



April 20, 2004

Dr. Mark B. McClellan  
Administrator, Centers for Medicare and Medicaid Services  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W., #314 G  
Washington, D.C. 20201

Dear Administrator McClellan:

On behalf of the 210,000 members and 1,200 affiliates of the National Alliance for the Mentally Ill (NAMI), I am writing to congratulate you on your appointment and Senate confirmation as the new Administrator of the Centers for Medicare and Medicaid Services (CMS). As the nation's largest organization representing individuals with severe mental illnesses and their families, NAMI looks forward to working with you in your new position and to ensuring effective implementation of the new Medicare Prescription Drug, Improvement and Modernization Act (MMA).

NAMI was proud to support congressional passage of MMA when it was before the House and Senate in November 2003. We are pleased that when it is fully implemented in 2006 it will offer unprecedented coverage of outpatient prescription medications for Medicare beneficiaries. Coverage of prescription drugs under Medicare is long overdue. While this new law is not perfect, it is a major step forward, especially for low-income Medicare beneficiaries and individuals dually eligible for Medicare and Medicaid. NAMI is firmly committed to working with CMS to ensure that the new law reaches its full potential to provide coverage and protections for Medicare beneficiaries living with severe mental illnesses.

### **Coverage of Prescription Drugs is Critical for Medicare Beneficiaries With Mental Illnesses**

Current estimates are that as many as 40% of beneficiaries dually eligible for both Medicare and Medicaid have a severe mental illness such as schizophrenia or bipolar disorder. As you know, prescription medications play a critical role in successful treatment and recovery for these beneficiaries. In treating an individual with mental illness, a physician often must try different drugs in the same class before finding the one that works. Even then, treatment plans must often be adjusted as medications sometimes lose their effectiveness for a particular individual and must be replaced with other similar medications.

More importantly, side effects, efficacy, and effects on cognitive functions all vary greatly between individuals. Thus, access to a wide array of medications, even if they differ from each other only slightly, is (in NAMI's view) medically necessary and critical

to clinical success and eventual recovery. At the same time, restricted access too often results in treatment failure with exacerbated symptoms, debilitating and permanent side effects, and in extreme cases, suicide and death.

In passing the MMA, Congress emphasized the unique needs of Medicare beneficiaries with mental illness in the MMA and included in the bill's conference committee report specific language directing CMS to ensure open access to medications used to treat mental illness. Specifically, this language directs that before the first open enrollment period for the new Medicare drug benefit, beneficiaries with mental illnesses "including but not limited to schizophrenia, bipolar disorder, dementia, and attention deficit disorder/attention deficit hyperactivity disorder" shall have clinically appropriate access to the "full complement of medicines, including atypical antipsychotics to treat the severely mentally ill" [Report No. 108-391, pp. 769-770].

To respond to this direction, CMS's regulations implementing the MMA must, in NAMI's view, take into account the fact that beneficiaries with mental illness must have broader access to specific medications than the average beneficiary because, as the conference report states, "individual responses to mental health medications are different." [ p. 770]

In addition to this compelling legislative history, there is ample policy precedent for these special patient protections. Currently, as many as 25 states have exempted medications to treat mental illness when developing their pharmaceutical formularies and prior authorization programs under Medicaid. Both Republican and Democratic governors have issued appropriate rules – as we are urging you to do – or signed these protections into law. Typically, states are motivated by a bipartisan desire to protect people with mental illnesses from the irreversible clinical consequences occurring when these highly vulnerable individuals do not obtain the medications they desperately need. NAMI urges you to include similar protections in the regulations implementing the new Part D program.

### **Special Provisions Needed for Dual Eligibles**

NAMI is especially concerned that CMS initiate a requirement for "continuity of care" for those Medicare beneficiaries who are simultaneously eligible for the Medicaid program (i.e., the "dual eligibles"). These very low-income individuals are among the most vulnerable populations impacted by the MMA, and a very large proportion of them are diagnosed with a mental illnesses. In NAMI's view, they are the Medicare beneficiaries most likely to have the specific mental diseases referenced in the conference report language noted above.

Through the Medicaid programs in their states, dual eligibles currently receive coverage of prescription medications for mental illness. NAMI is very concerned that unless protections are put in place, many dual eligibles will face enormous difficulties with the new Part D benefit because they will lose access to needed medications that are currently

covered for them by Medicaid. In referencing specific mental diseases, the conference report provisions noted above indicate clear congressional intent that special accommodations be made for dual eligibles.

Accordingly, NAMI strongly recommends that the regulations implementing the drug benefit require “continuity of care” for the dual eligibles by covering the wide array of mental health medications they can access through their Medicaid programs. At the very least, the regulations must maintain coverage for those dual eligibles already receiving treatment, i.e. to “grandfather in” this coverage, as a number of states have adopted with regard to certain restrictions in their Medicaid programs. Such a requirement should include a specific prohibition barring Medicare Part D from switching dual eligible beneficiaries off of medications that are effective for them at the time of their enrollment and transition from expiring Medicaid coverage.

Under Medicaid law, dual eligibles may not be denied access to medications for failure to pay a co-payment. Although co-payments under both Medicaid and the new Medicare drug benefit may seem nominal, individuals with mental illness have high rates of co-occurring disorders and thus require a treatment plan that includes multiple medications. Co-pays for multiple medications can quickly add up to significant amounts, particularly for dual eligibles, most of whom have incomes far below the poverty level. NAMI therefore urges CMS to maintain the protection against denial of access to medications for failure to pay, for dual eligibles with mental illness, under the new Medicare drug benefit.

#### **P&T Committees/Formulary Development**

While the MMA outlines very basic standards for the development of formularies and the membership of pharmacy and therapeutic (P&T Committees), the statute also grants CMS considerable authority to establish specific guidelines that will make this entire process sensitive to the specific needs of beneficiaries living with severe mental illnesses.

For example, NAMI strongly urges CMS to include in the regulations a requirement for psychiatrists to be represented on all P&T Committees created under the new Medicare prescription drug law. Although practicing physicians and pharmacists certainly have a general clinical understanding of how neuroscience medications work in the body, they often lack direct first-hand experience in treating individuals with severe mental disorders. Modern psychiatry is a highly complex discipline where front-line clinicians often use multiple medicines to address very challenging cases. As a result, psychiatrists are in a unique position to judge the clinical utility of specific pharmaceuticals. Further, they possess special knowledge on how these medications interact with one another.

Similarly, while Congress intended Part D plans to have considerable flexibility in determining the array of drugs they will cover, there is significant authority granted to CMS under MMA to ensure that the clinical needs of people with chronic health conditions are met. NAMI urges that CMS use this authority to ensure maximum access

to the broadest range of treatments for mental illness. Specifically, NAMI believes that it is impossible to adequately treat people with schizophrenia if the relevant therapeutic class is limited to two (2) antipsychotic medications.

Congress clearly inserted the conference committee report language referenced earlier to avert such an outcome, and CMS has the unambiguous authority to institute rules creating an exemption guaranteeing access to the “full complement of . . . . atypical antipsychotic . . . . medicines.” Moreover, given the fact that people with severe mental illness have co-occurring medical/surgical conditions, the United States Pharmacopeia should, in NAMI’s view, recognize the 209 therapeutic classes reflecting the medical problems typically encountered by Medicare beneficiaries.

### **Role of Ombudsman/Appeals Process**

In NAMI’s view, the right to appeal for coverage of medicine excluded from a particular Part D plan’s formulary has to be meaningful. It is obvious that Congress would not have bothered with creation that did not offer beneficiaries a reasonable expectation of fairness and expeditious review of an appeal. It is certainly true that the MMA prohibits doctors from pursuing appeals before the Secretary or the judiciary on behalf of their patients. This provision creates an enormous hurdle for people with mental disabilities who are likely to experience serious difficulties in understanding the appeals process and filing the appropriate documentation supported by related medical records.

Did Congress intend to deny beneficiaries with severe mental illness and other mental and cognitive impairments (e.g., Alzheimer’s disease) effective access to the appeals process? Clearly not. A careful reading of the statutory provisions authorizing the Beneficiary Ombudsman reveals that this Office is specifically permitted to pursue “complaints” or “grievances” on behalf of patients along with “assisting beneficiaries in collecting relevant information to seek an appeal.”

Indeed, prudent public policy – as embodied in the CMS regulations – seems to dictate that the Beneficiary Ombudsman should be empowered to file appeals on behalf of people with mental disabilities or other cognitive impairments. As the nation’s largest organization representing family members of individuals living with mental illness, NAMI believes that it is unreasonable to assume that loved ones of beneficiaries with mental illnesses will always be in a position to take on this essential function.

In addition, NAMI feels strongly that CMS must ensure that the procedures plans must establish for expediting determinations and reconsiderations, accommodate the necessity that individuals with mental illnesses receive rapid responses. Accordingly, Part D plans should be required to respond to requests for expedited determinations as quickly as possible (e.g., within 24 hours) by either approving the request for coverage, or contacting the prescribing physician to suggest an alternative that is covered already. It is critical for CMS to emphasize that denials should only take place when a person with appropriate clinical training determines that medical necessity criteria are not met.

Likewise, independent review entities charged with conducting reconsiderations of coverage denials should be required to respond to requests for expedited review within 24 hours. Further, it seems reasonable for the regulations to require Part D plans and independent review entities to establish call centers that are open 24 hours a day seven days a week to respond to these requests for expedited determinations and reconsiderations.

Finally, a special expedited appeals process should also be established for beneficiaries with mental illness to access when expedited determinations and reconsiderations are denied and emergency supplies of medications are not dispensed. In such circumstances, monetary thresholds should not apply and standards should be put in place making it clear that hearings be held within two calendar days, with a determination in five business days. During such appeals, it will be important for an emergency supply of medications to be dispensed until a final resolution of a request for an expedited determination, reconsideration, or appeal has been made. Once beneficiaries receive coverage for a needed medication through this process, they should not be required to go through it again to maintain coverage for that medication.

### **Education and Outreach**

Education and outreach efforts that will be undertaken by CMS regarding the new drug benefit must be, in NAMI's view, specifically tailored to assist beneficiaries with mental illness, in particular, dual eligibles with mental illness. NAMI strongly encourages CMS to invest in specific efforts to ensure that these beneficiaries are well-informed about the choices they may have and actions they will have to take to ensure there is no lapse in coverage and that they are able to choose the best plan available to meet their needs. Experience informs us that general public advertising campaigns are unlikely to effectively reach many of these individuals. Instead, CMS should consider investment of appropriate resources toward an outreach campaign specifically targeted to beneficiaries with severe mental illnesses and other mental impairments.

In this regard, NAMI recommends that CMS quickly initiate collaborations with "public, voluntary and private community organizations" as directed in the conference report and to provide sufficient resources to enable these organizations to effectively educate and help enroll "disadvantaged and hard-to-reach populations," including individuals with mental illness, and particularly to help those that are dually eligible and will be transitioning into the new Part D benefit. In particular, beneficiaries with mental illness and their families need to be well-informed about the specific medications covered by a plan and the amount of any required co-payments.

Further, if a beneficiary joins a drug plan because it covers a specific medication, any subsequent changes to remove that drug from the formulary should not apply to that individual. At minimum, CMS should designate in regulation that any change in the formulary would serve as grounds for that individual to change plans, thereby triggering a

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special enrollment period for such purpose. Moreover, given the unique factors associated with medications to treat mental illness, when a plan changes the status of these medications on its formulary, it should be obligated to provide additional notice beyond minimal requirements associated with posting such changes on its website (e.g. written notices provided to the beneficiaries, with copies forwarded to their physician and family members where possible).

### **Prohibit Plan Discrimination**

As you know, the Medicare program has a long history of discrimination against beneficiaries with mental illness. For decades, both Part A and Part B have maintained higher co-payments and arbitrary limits on inpatient care that apply only to psychiatric treatment. These Part D regulations afford CMS a unique opportunity to reverse this legacy of discrimination within Medicare by specifically prohibiting Part D plans from offering a drug benefit that is structured in ways that discourage individuals with mental illness from enrolling by offering less adequate coverage of medications used to treat mental illness, or by charging higher co-payments for these medications.

### **Conclusion**

Thank you for your attention on these important issues that CMS will be considering as part of the development of regulations implementing the MMA. NAMI would look forward to the opportunity to meet directly with you and senior staff to discuss these matters further. We share your goals of making sure that this new law reaches its full potential and that Medicare beneficiaries, especially vulnerable individuals with severe mental illnesses, are able to effectively access the long overdue improvements and added benefits in the MMA.

Sincerely,

A handwritten signature in black ink that reads "Michael J. Fitzpatrick". The signature is written in a cursive, flowing style.

Michael J. Fitzpatrick, M.S.W.  
Acting Executive Director