutic category, are not clinically interchangeable . . . each has a different set of action and patient tolerability factors which only the patient's physician is qualified and in a position to consider when making individual patient care decisions."

Mental illnesses themselves are highly variable in terms of symptoms and effects on consumers. Physicians have to 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. Thus, **the final rule must prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution**. Physicians must retain the ultimate authority to decide which specific medication a Medicare beneficiary will receive.

Given the high degree of variability in the symptoms and effects of mental illnesses, the clinical and side effects of medications, and the myriad of factors that physicians must take into account in prescribing medications, Medicare beneficiaries must be assured access to the full array of medications. A recent poll by *Consumer Reports* of over 3,000 members with commentary by national experts found that it is essential to have a wide choice of anti-depressants because most people need to try several before they find one that works and it is impossible to predict with certainty which one that will be.[13]

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[9] American Psychiatric Association (2004), *Maximizing Pharmacotherapy in the Treatment of Major Depression: The Case for Maintaining Open Access to Medically Indicated Medications*, White Paper, p. 2.
[10] Id., p. 10.
[11] Horn, S. (pending December 2003). Unintended Costs and Outcomes: The Fiscal Case for Open Access. *Drug Benefit Trends*, Vol. 15, Supplement 1.
[12] American Psychiatric Association (2004), *Maximizing Pharmacotherapy in the Treatment of Severe and Persistent Mental Illness: The Case for Maintaining Open Access to Medically Indicated Medications for Schizophrenia*, White Paper, p. 5.
[13] Consumer Reports (October, 2004), *Drugs v. Talk Therapy: 3,079 Readers Rate Their Care for Depression and Anxiety*.

The final Part D rule must assure Medicare beneficiaries access to newer, generally more effective medications in particular. 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."[14] For example, SSRIs are generally the first-line of treatment recommended and prescribed by psychiatrists today because of improved effectiveness and more manageable side effects. The older tricyclic medications and MAOIs can cause very dangerous side effects. Newer, atypical anti-psychotics have been shown to be more effective and display fewer side effects. Older medications are not as effective (for instance, they do not alleviate the symptoms of apathy and withdrawal) but even worse are the pervasive, uncomfortable, and sometimes disabling and dangerous side effects evident in an estimated 40 percent of patients (e.g., muscle spasms resulting in abnormal and usually painful body positions, tremors and muscle rigidity, involuntary repetitive movements often of the face, mouth, or hands, and painful muscular restlessness requiring the person to move constantly.)[15]

Fewer side effects generally results in better compliance with medication.[16] The introduction of SSRIs significantly reduced the number of patients who stopped taking their medication compared with those who were given tricyclic antidepressants, according to a study that contained an analysis of the outcomes of 2,678 patients who were diagnosed with depression and received prescriptions for anti-depressant medications.[17]

In a recent report, CMS itself has recently stated that the newer mental health medications including SSRIs and atypicals are more efficacious and that limiting access to these medications can have a negative effect on quality. In this report, CMS thus encourages State Medicaid Directors to consider innovative alternatives to restrictive policies like prior authorization requirements with regard to managing utilization of mental health medications. CMS also refers to restrictive formularies and prior authorization requirements as "increase[ing] the risk of use of multiple prescriptions, reduced compliance, and poor outcomes."[18] We urge CMS to incorporate this important recognition into the final Part D regulations by prohibiting the use of restrictive formularies and fail first, step therapy, and prior authorization requirements for mental health medications by private plans offering the new Medicare drug benefit.

CMS has recognized the special needs of individuals with mental illness and states in the preamble that certain vulnerable populations, including individuals with mental illness, need access to a wide range of drugs and that restrictive policies like prior authorization may not be appropriate for these populations. CMS states that these populations may be "negatively impacted financially" by restrictions on access to medications. These types of restrictions will have far more than just a financial impact on these vulnerable populations. Most beneficiaries, and especially the very low-income dual eligibles, will not have the resources to pay for

[14] New Freedom Commission on Mental Health, Final Report, *Achieving the Promise: Transforming Mental Health Care in America*, p. 26.
[15] U.S. Department of Health and Human Services (1999), *Mental Health: A Report of the Surgeon General*, p. 281.
[16] Id., p. 282
[17] Dobrez, D., et al. (2000, December). *Antidepressant treatment for depression: Total charges and therapy duration*. Center for Policy Research.
[18] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, (August 20, 2004), Report to State Medicaid Directors, *Psychiatric Medications: Addressing Costs without Restricting Access*, p. 2.

medications out of pocket and as a result would be forced to switch abruptly to a different and probably less efficacious medication. For those with mental illnesses, switching medications can be very detrimental risking dangerous drug interactions, harmful relapses in symptoms, and increased suffering. Once someone is stabilized on a particular drug regimen, forcing them to switch is akin to removing a cast from a broken limb, re-injuring it, and then applying a cheaper, inferior cast. This should never be required.

The unwarranted and abrupt switching of medications required by restrictive policies like prior authorization, fail first, and step therapy can have grave clinical consequences and cause psychiatric crises in beneficiaries. As a result, most states that have imposed prior authorization requirements in their Medicaid programs have exempted mental health medications. In a June 10, 2004 letter to Dr. McClellan, Michael Hogan, former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, points out that states have also struggled in their Medicaid programs to find a balance between containing the costs of drug benefits while also ensuring beneficiaries have access to all clinically appropriate treatment options. He also advises that the states have come to understand that "[f]or any individual suffering from a serious mental illness, access to the right treatment in a timely manner is the key to clinical stability and reduced overall cost of their health care." The final Part D regulations must follow the states' lead and exempt mental health medications from restrictive policies like prior authorization, fail first, and step therapy requirements.

Alternative, Flexible Formulary

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 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.

Policies like fail first and step therapy, which force individuals to try other medications before receiving the one prescribed by their physician, are inappropriate for mental health consumers. This is due to the non-interchangeable nature of mental health medications and the fact that choosing the first course of treatment is critically important since the chance of recovery can diminish significantly if that first treatment fails. But it does not disappear and thus it is important that consumers have access to the full array of medications.[19]

For individuals with mental illness, restrictions on access to medications for these diseases results in prolonged illness, decreased patient compliance, worsened outcomes and increased utilization and costs to the health care system more broadly. Research findings from a series of

[19] Letter from Michael Hogan, Ph. D., Director of the Ohio Department of Mental Health to Dr. Mark McClellan, Administrator of the Centers for Medicare and Medicaid Services, June 10, 2004.

focus groups, interviews and literature reviews reveal that restrictive drug formularies decrease drug costs, but tend to shift these costs to other service sectors.[20] The costs of limiting access to three psychotropic medications per month for people who are enrolled in Medicaid and have been diagnosed with schizophrenia has been associated with an estimated average increase in mental health care costs of $1,530 per patient during the cap; these costs exceeded the Medicaid program's savings in drug costs by a factor of 17.[21]

According to Michael Hogan, former chair of the President's New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department, the states have found in their Medicaid programs that "[p]atients who are not adequately treated, or treated with the wrong therapeutic agent, tend to utilize more costly crisis intervention, inpatient hospital, and intensive case management services. They also will tend to be less adherent to prescribed medications from that point forward, even when a more clinically appropriate treatment regimen has been prescribed."[22] Dr. Hogan also points out that "some providers may prescribe multiple 'approved' but less effective medications to replicate the effect of restricted medication's benefit" which reduces any savings from restricting access to newer, more effective drug therapies.

Limits on access to appropriate medications results not only in added costs to the healthcare system when consumers are unable to recover and risk potential relapse, but also a significant risk of death. Persons with depression or schizophrenia are at significantly higher risk of suicide compared to the general population.[23] Numerous studies have documented rates of attempted suicide among people with schizophrenia at nearly 50 percent and completed suicide at 10 percent to12 times the rate of the general population.[24]

Rather than placing the burden of cost containment on vulnerable beneficiaries, the alternative, flexible formulary we are proposing 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 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.

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[20] Harrington, C., Scallet, L., Goplerud, E., Robinson, G.K, Gregorian, R.S., Hughes, C., Treciak, K. (1998), *Health Plan Benefit Barriers to Access to Pharmaceutical Therapies for Behavioral Health,* SAMHSA Managed Care Tracking System. Prepared by the Lewin Group.

[21] Soumerai, S. B., McLaughlin, T. J., Ross-Degnan, D., Casteris, C. S., and Bollini, P, (September 8, 1994), Effects of limiting Medicaid drug-reimbursement benefits on the use of psychotropic agents and acute mental health services by patients with schizophrenia, *New England Journal of Medicine*, 331, 10, pp. 650-655.

[22] Letter from Michael Hogan, Ph. D., Director of the Ohio Department of Mental Health to Dr. Mark McClellan, Administrator of the Centers for Medicare and Medicaid Services, June 10, 2004.

[23] American Psychiatric Association (2004), *Maximizing Pharmacotherapy in the Treatment of Severe and Persistent Mental Illness: The Case for Maintaining Open Access to Medically Indicated Medications for Schizophrenia,* White Paper, p. 6.

[24] Id., p. 14.

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 to restrictive formularies and prior authorizations that increase the risk of use of multiple prescriptions, reduced compliance, and poor outcomes.[25] The innovative alternatives discussed by CMS in this report include a physician educational intervention and outlier management program in Pennsylvania designed to align physician prescribing practices with best practice guidelines. At the end of the first year of operations, key findings include reduced polypharmacy, reduced multiple prescribers, reduced therapeutic duplication of atypical anti-psychotics, and reduced per consumer costs.[26] CMS also points to a program implemented in Massachusetts to educate providers about the inefficiencies of polypharmacy and targeting outlier providers (who routinely use polypharmacy). According to CMS, "[a]n estimate of savings in psychiatric drug costs for the state of Massachusetts . . . is $10 million".[27]

Another alternative utilization management technique highlighted by CMS in this report is the Texas Medication Algorithm Project (TMAP). TMAP is a structured decision-making framework for the treatment of schizophrenia based on updated research and expert opinion with concrete guidelines for clinicians, clinical and technical support to help clinicians implement the guidelines (i.e., algorithms), patient and family education programs allowing the patient to be an active partner in care, and uniform documentation of care provided and resulting patient outcomes. According to the CMS report, "[e]valuations of TMAP have shown that it is more effective than standard treatment" for schizophrenia, depression and bipolar disorder. Outcomes include faster response to treatment, greater improvement in cognition, and positive clinical outcomes being maintained more effectively over time.[28]

Since CMS has encouraged the use of these alternative cost management techniques for psychiatric medications in state Medicaid programs, it surely makes sense to implement the same innovative techniques in the alternative formulary that CMS has acknowledged will be needed in order for Medicare beneficiaries with mental illness to receive access to necessary medications under the new Part D benefit.

Under this alternative, flexible formulary, in addition to limiting co-pays for dual eligibles and other beneficiaries enrolled in the low-income subsidy program just as in the rest of the Part D program, CMS must also limit the co-pays for other beneficiaries in need of mental health medications who qualify for this alternative formulary. Recent literature reviews have revealed that cost-sharing requirements decrease access to services in general, especially among those who are impoverished. Cost-sharing requirements for prescription drugs, even at the most nominal levels, have been found to jeopardize the ability of people who are living in poverty to afford the medications they need. Those who were most ill and most impoverished were the least likely to fill prescriptions that required them to make co-pays. Finally, these studies

[25] U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Report to State Medicaid Directors (August 20, 2004), *Psychiatric Medications: Addressing Costs without Restricting Access*, p. 2.
[26] Id., p 4
[27] Id., p. 10
[28] Id., p. 8.

revealed that consumers in states whose programs required co-pays had worse health outcomes than those in states that had not instituted cost-sharing requirements.[29]

PDPs and MA-PDPs will undoubtedly argue that this alternative, flexible formulary proposal will be too expensive for them to implement. Plans should be paid more for providing comprehensive access to the full array of mental health medications that would be required under the alternative, flexible formulary. We propose that for covering the mental health needs of Medicare beneficiaries with an alternative, flexible formulary, drug plans should be paid using the same approach that CMS has proposed to use in paying a fallback plan, namely that plans would be paid for all "allowable and allocable costs."

These increased payments are equitable in light of the fact that providing comprehensive drug coverage "up front" for beneficiaries with mental illnesses will prevent increases in federal Medicare costs by greatly reducing the degree to which these individuals need more costly crisis intervention, inpatient hospital, and intensive case management services covered by Parts A and B of Medicare. For example, a study of the overall medical costs and use of services among people who had mental illnesses and were uninsured revealed that continuity of medication therapy resulted in a 65 percent reduction in inpatient costs, a 55 percent reduction in emergency costs, a 23 percent increase in outpatient care and an overall mean costs savings of $166 per patient per month.[30] Moreover, from 1996 to 2000, when the Veterans Health Administration (VHA) made mental health medications available as needed, the VHA reported an 8 percent increase in the number of people who sought and received treatment for serious mental illnesses, but the total cost of treatment decreased by 8 percent, the average length of stay at hospitals decreased by 13.2 days, and the number of psychiatric hospitalizations decreased by 33 percent.[31]

Pharmaceutical and Therapeutics Committee

We strongly recommend that the final rule ensure that pharmaceutical and therapeutics (P&T) committees are composed in a manner to have broad expertise and independence, and that the decisions of those committees are binding on the drug plans. P&T committees that are staffed with independent and practicing experts can provide important input into formulary development process, but the role of the P&T committee would be nullified if their decisions carried no weight. P&T committees can provide important checks on the profit-seeking motives of private drug plans by bringing research findings and clinical experience to bear on decisions that will restrict access to certain medications. P&T committees must be empowered to make policy

[29] Hudman, J. and O'Malley, M. (2003), Health Insurance Premiums and Cost-Sharing: Findings from the Research on Low-Income Populations, Kaiser Commission on Medicaid and the Uninsured.

[30] Del Paggio, D., Finley, P., and Cavano, J. (2002), Clinical and economic outcomes associated with Olanzapine for the treatment of psychotic symptoms in a county mental health population, *Clinical Therapeutics*, 24.5, pp. 803-817.

[31] Nelson, M. (December 2002), *Individualizing Treatment with Atypical Antipsychotics: Factors to Consider in Decision Making*, Drug Benefit Trends Supplement.

decisions regarding formulary tiers and any clinical programs to encourage the use of preferred medications, including prior authorization, fail first, and step therapy.

P&T committees must be charged with a strong mission to promote and protect the health of beneficiaries. Their responsibilities must include permission to modify prior authorization review processes and other restrictive policies as necessary to ensure appropriate coverage. P&T committees must be charged with ensuring that each therapeutic drug class included in the formulary contains enough variety and number of agents to reflect current utilization patterns and meet the needs of the Medicare beneficiaries who are older, have complex medical problems, and a high degree of comorbid conditions.

CMS states in the preamble that it would encourage plans to include representatives of various specialties on their P&T committees. Rather than expressing in the preamble a preference regarding the composition of P &T committees, the regulations must require that such committees include various specialists, and in particular must require that drug plans' P&T committees include a practicing psychiatrist with recent clinical experience. CMS also suggests that it may require that more than one pharmacist and one physician be independent. The statute does state, in section 1860D-4(b)(3)(A), that "[s]uch (P&T) Committee shall include *at least* one practicing physician and at least one practicing pharmacist each of whom – is independent. . . and has expertise in the care of elderly or disabled persons." If P&T committees are to add any value to the formulary development process, the majority must be independent and the statute allows for this. P&T committees should include consumer members and P&T committees should be required to seek input from affected enrollee populations, including older adults and people with disabilities, as they consider medications to treat different conditions and disorders.

The final rule must ensure that the processes used by P&T committees to develop formularies for the Medicare Part D benefit are transparent to enrollees and the public. CMS must require that P&T committees hold public hearings with notice to the public well in advance and provide an opportunity for consumers and family members to be heard.

In the preamble, CMS encourages P&T committees to look to HIV guidelines developed by the Public Health Service. The final rule should also require P&T committees to follow evidence-based guidelines for people with mental illness, for example the American Psychiatric Association Practice Guidelines and the Texas Medication Algorithm Project (TMAP) guidelines.

Coverage of Off-Label Uses

In the preamble, CMS states that model formulary guidelines developed by the U.S. Pharmacopeia should not include classifications that only include off-label uses of FDA-approved medications. Although this proposal would not preclude providers from prescribing medications for off-label uses, CMS also strongly encourages plans to require additional documentation for these prescriptions justifying the off-label use. We do not agree with CMS's position that the USP model guidelines should not take into account off-label uses. Off-label uses offer some of the most efficacious treatments for mental illness; for example, certain anti-

convulsants and calcium channel blockers have proven effective for the treatment of mania and certain anti-convulsants have proven effective for treatment of bipolar disorder.[32] We also oppose CMS's recommendation that plans constrain the ability of providers to prescribe medications for off-label uses by requiring additional justification and establishing additional burdens on prescribers. These recommendations send a clear message to plans that off-label uses are suspect and that they do not necessarily have to be covered. We strongly oppose any provisions in the final rule that would impose limits on or discourage coverage of off-label uses of FDA-approved medications and we urge CMS to include a provision in the final rule to prohibit plans from denying coverage for a covered Part D drug solely because it is prescribed for an off-label use.

Mid-Year Formulary Change

Although drug plans are permitted to effect mid-year formulary changes under the Medicare Modernization Act, once an individual is stabilized on a mental health medication, coverage of that medication must be maintained unless and until that individual and his/her physician determines the medication is no longer efficacious. Changing psychiatric medications is very difficult and dangerous. It can take as much as six to 12 weeks to determine if a medication works and almost as long to wash a medication out of a consumer's system. Abrupt changes in psychiatric medications bring the risk of serious adverse drug interactions. Moreover, each failed trial results in suffering and possible worsening of a person's condition. People who switch from one SSRI to another, for example, tend to remain in treatment 50 percent longer than those who do not switch and their treatment typically costs about 50 percent more than it would have if they had been allowed to continue taking a medication that had already been deemed appropriate.[33]

In the preamble to the proposed regulations, CMS points to the exceptions process for off-formulary drugs as a means to maintain coverage of needed medications. But the process proposed is extremely complex and impossible to navigate for people experiencing psychiatric crises or facing cognitive impairments. Moreover, the timelines established are extremely drawn out; for example, an expedited determination could take as long as two weeks. Drug plans are not required to provide an emergency supply of medications until at least two weeks following a request. As Michael Hogan, former chair of the President's New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department, has pointed out in a June 10, 2004 letter to Dr. 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."

If CMS fails to require continued coverage for those already stabilized on the medication being removed from the formulary, we urge CMS to at least limit the incidence of mid-year formulary changes to only those circumstances when a change is necessary to protect the health and safety of beneficiaries, for instance, when new clinical evidence indicates a particular medication on the

[32] U.S. Department of Health and Human Services (1999), *Mental Health: A Report of the Surgeon General*, p. 268.
[33] Hensely, PL and Nurnberg, H.G. (2001), *Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls*, Pharmacoeconomics, Vol. 19, No. 10, pp. 973-982.

formulary is unsafe. The final regulation must require drug plans to send affected beneficiaries notice of any formulary change, in writing, mailed directly to the beneficiary 90 days prior to the change. The 30-days' notice that CMS proposes does not give beneficiaries enough time to get a doctor's appointment and determine an alternative to the medication being dropped from the formulary or determine whether a medication being added would be better. This notice must also inform the beneficiary about the exceptions process.

Review of Formularies for Discrimination

The Medicare Modernization Act prohibits the design of a plan and its benefits (including any formulary and tiered formulary structure) that substantially discourages enrollment by certain Part D eligible individuals.[34] In the preamble, CMS notes that "even if a plan's formulary classifications conform to the USP classification model, its overall formulary design could still be found to substantially discourage enrollment by certain Part D individuals (for example, based on particular drugs selected for inclusion in the formulary and/or proposed cost-tiering structure)". However, CMS must go further and specify in the regulations that it will scrutinize all drug plan formularies to ensure that they would not discriminate against certain enrollees.

CMS invites comments on the criteria it should use to determine that a plan not in compliance with the USP classifications does not discriminate. **CMS should be focused instead on finding plans that do discriminate, not focused on how to find that plans do not discriminate**. The proposed regulations fail to ensure adequate oversight to detect discriminatory practices. This is a serious concern for individuals with mental illness who have consistently faced horrible discrimination in the private insurance market. CMS has indicated that it will issue guidelines for how it will review plan formularies for discriminatory practices. Given the importance of this oversight role, CMS must establish review standards, not simply guidelines, and such standards must be included in the regulations, not just in a non-binding report or white paper.

Dissemination of Plan Information (§ 423.128)

Under the proposed regulations, drug plans would only have to disclose up front how any formulary works and how to obtain a copy of the formulary as well as general information regarding cost-sharing. The proposed regulation also gives prospective enrollees the right to obtain upon request specific information regarding, for example, any formularies used by a plan, any utilization controls, and the number of disputes and their disposition in aggregate. This information must include specific information regarding the amount of cost-sharing required for specific drugs. Moreover, this information should be available up front and without a special request because all of this information is critical to ensuring that beneficiaries know the terms and benefits of each plan available in order to be able to make an informed choice among them. CMS has indicated that it will extend the price comparison website that shows the cost of medications covered by each discount drug card to provide information regarding drugs covered by the different Part D drug plans. However, many beneficiaries do not have access to the

[34] Sec.1860D-11(e)(2)(d)(i)

internet. This information must also be available in written form through direct mail. The final rule also must require that all drug plans offering the Part D drug benefit provide enrollees with access to toll-free customer call centers 24 hours a day and seven days a week.

Cost Effective Drug Utilization Management (§ 423.153(b))

The statute and corresponding proposed regulations require drug plans to implement cost-effective drug utilization management programs that reduce costs when medically appropriate and prevent over- and under-utilization of prescribed medications. However, in the preamble CMS goes further in specifically recommending that plans use prior authorization, step therapy and other similar techniques. Medications to treat mental illness are not generally interchangeable, including those with the same mechanism of action, and common utilization management strategies that require substitution with similar medications can cause psychiatric crises and irreparable harm to consumers subject to these restrictions. They also significantly increase costs when these individuals require higher cost inpatient services as a consequence of being denied the medications they need (please see comments to § 423.120 for a more detailed discussion).

Utilization management techniques (such as prior authorization, fail first, step therapy, and therapeutic substitution) that require consumers to try other medications before receiving the drug they need are inappropriate for this population and can have grave clinical consequences. It is critically important that people with mental illness receive the medication best suited to them at the outset of treatment because the chance of recovery diminishes significantly if the first course of treatment fails. Each failed trial results in suffering and possible worsening of a person's condition.

Requiring consumers who have been stabilized on a particular psychiatric medication to switch to another drug can be very dangerous for the consumer and is not fiscally prudent. It is very difficult to determine which medication will work best for an individual and most have to try many different kinds of medications. Moreover some of these medications stay in the system for a long time (e.g., up to six weeks) and modifications of drug therapy must be done very carefully to avoid dangerous drug interactions.

Limits on access to appropriate medications not only impair a consumer's ability to recover and risk potential relapse, but also impose a significant risk of death. People with depression or schizophrenia are at significantly higher risk of suicide compared to the general population.

Recognizing that mental health medications have unique properties and that mental health consumers have extraordinary needs, 30 out of 40 states that have implemented preferred drug lists (i.e., formularies) and prior authorization requirements in their Medicaid programs have exempted mental health medications. In addition, states have recognized that restricting access to mental health medications results in increased costs overall. A June 10, 2004 letter to Mark McClellan from Michael Hogan, former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, states that "patients who are not adequately treated or treated with the wrong therapeutic agent tend to utilize more

costly crisis intervention, inpatient hospital, and intensive case management services. They also will be less adherent to prescribed medications from that point forward – even when a more clinically appropriate regimen has been prescribed."

We urge CMS to specify in the regulations for the Medicare Part D and Medicare Advantage programs that for mental health medications, the drug plans' utilization management programs must incorporate innovative alternative techniques to the more common restrictive cost control strategies like prior authorization. Indeed, this approach was recommended in a very recent report by CMS entitled *Psychiatric Medications: Addressing Costs without Restricting Access* In this report, CMS states that the newer mental health medications, including SSRIs and atypical antipsychotics, are more efficacious and that limiting access can have a negative effect on quality.[35] Thus, CMS encourages states to consider alternative approaches to utilization management for these medications, including an educational intervention in Pennsylvania designed to align physician prescribing practices with best practice guidelines. CMS describes this program as "an alternative to restrictive formularies and prior authorizations which increase the risk of use of multiple prescriptions, reduced compliance, and poor outcomes."[36] At the end of the first year of operations, key findings from this program include: reduced polypharmacy, reduced multiple prescribers, reduced therapeutic duplication of atypical anti-psychotics, and reduced per consumer costs.[37]

Another innovative alternative to restrictive policies that CMS encourages Medicaid directors to implement is the structured decision-making framework developed by the Texas Medication Algorithm Project (TMAP). As CMS points out, "[e]valuations of TMAP have shown that it is more effective than standard treatment" for schizophrenia, depression and bipolar disorder, including: faster response to treatment, greater improvement in cognition, and positive clinical outcomes being maintained more effectively over time.[38] The focus of the TMAP program is on implementing a set of prescribing guidelines or algorithms which create a step-by-step decision-making process that incorporates the most recent research findings on medication effectiveness and the consumer's specific needs while ensuring that all medications are available. These guidelines are useful for some other chronic illnesses as well [unless we know that the asthma and diabetes communities support this approach, I would not use these specific examples]. Thirteen states are working to implement the principles of TMAP in their Medicaid programs.

Finally, CMS also describes a program that Massachusetts has implemented to educate providers about the inefficiencies of polypharmacy and to target outlier providers who routinely use polypharmacy.[39] According to CMS, "[a]n estimate of savings in psychiatric drug costs for the state of Massachusetts . . . is $10 million".[40] Polypharmacy is a complex issue in the mental health field: research has shown that the use of more than one medication from different classes can be helpful, but there is disagreement over whether using more than one drug from a single

[35] Centers for Medicare and Medicaid Services, *Psychiatric Medications: Addressing Costs without Restricting Access*, August 20, 2004, p. 2.
[36] Ibid.
[37] Id., p. 4.
[38] Id., p. 8.
[39] Polypharmacy is defined as the use of two or more drugs 1) to treat same condition, 2) in the same chemical class, or 3) with the same or similar pharmacologic action to treat different conditions.
[40] Id., p. 10.

class is effective. Generally, researchers believe that combination therapy should only be used as a last resort.

Other alternative approaches include pharmacy case management programs that a number of states have implemented that use claims data to identify consumers with a large number of prescribers and/or prescriptions or physicians who provide a large number of prescriptions to many consumers. In addition, utilization review programs can be developed to create a notification system that alerts medical review teams whenever a consumer takes more than a specific number of medications over a short period of time (e.g., more than 10 medications within 60 days). The review teams can then take action to determine whether all the medications are being administered appropriately.

A number of states (e.g., Maryland and Colorado) have developed disease-driven case management programs in their Medicaid programs that could serve as a model for Medicare drug plans. These programs use claims data and physician referral triggers to identify physicians and consumers who have specific diseases such as asthma, diabetes, schizophrenia, and depression and provide educational tools and materials to these providers to encourage more coordinated care for these consumers, often by establishing nurse case manager teams. This approach can be especially effective with primary care physicians who are less likely to be aware of the latest research on all chronic health disorders – but who often are the main prescribers of mental health medications.

These innovative approaches to cost containment all share the important feature of not placing the burden of cost-containment on the backs of vulnerable beneficiaries by imposing unacceptable restrictions on access to needed medications and instead contain costs by focusing on provider behavior and reducing inappropriate prescribing practices. We urge CMS to require drug plans to structure their utilization management programs to apply these alternative approaches to cost containment for mental health medications and rule out the use of restrictive polices like prior authorization, fail first, and step therapy.

CMS invites comment on whether the utilization management programs of drug plans should be overseen by the plans' pharmaceutical and therapeutics (P&T) committees. P&T committees should oversee utilization management activities of PDPs and MA-PDPs. A majority of the members of each plan's P&T committee should be unbiased, practicing physicians, and P&T committees must include physicians with expertise in a range of chronic illnesses and disabilities, including mental illness, and geriatric care. These committees should be empowered to make policy decisions and be charged with a mission to promote and protect the health of beneficiaries. In overseeing utilization management activities, P&T Committees must be authorized to ensure that beneficiaries have access to a variety of drugs that reflect current research findings and utilization patterns, and that take into account the efficacy and side effects of medications in each therapeutic class and the complex needs of an ethnically diverse, elderly, co-morbid, and medically complex population.

Quality Assurance (§ 423.153(c))

CMS must require PDPs and MA-PDPs to include in their quality assurance programs clinical decision support systems and educational interventions that incorporate provider and patient education as well. These educational interventions should include programs that use claims data and physician referral triggers to identify physicians and consumers who have specific diseases such as asthma, diabetes, schizophrenia, and depression and provide educational tools and materials to these providers to encourage more coordinated care for these consumers. They should also include programs that use claims data to identify consumers with a large number of prescribers and/or prescriptions or physicians who provide a large number of prescriptions to many consumers and provide educational interventions designed to align these physicians' prescribing practices with best practice guidelines. These clinical decision support systems should include algorithms and other practice standards that promote appropriate prescribing based on clinical data and evidence-based practice. Educational interventions and clinical decision support systems as described above must be required minimum elements for all plans' quality assurance programs. These interventions not only serve to contain drug costs as discussed above, but also improve the quality of patient care.

Information regarding all utilization management as well as quality assurance strategies must be included in the information distributed to all prospective enrollees. These programs and activities will be central to determining the benefit that is available to enrollees under each plan and beneficiaries must have this information in order to make an informed decision as to which plan is best for them.

Medication Therapy Management Programs (§ 423.153(d))

The preamble lists a number of services that plans may incorporate into medication therapy management programs (MTMPs) that the statute requires them to establish, including enrollee education and counseling to promote appropriate use of medications, use of data to detect patterns of overuse and underuse, and coordinating medication therapy with other case management and disease management services. States are providing many of these services in their Medicaid programs for individuals with mental illness and other chronic illnesses with improvements in treatment outcomes, reductions in polypharmacy and multiple prescribers, and containment of costs. For examples of best practices, CMS should look to its own recent report to state Medicaid directors entitled *Psychotropic Medications: Addressing Costs Without Restricing Access*. This report highlights a number of innovative programs "to establish educational interventions and outlier management programs designed to align physician prescribing practices with best practice guidelines for prescribing, treatment algorithms developed for three major psychiatric disorders, and a program to identify and reduce polypharmacy."[41]

In the preamble, CMS states that plans should have discretion to design or "customize" their MTMPs because the best approach is to let the market shape these programs. We disagree with

[41] Id., p. 2.

this reliance on the market to set required parameters for their MTMPs. CMS must set needed parameters for these programs with the goal of improving overall health instead of allowing market forces to determine how these programs will be designed. We do not believe that stand-alone prescription drug plans have sufficient incentives to devote adequate resources to developing MTMPs that would improve overall health.

The proposed rule would delegate to private prescription drug plans the authority to set the annual cost threshold that beneficiaries must meet in order to qualify for MTMP services, even though CMS acknowledges that the statute clearly states that CMS must set this threshold. Although the types of activities described by CMS as components of MTMPs would save drug costs in the long run, in the short term there will be added costs in implementing these activities, and thus PDPs and MA-PDs will have a disincentive to identify enrollees as qualifying for this additional benefit. Therefore, it would be highly inappropriate for CMS to delegate to these plans authority to determine the annual cost threshold to qualify for this benefit. Furthermore, plans will not be interested in attracting enrollees who would qualify for these benefits, and thus they would naturally want to set the threshold drug cost amount too high. We recommend that CMS look to Medicaid claims data for dual eligibles to develop estimates of annual drug costs of beneficiaries with multiple medications and multiple chronic diseases for purposes of developing the annual cost threshold.

As CMS points out in the preamble, all MTMP services cannot be appropriately provided by pharmacists. Many of these activities will require complex interactions with a trusted provider and will require face-to-face consultations that cannot be adequately performed over the telephone – e.g., health status assessments, monitoring patient response to drug therapy, and coordination with other case management. As discussed in the preamble, to ensure the effectiveness of their MTMPs, plans must develop and maintain on-going beneficiary-provider relationships and enable beneficiaries to choose providers of these services. Having services delivered by a trusted provider is critical to successful medication therapy.

However, CMS leaves it up to the plans to determine whether to pay other providers to perform MTMP services. Given the importance of the beneficiary-provider relationship, that CMS acknowledges, and the fact that, as CMS points out, all MTMP services should not be performed by pharmacists (e.g., the development of drug treatment plans for complex and comorbid conditions), CMS must specify in the regulations that MTMPs are to incorporate the services of physicians as well as pharmacists and that beneficiaries shall be able to choose the providers from whom they would receive MTMP services and to the greatest extent possible, beneficiaries may receive these services from their current providers.

To ensure that MTMP services are readily available to those beneficiaries who qualify for them, adequate fees must be provided to the pharmacists and physicians offering these services. Adequate fees are also critical to ensuring that beneficiaries have a meaningful choice among pharmacist- and physician- providers of the MTMP benefit.

Treatment of Accreditation (§ 423.165, § 423.168, and § 423.171)

The preamble states that a plan may be deemed to meet the requirements relating to access to drugs, quality, utilization review, MTMP, fraud, and confidentiality of records – as long as accredited by a private accrediting organization. Deeming compliance significantly diminishes the beneficiary protections required by the Medicare Modernization Act and serves only to protect plans from having to comply with key provisions of the statute. It would inappropriately substitute a wholly inapt standard (that is subject to change) for express safeguards mandated by Congress. Accordingly, the proposed regulations in § 423.165 must not be included in the final rule.

In § 423.168(c)(4), CMS would require accrediting organizations to notify CMS within three days of identifying a deficiency that poses immediate jeopardy to PDP or MA-PDP enrollees or the general public. This notification should happen immediately or within 24 hours at the latest.

In § 423.168, CMS must require accreditation organizations to include consumer representation on their governing bodies. In addition, plans should be required to notify beneficiaries of the accreditation organization that handles that plan's accreditation so that beneficiaries can lodge complaints directly with those organizations.

Grievance and Appeals—General Provisions (§ 423.562)

In general, the grievance and appeals processes that would be established under the proposed regulations are far too complex and drawn out in terms of timelines. As Michael Hogan, former chair of the President's New Freedom Commission on Mental Health and Director of the Ohio Mental Health Department, has pointed out in a June 10, 2004 letter to Dr. 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." At the very least, CMS must establish a simpler and truly expedited process for Medicare beneficiaries dealing with mental illness. The expedited determination and exceptions processes proposed in the NPRM could take as long as 14 days, if the plan chooses to extend the time and makes some nominal showing that an extension is in the interests of the enrollee. Moreover, a temporary supply of medications would not be provided during this time – the proposed rule would only require that an emergency supply be provided after a plan fails to make a determination within the 14-day time frame. To characterize such a process as "expedited" is to make a mockery of the word, and a hollow remedy for the beneficiary. An alternative, expedited process must be established for individuals with more immediate needs, including individuals with mental illness, that would be modeled after the provision in Medicaid law that requires states to respond in 24 hours to prior authorization requests.[42] In addition, the medication at issue must be provided at the lowest co-pay level until the appeal is completely resolved.

[42] 42 U.S.C. 1396r-8(d)(1)(A), 1396r-8(d)(5).

In addition, this section would preclude an enrollee who has no further liability to pay for prescription drugs from appealing. The section should clarify that a low-income institutionalized individual can appeal a determination, even if she has no co-payment responsibilities.

This section would also preclude an enrollee from challenging a plan's determination that it has no obligation to cover a drug received from a non-network pharmacy; this provision should be deleted. As stated elsewhere in these comments, the actual regulatory language in 423.124 does not establish clear criteria as to when a plan must cover drugs received from non-network pharmacies. Thus, there is no guarantee that plans will interpret the regulation as CMS describes in the preamble. Taken together, sections 423.124 and 423.562(c)(2), as proposed, place at risk vulnerable individuals such as those in institutions whose purchases from long-term care pharmacies are all treated as if they are from a non-network pharmacy.

Definitions (§ 423.560)

The term "appeal" is defined as excluding grievances and exceptions processes. However, the term "authorized representative" is defined as someone authorized by an enrollee to deal with any level of appeal for that enrollee and § 423.578 would authorize an enrollee's authorized representative or prescribing physician to file a request for an exception. The definitions of "appeal" and "authorized representative" must clarify that a physician or representative is also authorized to act on behalf of an enrollee in exceptions and grievances proceedings.

Grievance Procedures (§ 423.564)

In the proposed regulations, if a beneficiary disagrees with a plan's decision not to grant a request for an expedited determination or redetermination or disagrees with a decision by the plan to extend the timeframe for responding to a determination or redetermination request, a beneficiary would be required to utilize the plan's grievance process to register that complaint. However, the plans themselves determine what to do about grievance complaints and there is no mechanism to appeal. Given the critical nature of these plan decisions, enrollees should be able to appeal an adverse determination in a grievance proceeding directly to the independent review entity responsible for responding to reconsideration requests from enrollees. In the alternative, at the very least, these plan decisions regarding expedited processing or extensions of timeframes should be considered determinations under §423.566 [to allow for a full range of appeal rights for the enrollee.

Standard and Expedited Timeframe and Notice Requirements for Coverage Determinations (§§ 423.568 and 423.572)

The proposed rule would require notices regarding coverage denial determinations to be "readable" and understandable, state specific reasons for the denial, and inform the enrollee of his/her right to appeal. We presume that the term "readable" implies that the notice must be in writing, but a clearer requirement that denial notices must be in writing must be included in the

final rule. The proposed rule must also require that this written notice be presented immediately upon a determination being made regarding coverage including the common situation where a pharmacist must communicate a denial. Plans must develop systems for providing pharmacists with the required written notice which they can then deliver to the beneficiary. This written notice must include the clinical or scientific basis for denying coverage and inform the beneficiary of steps he/she can take to receive medication coverage pending the outcome of an appeal. The notice also must inform the beneficiary of his/her appeal rights – as CMS has proposed. In addition, all notices need to be available in alternate formats to accommodate people with disabilities, and in languages other than English where a portion of the population is not English speaking.

Under the proposed regulations, the deadline for plans to issue a decision on a determination request is doubled (from 14 to 30 days) if the enrollee has already paid for the medication at issue and expedited determinations are not provided at all if the enrollee has paid out of pocket. This penalty for paying out of pocket is patently unfair. It is extremely unlikely that beneficiaries would be aware of this consequence of paying for their medications on their own when told by the pharmacist that their drug plan has denied coverage. Many beneficiaries may decide that taking their medicine is so important, they will do without other necessities instead of foregoing their prescription medications. Doubling the time frames for determinations and disallowing expedited review would seriously jeopardize the health of beneficiaries who could not actually afford to pay out of pocket but decide to use funds needed for other necessities like food and heat.

The proposed rules would allow plans to extend the standard and expedited timeframes for determinations of 14 days and 72 hours respectively by up to an additional 14 days if the enrollee requests the extension or the plan justifies a need for additional information and explains how the delay is in the interest of the enrollee. The regulations should require that an extension be in the *best* interest of the enrollee and define interests of the enrollee to include those situations in which the drug plan seeks additional information to substantiate the enrollee's request, or when the enrollee requests additional time to gather supporting information. Moreover, it is unclear from these proposed regulations, who will determine whether the plan has met this very minimal requirement for extending the time frame included in the proposed regulation. Presumably, the plan itself would decide and the enrollee could then appeal that decision through the grievance process which once again the plan itself decides. There must be more oversight in this process. The final rule must require that independent review entities review whether plans have made a sufficient showing that it is in the best interest of the enrollee to give the plan an extension on making a determination. In addition, the final rule must require drug plans to notify the affected enrollee of an extension immediately orally and in writing, instead of by the expiration of the extension as the proposed rules would require.

Expediting Certain Coverage Determinations (§ 423.570)

In the preamble, CMS states that for both standard determinations and expedited determinations, the enrollee as well as his or her authorized representative and the prescribing physician can make the request. However, the text of § 423.570 only states that an enrollee or an enrollee's

prescribing physician may request an expedited coverage determination. It is even more critical in emergency situations, when an enrollee may be fully or partially incapacitated, that an authorized representative be able to act on behalf of the enrollee and request an expedited determination. The final rule must clarify that an enrollee's authorized representative may request an expedited determination.

The final rule should require plans to give enrollees an emergency supply of medications for the duration of the expedited appeal. This emergency supply should be treated as on-formulary and this supply must be extended until the appeal is complete.

Exceptions to a Plan's Tiered Cost-Sharing Structure (§ 423.578(a))

The proposed regulations fail to comply with the statutory requirement that the Secretary establish guidelines for an exceptions process. The MMA directs plans to establish exceptions processes consistent with "guidelines established by the Secretary". CMS claims that this language indicates that plans should be given discretion to establish their own criteria. We disagree. The statute states that the Secretary is to establish guidelines and the plans are to abide by them. The so-called guidelines proposed simply list the likely scenarios when the exceptions process would be relevant. They do not provide any guidance on how the exceptions process should be structured and what beneficiary protections must be provided. In the preamble, CMS states that it is uncertain how plans will design their tiering structures and that uncertainty dictates that CMS not include overly detailed requirements regarding plan exceptions criteria – but this uncertainty is precisely why there must be strong guidelines to protect beneficiaries.

The regulations do propose a "limited number of elements that must be included in any sponsor's exception criteria," but this list includes criteria that do not apply based on the statutory provision that states that an exception is warranted if a physician determines that the preferred drug would not be as effective or would have adverse effects or both. As a result, the following proposed criteria have no bearing on whether an exception must be provided and should be deleted from the proposed regulation:

- Consideration of the cost of the requested drug compared to the cost of the preferred drug has no bearing on whether a drug would not be as effective or would have adverse effects and should not be a consideration.
- Consideration of whether the formulary includes a drug that is the therapeutic equivalent also is not relevant to the statutory standard. Treatment for certain conditions, including mental illness, is highly individualized given the non-interchangeability of many medications even within the same class, the high degree of variability in how these diseases present themselves in terms of symptoms, and the many other factors that must be taken into account, including overdose lethality in light of heightened risk of suicide. If a doctor determines, as the statute provides, that the preferred drug will not be as effective or harmful, that must be the deciding factor.
- Consideration of the number of drugs in the plan's formulary that are in the same class as the requested drug, for the reasons stated above, also is not relevant to the determination of the treating physician that the requested drug is needed.

The following requirements which CMS indicated they purposefully excluded must be included because they would help to ensure that beneficiaries receive the medications they need:

- Requiring continued access to a drug at given price when there is a mid-year formulary change; and
- Requiring sponsors to give enrollees an opportunity to request exceptions to a plan's tiered cost-sharing structure other than on a case-by-case basis.

The proposed rules fail to provide adequate guidance concerning whether the standard requiring the doctor to certify that a preferred drug would not be as effective or cause adverse effects has been met. The statement in the preamble that plans could require an enrollee to first try the preferred drug, i.e., a fail first requirement, conflicts with the statutory language of the standard that the doctor only has to certify the preferred drug would not be as effective or cause adverse effects. The statutory language does not support allowing plans to impose a fail first requirement. If the statute said that a physician must certify that the drug is not as effective or causes adverse effects, then the statute might allow for fail first requirements—but that is not how the statute reads.

CMS is proposing to allow plans to require written certification from the physician that the preferred drug would not be as effective or would cause adverse effects. The proposed regulations include a list of information that a plan may require be included in this written certification, but this list is too long and burdensome and includes an overly broad catch-all phrase - "any other information reasonably necessary to evaluate the medical necessity of the exceptions request." In addition, the language of this provision is unclear and should be restated to read as follows: "the PDP sponsor may only require the written certification to include the following information" (instead of "the PDP sponsor may require the written certification to include only the following information…").

The preamble states that a PDP's exceptions process would also have to describe how a determination on an exception request would affect the enrollee's cost-sharing under the PDP's tiering structure. The final regulation should require that the lowest co-pay that applies should apply to drugs for which an enrollee has won an exception to the tiered cost-sharing structure. That is the whole point of this process – to infuse some equity upon a showing that none of the other medications covered are as effective or may cause harm.

Requests for Exceptions Involving a Non-Formulary Drug (§ 423.578(b))

In the preamble, CMS states that "[r]equiring sponsors to use an exceptions process to review requests for coverage of non-formulary drugs will create a more efficient and transparent process and will ensure that enrollees know what standards are to be applied" and will help ensure these formularies "are based on scientific evidence rather than tailored to fit exceptions and appeals rules for formulary drugs " (p. 46720). However, the proposed regulations give drug plans complete discretion in determining the criteria they will use to determine exceptions requests. In addition, independent review entities "would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary" (p. 46721). By failing to adequately define the criteria plans may use to consider exceptions requests or provide any meaningful oversight over

these criteria, these proposed regulations would not ensure that formularies are based on scientific evidence and would not establish a transparent process -- CMS's stated goals. The regulations must establish standard criteria that plans must use in evaluating a prescribing physician's determination that any on-formulary drug would not be as effective or would cause adverse effects. In addition, independent review entities must be charged with reviewing plan criteria to ensure that they comply with these federal standards and implement the statutory standard requiring that the prescribing physician determine that all on-formulary drugs would not be as effective or have adverse effects.

The proposed rules do set an impossibly high bar for receiving an exception in requiring prescribing physicians to produce clinical evidence and medical and scientific evidence to demonstrate that the on-formulary drug is likely to be ineffective or have adverse effects on the beneficiary. Clinical trials generally do not include older people, people with disabilities and people with co-morbidities. While some such evidence does exist, it has not been developed for all drugs and conditions. However, a physician may have extensive experience treating these kinds of patients with the condition or illness at issue and this experience should be given at least equal weight in making such determinations. In fact, the statutory standard requires deference to the doctor's determination that all on-formulary medications would not be effective or cause adverse consequences. This required deference is not reflected in the proposed rules.

An important provision was left out of the requirements for receiving a dosing exception. The proposed rule states that in order to receive an exception, the physician must demonstrate that the number of doses available is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. This rule must also allow exceptions if the prescribing physician demonstrates that the number of doses available would cause an adverse reaction or harm to the enrollee – as provided in the proposed rules for other kinds of exceptions requests.

The NPRM proposes to authorize plans to require a long list of information in the written certification from the prescribing physician that an off-formulary drug is needed. This list is overly long and repetitive and may encourage drug plans to establish burdensome paperwork requirements as a hurdle preventing physicians and consumers from following through on an exceptions request. Moreover, this proposed rule also leaves the required contents entirely in the plan's discretion by including the catch-all phrase – "any other information reasonably necessary." The requirements for this written certification should be standardized to facilitate use of the exceptions process by providers and consumers. These standards would also help achieve CMS's stated goal of establishing a transparent process.

If a consumer is awarded an exception by a drug plan, the lowest co-pay that that drug plan requires should apply to the drug at issue because that drug has been determined medically necessary with no on-formulary drug as a suitable alternative – thus meeting the criteria for an exception to the tiered cost-sharing structure as well.

PDP Sponsor Requirements for Exceptions Determinations (§ 423.578(c))

The timeframes for exceptions determinations are far too long. Mirroring the timeframes for plan determinations, these proposed provisions raise similar concerns. It is extremely unfair to require longer time frames if a beneficiary has paid out of pocket for a needed medication when their alternative would be to wait two weeks to a month for a determination or an emergency one-month supply of the drug needed. Their health and safety may well be at risk if they are forced to forego other necessities because of the added, and most likely very significant, expense of paying out of pocket for their medicines. Although the proposed regulations include some provisions for an emergency supply of medications while a plan is considering an exceptions request, it is altogether unreasonable to make beneficiaries wait two to four weeks before the drug plan must provide an emergency supply. In addition, plans should be required to demonstrate that an extension of the standard or expedited time frames for exceptions determinations is in the best interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions. Plans should be required to make determinations regarding exceptions requests and notify the enrollee of these determinations in 24 hours as required under Medicaid for determinations regarding prior authorization requests.[43]

Right to a Redetermination and Expediting Certain Redeterminations (§§ 423.580 and 423.584)

These proposed regulations only authorize an enrollee or an enrollee's prescribing physician (acting on behalf of an enrollee) to request a redetermination or an expedited redetermination. The enrollee's authorized representative must also be allowed to request a redetermination and an expedited redetermination. Since the proposed regulations would allow an enrollee's authorized representative to file a request for determinations and exceptions, it does not make sense to then disallow an enrollee's representative from pursuing a claim further through the redetermination, reconsideration, and higher levels of appeal. In fact, the proposed regulations define an authorized representative as an individual authorized to act on behalf of an enrollee "in dealing with any of the levels of the appeals process."

Timeframes and Responsibility for Making Redeterminations (§ 423.590)

The proposed rules would allow plans to extend the 30-day timeframe for an additional 14 days if the delay would be in the interest of the enrollee. Again, as with determinations and exceptions requests, plans should be required to demonstrate that an extension of the standard or expedited time frame is in the *best* interest of the enrollee and the final rule must charge independent review entities with exercising oversight over these extensions (see comments on timeframes for determinations (§§ 423.568 and 423.572) above) . In addition, the final rule must require drug plans to notify the affected enrollee of an extension immediately -- orally and in writing.

[43] See 42 U.S.C. 1396r-8(d)(5)(A).

If enrollees pay for their medications out of pocket, then once again they are penalized with a standard timeframe for redeterminations that is twice as long as would otherwise have applied (60 days instead of 30 days). Again, this will impose extreme hardship on low-income beneficiaries and those with multiple prescriptions who may choose to spend money they need for other necessities to pay for their medicine instead because of the uncertainty of the appeals process or because, by chance, they understand the many hurdles they would face to get an exception and the many delays that plans can impose. Once again, imposing additional delays on the redetermination process for beneficiaries who pay out of pocket, poses risks to their health and well-being by requiring them to shoulder additional costs that few will be able to afford.

The final regulations must include detailed requirements regarding information that drug plans must include in notices regarding final decisions on redetermination requests. Detailed notices regarding further appeal rights of enrollees are critical given that the next level of review to the IRE would not be automatic under these proposed rules as it is in the Medicare Advantage program. This notice must explain the reason for the denial, including the medical and scientific evidence relied upon, the right to request review or expedited review to the IRE, including timeframes, and the right to submit evidence – written and in person.

The proposed rules state that if a plan fails to meet the timeframe for standard or expedited redeterminations, this failure constitutes an affirmation of its adverse determination. This rule should be reversed to say that a failure to comply with timeframes constitutes a reversal of its adverse determination. Otherwise, plans would have no incentive to comply with the required timeframes that CMS has detailed in these proposed regulations.

Reconsideration by an Independent Review Entity (IRE) (§ 423.600)

The final regulations must ensure that independent review entities (IREs) provide independent, de novo review, in considering reconsideration requests – especially with regard to the exceptions process. The preamble states that the "IRE's review would focus on whether the PDP had properly applied its formulary exceptions criteria" and that "the IRE would not have any discretion with respect to the validity of the plan's exceptions criteria or formulary" (p. 46721). IREs must be charged with reviewing all of the relevant issues raised by a determination or exception request and considering all of the evidence before making its own decision as to whether a drug plan must cover the drug in question. To disallow IREs from considering the validity of the exceptions criteria established by a plan would deny enrollees meaningful independent review. Furthermore, because the statute requires CMS to establish standards for the exceptions process, the IRE must have authority to determine whether the plan's exceptions criteria comply with these standards. Otherwise, enrollees will have no means of challenging arbitrary and improper standards.

The preamble states that, although under the Medicare Advantage (MA) program where denials of determinations are automatically referred to an IRE, under the proposed Part D regulations, enrollees would have to specifically request an IRE review of redeterminations involving tiering or coverage of nonformulary drugs. These Part D regulations should follow the MA rules and

require automatic referral of these redeterminations to IREs. CMS has repeatedly stated that the Part D regulations will follow the MA rules as much as possible. The reason for failing to coordinate MA and Part D rules in this case are not convincing much less compelling. The rationale given is that appeal of these exceptions requires a physician to determine that all covered drugs would not be as effective or have adverse effects and that the monetary amounts in question may be relatively small. These proposed rules are already proposing to require the IRE to "solicit the views of the prescribing physician" and a determination that all covered drugs would not be as effective or cause adverse effects in exceptions requests for coverage of non-formulary drugs. Thus, there is no reason to require that enrollees specifically request an appeal to an IRE before the IRE can begin seeking this input from the prescribing physician. Furthermore, we dispute CMS's assertion that the monetary amounts in question will be relatively small. Mental health medications which must be taken on an on-going basis, just as many other medications commonly taken by Medicare beneficiaries, can be very costly, especially considering the income level of most people with Medicare. This requirement that enrollees specifically request in writing a review by an IRE will only serve to delay or discourage enrollees from seeking a review. At the very least, the regulations must allow beneficiaries to make this request for IRE review orally instead of requiring a written request as proposed.

The final rule must clarify that authorized representatives may act on behalf of enrollees in requesting a reconsideration by an IRE. The appeal processes that CMS is proposing to establish for the Part D benefit are extremely complex. Most Medicare beneficiaries struggle with chronic illnesses or conditions or disabilities. They will need assistance navigating the complicated processes CMS has developed.

The final rule must specify a timeframe within which IREs must complete reconsiderations. The proposed rule simply states that reconsiderations are to be done as expeditiously as an enrollee's health requires but not to exceed deadlines specified in the IRE's contract with CMS. Enrollees will have no knowledge of the contract between CMS and the IRE and thus will not know how long they must wait for a reconsideration decision. Under this proposal, the time frame could change without any public input, putting enrollees at greater risk of adverse health consequences from being denied needed medications. The final rule also must state that an enrollee may appeal to an administrative law judge if the IRE fails to act within the required timeframe.

Notice of Reconsideration Determination by the Independent Review Entity (§ 423.602)

The final rules must specify that notices regarding reconsideration determinations by an IRE must inform the enrollee of his/her right to a hearing before an ALJ and must indicate whether the threshold dollar amount for such a hearing has been met by the enrollee.

Right to an Administrative Law Judge (ALJ) Hearing (§ 423.610)

The final regulation must clarify that in determining whether the threshold amount has been met, CMS will add up the cost of the medicine at issue over the course of a year if the medication

treats an on-going chronic condition or for the number of refills authorized if the underlying condition is not chronic. The proposed regulation regarding aggregation of appeals to meet the amount in controversy is confusing and overly burdensome. This proposal would seem to require beneficiaries to file separate claims and go through the entire complicated process for each prescription or refill. This approach compounds the many problems raised by the overly complicated processes proposed by CMS. The delays that would ensue from this requirement would greatly endanger the health of beneficiaries.

Deadlines for Effectuating Reversals by ALJ or Higher Level of Appeal (§§ 423.636(c) and 423.638(c))

The proposed regulations would allow plans to take up to 60 days to implement a reversal by an ALJ or at a higher level of appeal. There is no reasonable basis for delaying implementation for this long and no reason is given in the NPRM. These delays once again impose unacceptable burdens on beneficiaries and risk additional harm to their health by extending the time they must wait to receive needed medications or reimbursement.