



October 4, 2004

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

Attention: CMS-4086-P

On behalf of the 210,000 members and 1,200 state and local affiliates of the National Alliance for the Mentally Ill (NAMI), I am pleased to submit the following comments on Notice of Proposed Rulemaking (NPRM) implementing the Medicare Prescription Drug Improvement and Modernization Act (MMA, P.L. 108-173).

***Unique Needs of Medicare Beneficiaries Living with Mental Illness***

During Congressional consideration of the MMA last year, NAMI raised concerns to Congress regarding how the new drug benefit would impact beneficiaries with severe mental illnesses, particularly those disabled and currently receiving their drug coverage through state Medicaid programs. Specifically, NAMI supported the inclusion of appropriate safeguards to protect these beneficiaries and ensure open access to critically important medications. Congress recognized the unique needs of this population and attempted to begin to address this situation by adding the following language to the final House-Senate Conference Report on P.L. 108-173.

*“It is the intent of the Conferees that Medicare beneficiaries have access to prescription drugs for the treatment of mental illness and neurological diseases resulting in severe epileptic episodes under the new provisions of Part D. To fulfill this purpose the Administrator of the Centers for Medicare Choices shall take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness, including but not limited to schizophrenia, bipolar disorder, depression, anxiety disorder, dementia, and attention disorder/attention deficit hyperactivity disorder and neurological illnesses resulting in epileptic episodes.*

*The conferees anticipate that disabled individuals will enroll in one of the many private sector prescription drug plans or MA-PD plans. Competition will necessitate plans offering the full complements of medicines including atypical antipsychotics, to treat the severely mentally ill. If a plan chooses not to offer or to restrict access to a particular medication to treat the mentally ill, the disabled will have the freedom to chose a plan that has appropriate access to the medicine needed. The Conferees believe this is critical*

*as the severely mentally ill are a unique population with unique prescription drug needs as individual responses to mental health medications are different.”<sup>1</sup>*

In NAMI’s view, it is extremely important that Medicare enrollees with severe mental illness, such as schizophrenia, bipolar disorder and major depression have sufficient protections to ensure access to the full range of treatments currently available to them. Without such protections, beneficiaries could suffer substantial irreversible clinical harm resulting in significantly higher overall Medicare costs, if their access to psychotropic pharmaceuticals is compromised. In moving forward in developing the final regulations, NAMI would like to remind CMS that:

***Psychiatric medications are unique, different from other classes and each other***

- Individual responses to psychotropic medicines vary as a result of many factors, including race, ethnicity, gender, severity of illness, and other illnesses or medicines.
- It can take weeks or even months to determine whether mental health medicines are having their intended effect. Delaying access to appropriate medicines may leave some patients without effective treatment for months.
- Psychiatric medications in the same class can work on different areas or chemicals in the brain, so they may be effective for one consumer, but not another.
- Psychotropic medications differ in their side effects, dosing and interactions with other medicines or health conditions. Minimizing side effects and interactions is critical to encourage patients to take their medicines and control their illness.
- Newer psychotropic medications generally offer improvements in effectiveness and have fewer and more tolerable side effects. Older anti-psychotics in particular have debilitating side effects that make compliance extremely difficult.

***Restrictions on access harm vulnerable individuals living with mental illness***

- A recent study of 47 Medicaid programs found that restrictive formularies decreased drug spending by 13.4%. However, these savings were more than offset by a 28.7% increase in physician spending and a 39.1% increase in mental health hospital spending.
- Adding short-sighted bureaucratic hurdles makes it even more difficult and more costly to treat complex brain disorders.
- Treatment failures usually mean a further spiraling down for the individual, leading to more intensive, and more costly medical treatment than would previously have been required.
- The personal and social costs of getting it wrong can be too high to calculate when dealing with individuals with mental illness. It does not mean a lost work day or simple inconvenience or discomfort. Psychotic breaks put vulnerable beneficiaries and their families at risk. These treatment failures have enormous costs for states and communities including incarceration, homelessness and even suicide.

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<sup>1</sup> H.Rpt. 108-391, p. 769.

NAMI would therefore make the following recommendations with respect to the final regulations implementing the MMA.

- 1) **Continuity of Care for Dual Eligible Beneficiaries:** NAMI urges CMS to include in the Final Rules a requirement to ensure “continuity of care” for dual eligibles with mental illnesses by requiring prescription drug plans and Medicare Advantage plans to continue coverage for medications that are already effective in maintaining stability for individual beneficiaries.
- 2) **Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses:** NAMI urges the inclusion of a requirement for prescription drug plans and Medicare Advantage plans to put in place alternative, flexible formularies for beneficiaries with mental illnesses that do not incorporate restrictive policies like prior authorization, fail first, step therapy, and therapeutic substitution.
- 3) **Pharmacy and Therapeutic Committees:** NAMI urges greater clarity to ensure that P&T Committee operations are more transparent and reflect an independent assessment of all coverage restrictions.
- 4) **Therapeutic Substitution:** NAMI recommends that the Final Rules incorporate protections for therapeutic substitution and, in particular, a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician.
- 5) **Changes in a Plan Formulary:** NAMI urges CMS to expand beneficiary protections in cases where a prescription drug plan enacts a change in the plan formulary in the midst of a plan year.
- 6) **Appeals and Grievance Procedures:** NAMI urges CMS to simplify the grievance and appeals procedures detailed in the Notice of Proposed Rulemaking (NPRM) by easing access, ensuring rapid results for beneficiaries and their doctors, and providing greater clarity for the expedited process for individuals with immediate needs.
- 7) **Outreach and Enrollment:** NAMI urges CMS to partner with, and provide support to, community-based organizations to carry out extensive outreach and enrollment activities for beneficiaries facing additional challenges, including mental illnesses.
- 8) **Involuntary Disenrollment for Disruptive Behavior:** NAMI urges CMS to establish greater protections for beneficiaries with mental illnesses threatened with and subjected to involuntary disenrollment by prescription drug plans and Medicare Advantage plans for “disruptive behavior.”
- 9) **Exclusion of Benzodiazepines:** NAMI recommends that CMS create an exception to the general requirement for prescription drug plans to exclude coverage for benzodiazepines in cases where they are prescribed consistent with accepted clinical treatment guidelines for severe anxiety disorder and acute mania.

Included below is a more detailed discussion of the recommendations summarized above.

### **Continuity of Care for Dual Eligible Beneficiaries (§ 423.34)**

NAMI feels strongly that the final regulations should address the unique problems faced by beneficiaries who qualify for both Medicare and Medicaid (so-called “dual eligibles”). These individuals are particularly vulnerable because of their low incomes. Significantly, a large percentage of dual eligibles (by some estimates as many as 25%) are living with severe mental illnesses.

Currently, these beneficiaries are receiving coverage for medications under Medicaid. To protect these vulnerable beneficiaries, CMS should enforce a “continuity of care” requirement to ensure access to the same array of mental health and other medications that are available under Medicaid. At a minimum, dual eligibles with mental illnesses should be allowed to continue on the medications they are currently taking and not be required to switch to another drug.

#### *Why is a “continuity of care” requirement for dual eligibles justified?*

As noted above, medications to treat mental illnesses are not generally interchangeable. It is imperative that the Final Rules recognize that mental illnesses themselves are highly variable in terms of symptoms and their impact on individual beneficiaries, and the treatment currently being provided to many dual eligibles has been carefully tailored with specific drug therapies. Such treatment typically takes into account the individual’s current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide.

It is essential that under the MMA, dual eligible beneficiaries with mental illness be able to access existing medications that are best suited to their treatment needs and that are most likely to produce optimal treatment outcomes. In NAMI’s view, a “continuity of care” requirement is the most effective means for achieving the goals of ensuring a smooth transition to the Part D drug benefit for dual eligibles and maintaining access to effective treatments that ensure clinical stability.

In addition, under existing Medicaid law, dual eligibles cannot be denied access to their medications if they are unable to remunerate for their co-payments. While the co-payment for any single drug may be nominal, beneficiaries taking multiple drugs may face multiple co-payments that in the aggregate, can pose a substantial financial burden. Consequently, it is imperative that this Medicaid protection be included in the Final Rules so that beneficiaries who are unable to meet their co-payment responsibilities are not denied access to necessary medications.

### **Alternative, Flexible Formularies for Beneficiaries with Mental Illnesses**

As noted above, NAMI is extremely concerned that the NPRM appears to allow substantial discretion for Medicare prescription drug plans to use restrictive utilization management techniques, including prior authorization, tiered co-payments, “fail first”

requirements and step therapy. Given the overwhelming evidence demonstrating the dangers associated with such practices to individuals with mental illnesses, we believe protections are needed. NAMI is grateful for the recognition of these challenges in the NPRM and the need for special exemptions from these techniques for certain beneficiaries, including those with mental illness.

As the NPRM notes:

*We request comments regarding any special treatment (for example, offering certain classes of enrollees an alternative or open formulary that accounts for their unique medical needs, and/or special rules with respect to access to dosage forms that may be needed by these populations but not by other Part D enrollees), we should consider requiring of plans with respect to special populations, as well as suggestions regarding the particular special populations for whom we may want to make allowances.<sup>2</sup>*

In response to this request, NAMI respectfully proposes a requirement for Medicare prescription drug plans to incorporate an alternative, flexible formulary for enrollees with mental illness into their benefit designs. This formulary would provide access to the full array of medications to treat mental illness (without use of “fail first” requirements, prior authorization, step therapy, therapeutic substitution, or any similar restrictive policies). Eligibility for this alternative, flexible formulary would be restricted to enrollees diagnosed with a mental illness (including dual eligibles). Instead of imposing the burden of cost control on these vulnerable beneficiaries, utilization management would be carried out using policies that focus on improving the prescribing behavior of providers.

This alternative, flexible formulary would instead focus utilization management on practices designed to improve (or at least maintain) the clinical status of individual plan enrollees. Among the advantages and opportunities associated with this recommended alternative, flexible formulary are:

- integration of provider peer education initiatives designed to improve clinical practice,
- closer scrutiny and retrospective review of individual clinicians to address instances of “polypharmacy” or other inappropriate prescribing,
- enhanced data review to identify fraud, deviation from clinical best practice, outlier prescribers, and inappropriate dosing levels, and
- cost containment through techniques such as targeted case management of chronic illness to improve coordination of care and outcome measurement.

*Why is such an alternative, flexible formulary justified?*

In NAMI’s view, restrictive practices such as prior authorization, fail first, and step therapy are both inappropriate and unnecessary for people with mental illnesses. Medications to treat mental illness are not generally interchangeable, including those with the same mechanism of action, and differ in how they affect brain chemistry. It must be recognized that these illnesses themselves are highly variable in terms of symptoms and

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<sup>2</sup> 69 Fed. Reg. at 46,661

their impact on individual patients, and physicians must carefully tailor drug therapies to each individual to take into account the patients' current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide.

It is essential that under the MMA that beneficiaries with mental illness be able to access the medications that are best suited to their treatment needs. Utilization management techniques, such as "fail first" requirements and step therapy that require individuals to try and fail with preferred medications before being able to access coverage for the medication prescribed by their physician, can have severe and permanent effects on individuals with mental health disorders.

Likewise, use of therapeutic substitution for psychiatric medications is inappropriate for this population given the many factors that treating physicians must take into account including the wide range and varying side effects, the variability of mental illnesses themselves in terms of how these conditions present themselves, and the non-interchangeability of many of these medications given critical differences in mechanisms of action and how they affect brain chemistry.

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

Of the states that have imposed restrictive preferred drug lists and prior authorization requirements in their state Medicaid programs, most have recognized that these types of restrictive policies are inappropriate for beneficiaries with mental illnesses and elected to exempt such beneficiaries from restrictive preferred drug lists and prior authorization requirements.

NAMI strongly recommends that the Final Rules ensure that Medicare beneficiaries with mental illnesses have access to the newer medications that are generally more effective and have fewer side effects. Such a protection is consistent with the finding of President Bush's New Freedom Commission on Mental Health. In their Final Report from 2003, they noted that "efforts to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services."

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

example set forth in this report and integrate the same strategies in the Medicare prescription drug benefit.

### **Pharmacy and Therapeutic Committees (§ 423.120)**

NAMI supports a requirement for advance notice of P&T Committee meetings to ensure adherence to requirements in the MMA that coverage decisions be based “on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature.”<sup>3</sup> Such a process should also ensure that beneficiary protections for coverage decisions under the new drug benefit parallel those protections provided by the public comment process in the traditional Medicare program for developing national and local coverage policies. P&T Committees should also be required to document and explain the reasons for their formulary decisions and make these determinations public. This would ensure that the P&T Committee follows the intent of Congress and makes clinical, rather than financial, judgments when developing a formulary.

To ensure that all coverage policies are based on objective, clinical rationales and are developed by clinical experts, we also recommend that adoption of rules making it explicit that P&T committee responsibilities extend beyond the development of simple formularies to include the development of all restrictive coverage policies. In the preamble to the NPRM, CMS states that it interprets the MMA as “requiring that a P&T committee’s decisions regarding the plan’s formulary be binding on the plan.”<sup>4</sup> In addition, the NPRM states that it expects “P&T committees will be involved in designing formulary tiers and any clinical programs implemented to encourage the use of preferred drugs (e.g., prior authorization, step therapy, generics programs).”<sup>5</sup>

However, these provisions are not included in the actual regulations, but are only discussed in the preamble. NAMI therefore urges CMS to include these requirements in the regulations themselves to ensure that prescription drug plans understand their obligations. As noted above, the rationales and clinical justifications for these coverage policies should be subject to discussion and validation in an open forum with an appropriate opportunity for public input, including input from patient advocacy organizations.

NAMI also recommends limiting the number of voting P&T committee members with conflicts so as to avoid diluting the voices of independent members. The recent settlement of the government’s investigation of Merck-Medco Managed Care provides guidance in this regard.<sup>6</sup> Pursuant to that agreement, a majority of P&T committee members must be actively practicing physicians, pharmacists, or health care professionals and not be employed by Medco,<sup>7</sup> thus limiting the risk that conflicted members will

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<sup>3</sup> See 42 U.S.C. § 1394w-104(b)(3)(B).

<sup>4</sup> 69 Fed. Reg. at 46,659.

<sup>5</sup> Id.

<sup>6</sup> See United States v. Merck-Medco Managed Care, Civil Action No. 00-737, Consent Order of Court for Permanent Injunction (E.D. Pa.).

<sup>7</sup> See id.

marginalize the input of independent members. This protection should be incorporated into the Final Regulations.

### **Therapeutic Substitution (§ 423.153)**

As noted above, NAMI strongly recommends that the Final Rules include a requirement for drug plans to put in place an alternative, flexible formulary for beneficiaries with mental illnesses that prevents therapeutic substitution. In addition to including such a requirement in this alternative, flexible formulary, NAMI would also urge that the Final Rules incorporate the same as a basic patient protection for all beneficiaries, including a requirement that prescription drug plans not engage in such practices without the express consent of the prescribing physician. The preamble to the Proposed Rule indicates support for such a requirement.<sup>8</sup> Alternatively, CMS should also consider a requirement for plans to defer to state laws on therapeutic substitution. Many states have laws requiring prescriber consent before plans may make a substitution.

Preserving the physician's role in the prescribing process is an important beneficiary protection, particularly for vulnerable Medicare populations who may be on multiple medications and living with many co-morbidities. We believe that the patient-physician relationship in these situations is sacrosanct and should not be undermined by any implication that therapeutic substitution can be executed without explicit physician consent.

### **Protections in Cases of Mid-Year Changes in a Plan's Formulary (§ 423.120)**

The MMA allows prescription drug plans to change their formularies in the middle of the plan year. Such a change is allowed so long as the plans provide "appropriate notice" to affected beneficiaries and other stakeholders prior to removing a covered drug from a formulary or changing its cost-sharing status. "Appropriate" is defined as 30 days in the Proposed Rule. NAMI believes that this is insufficient notice and does not recognize the real world, crucial nexus between drug plan choice and access to vital medicines for beneficiaries. Medicare beneficiaries are locked into one plan for an entire year and may have specifically chosen the plan based on its formulary. Beneficiaries who cannot obtain the same treatment due to a formulary change may fail to complete their treatment regimens, thus increasing other Medicare costs if more expensive medical interventions are subsequently required.

If CMS believes that it cannot limit prescription drug plans in this manner, the agency should at a minimum require that plans "grandfather" coverage of chronic medications until the next open enrollment period. While this approach would still permit plans to use "bait and switch" marketing strategies involving popular medicines, it would provide the most vulnerable beneficiaries on established medicines the ability to continue their existing treatment regimen without having to pursue coverage through the plan's appeals process.

### **Appeals and Grievance Procedures (§§ 423.562-423.604)**

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<sup>8</sup> 69 Fed. Reg. at 46,667 ("Therapeutic substitution would always require explicit prescriber notification and approval.").

To ensure that beneficiaries' rights are protected, the final regulations should provide meaningful grievance and appeal procedures for denials of coverage and improper conduct by prescription drug plans. NAMI has a number of concerns with regard to these appeal procedures, not the least of which is their complete lack of clarity in establishing different processes and procedures for challenging different kinds of plan decisions. In general, we believe that CMS should endeavor to clarify these highly important procedures, so that beneficiaries and their families are fully aware of their rights under the new benefit.

Under the Proposed Rule, it is unclear when a decision is considered to be a coverage determination that requires a specific written notice with appeal rights and, in particular, whether a denial of a drug as a non-formulary drug at the pharmacy counter would constitute such a coverage determination. Without a written notice of appeal rights, the beneficiary may never realize that an additional step is required to trigger the appeals process. Consequently, CMS needs to clarify the Final Rule to require that a notice of coverage determination be issued at the time the prescription is denied at the pharmacy and that such notice include an explanation of the beneficiary's appeal rights.

Next, CMS should clarify that beneficiaries have the right to de novo review of denials of coverage and exception requests before an independent review entity (IRE). Specifically, the NPRM appears to treat IRE reconsiderations arising from formulary exception requests differently from those arising from other coverage determinations. CMS states that an IRE, when reviewing an appeal of a denial of a formulary exceptions request, is limited to determining whether the prescription drug plan properly applied its own formulary exceptions criteria and that "the IRE would not have any discretion with respect to the validity of the plan's exception criteria or formulary."<sup>9</sup> This limited review is not supported by the MMA. CMS should clarify in the final rule that it does not intend to limit the scope of IRE review.

Third, beneficiaries with chronic, mental, and other debilitating illnesses must be able to obtain rapid responses to their appeals and not have to navigate multiple procedures. Under the MMA and the NPRM, to obtain a non-preferred drug on the same cost-sharing terms as a preferred drug, the prescribing physician must demonstrate that the preferred drug "either would not be as effective . . . or would have adverse effects."<sup>10</sup> Similarly, to receive coverage for a non-formulary drug, the prescribing physician must demonstrate that "all covered Part D drugs on any tier of the formulary . . . would not be as effective for the individual as the non-formulary drug [or] would have adverse effects for the individual."<sup>11</sup>

This second showing necessarily encompasses the determination that the preferred formulary drug is not as effective as the non-formulary drug or would have adverse effects on the individual. Therefore, it would not make sense to grant preferred cost-

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<sup>9</sup> Id. at 46,721.

<sup>10</sup> 42 § 1395w-104(g)(2); see also 69 Fed. Reg. at 46,720.

<sup>11</sup> 42 § 1395w-104(h)(2) (emphasis added); see also 69 Fed. Reg. at 46,721.

sharing status to a second or third tier drug for which the beneficiary had demonstrated medical necessity, but not grant similar treatment to a non-formulary drug for which the beneficiary had made a similar showing. Patients should be able to obtain both coverage and preferred status in one appeal.

Further, assuming a beneficiary is successful in an appeal to obtain coverage or preferred status for a drug, the plan appears to have complete discretion to determine the beneficiary's cost-sharing obligations.<sup>12</sup> A beneficiary who obtains coverage of a necessary drug but cannot afford the plan-established cost-sharing has wholly illusory appeal rights. We strongly urge CMS to establish reasonable parameters for the cost-sharing obligations of beneficiaries who file successful appeals.

Finally, CMS should clarify the scope of the plan decisions that are appealable. To ensure that appeal rights are meaningful, the appeal provisions should apply to the full scope of coverage denials – including denials of requests for prior authorization.

### **Outreach and Enrollment (§ 423.34)**

NAMI urges that provisions in the NPRM on collaboration with state and local agencies and community-based organizations on outreach and enrollment for beneficiaries with disabilities need to be expanded. This is especially the case with respect to outreach and engagement needed to reach vulnerable beneficiaries living with severe mental illness. As noted above, the Conference Report accompanying the MMA directs CMS and the Center for Medicare Choices to “take the appropriate steps before the first open enrollment period to ensure that Medicare beneficiaries have clinically appropriate access to pharmaceutical treatments for mental illness”. (Report No. 108-391, pp. 769-770).

In order to ensure enrollment and comprehensive coverage for beneficiaries with mental illness, CMS should take every step necessary to partner with community-based organizations with experience in reaching out to and engaging Medicare beneficiaries with mental illness and state and local agencies that coordinate benefits for these individuals. Beneficiaries with mental illness will most likely turn to organizations that they know and trust with questions and concerns regarding the new Part D drug benefit. Making information and educational materials available through these agencies will help inform beneficiaries with mental illness about the new benefit. In order to address the many difficult, detailed, and time-consuming questions that beneficiaries are certain to have about the new program, extensive face-to-face counseling services will be needed. Community-based organizations can provide the kind of detailed help needed, but they will need additional resources.

CMS should also develop a specific plan for facilitating enrollment of beneficiaries with mental disabilities, especially severe mental illnesses, in each region that incorporates collaborative partnerships with and additional funding for state and local public and non-profit agencies and organizations with relevant experience in reaching out to people with mental impairments. NAMI would also suggest that CMS require drug plans to include

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<sup>12</sup> See 69 Fed. Reg. at 46,721, 46,844.

in their bids, specific plans for encouraging enrollment of often hard-to-reach, vulnerable beneficiaries such as individuals with mental disabilities.

### **Involuntary Disenrollment for Disruptive Behavior (§ 423.44)**

NAMI is concerned about provisions in the NPRM that will allow Medicare drug plans to involuntarily disenroll beneficiaries for behavior that is “disruptive, unruly, abusive, uncooperative, or threatening”<sup>13</sup>. This provision creates vast opportunity for discrimination against individuals with mental illness by prescription drug plans and Medicare Advantage plans. Individual beneficiaries subject to disenrollment 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 that would increase their premiums indefinitely. Plans should be required to develop mechanisms for accommodating the special needs of these individuals, and CMS should provide additional safeguards to ensure that they do not lose access to drug coverage.

It is further troubling that CMS is proposing an expedited disenrollment process that appears to undermine the minimal standards and protections included in the NPRM. This expedited process proposal should be excluded from the Final Rule. In addition, CMS needs to provide a special enrollment period for beneficiaries who are involuntarily disenrolled for disruptive behavior and with a prohibition on late enrollment penalties for beneficiaries that seek an enrollment in a new plan.

Moreover, NAMI recommends that drug plans should not be allowed to disenroll a beneficiary because of the refusal or inability of a beneficiary to adhere to a treatment plan developed by the plan or any health care professionals associated with the plan. Treatment adherence is already an enormous challenge for many beneficiaries living with mental illness under normal circumstances. Involuntary disenrollment as part of the Medicare drug benefit is certain to result in additional tragic and unnecessary setbacks for these individuals.

NAMI further recommends that plans seeking to disenroll an individual beneficiary be required to document efforts to provide a reasonable accommodation for a beneficiary with a mental disability in accordance with the Americans with Disabilities Act. Such documentation should be provided to beneficiaries and their family, with appropriate written notice of the consequences of continued disruptive behavior or written notice of its intent to request involuntary disenrollment from CMS.

### **Exclusion of Benzodiazepines (§ 423.100)**

The definition of a covered drug under the MMA contains a range of exclusions that are currently established in the Medicaid program.<sup>14</sup> This definition includes a class of medications identified as “benzodiazepines.” Benzodiazepines are currently used as the principal treatment for a range of mental illnesses including panic disorder, severe

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<sup>13</sup> (§ 423.44(d)(2))

<sup>14</sup> 42 USC 1927(d)(2)

anxiety disorders and acute mania in individuals with bipolar disorder (also known as manic depression). A range of studies has demonstrated the clinical effectiveness of benzodiazepines in treating the symptoms for these disorders.<sup>15</sup>

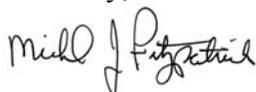
Unfortunately, since 1990, states have been allowed to exclude coverage of benzodiazepines from coverage under their state Medicaid programs. Such restrictions have been done consistent with a change made in federal Medicaid policy by Congress as part of the OBRA 1990 legislation as a result of concerns about abuse associated with a single drug within this broader class. While many states have restricted coverage benzodiazepines under their Medicaid programs, not all have done so. In fact, current estimates are that state Medicaid programs currently account for as much 11% of the current market for these products. Likewise, there is little evidence of private sector plans imposing a blanket exclusion for benzodiazepines to treat panic disorder, severe anxiety disorder or acute mania. Clearly, the evidence supports both clinical use of benzodiazepines and policy that supports coverage consistent with clinical practice.

NAMI therefore recommends that CMS create an exception to the general requirement for prescription drug plans to exclude coverage for benzodiazepines in cases where they are prescribed consistent with accepted clinical treatment guidelines for severe anxiety disorder and acute mania.

### **Conclusion**

NAMI is grateful for the opportunity to submit these comments on the Notice of Proposed Rulemaking. NAMI looks forward to working with CMS to ensure that these important changes to the Medicare program reach their full potential in assisting beneficiaries – both elderly and people with disabilities – to access prescription drug coverage.

Sincerely,



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<sup>15</sup> Journal of Clinical Psychiatry, 1997; 58 Suppl. 2:26-8, discussion 29-31.