



**COMMENTS TO THE CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) REGARDING
THE FORMULARY GUIDANCE ON THE MEDICARE MODERNIZATION ACT
(MMA)
SUBMITTED DECEMBER 30, 2004**

The National Alliance for the Mentally Ill (NAMI) is pleased to offer the following comments on the Centers for Medicare and Medicaid Services (CMS) Draft Formulary Guidance regarding the Medicare Modernization Act (MMA). As the nation's largest organization representing individuals with severe mental illnesses and their families (210,000 members and 1,200 affiliates), NAMI would like to thank CMS for this important step forward in implementing the MMA.

NAMI is very supportive of the approach that CMS proposes to take with respect to reviewing Part D plan benefit structures and formularies. We are also pleased to see that CMS recognizes the need to review Part D plan formularies to ensure that they do not discriminate or substantially discourage enrollment by certain groups of Medicare beneficiaries. NAMI supports the three major areas of focus of this guidance: pharmacy and therapeutics (P&T) committees, formulary lists, and benefit management tools as among the most critical areas for review of prescription drug plans that will be implementing the new drug benefit under the MMA.

NAMI is especially pleased that CMS is viewing the statutory requirement of two drugs per class as a floor, and not an absolute standard. NAMI is particularly encouraged that the Guidelines clearly set forth a goal for CMS to examine each plan's use of cost management tools and to show deference to widely accepted clinical practice guidelines. Further, making certain that the exceptions and appeals processes work effectively for beneficiaries is critically important and we are encouraged by CMS's statements that they will require standardized reporting by plans on denials, reconsiderations and appeals and exceptions processing, and will integrate this data into CMS management and oversight activities. In short, NAMI views these Guidelines as a major step forward and an important step in filling gaps in the draft regulations published this past summer. It is critical that the prescription drug plans that will be offering coverage to Medicare beneficiaries be held accountable for providing access to the full range of treatments needed for chronic diseases and disabilities that these vulnerable citizens confront every day.

In moving forward with this Guidance, NAMI would urge CMS to continue efforts to identify formularies that utilize prior authorization and step therapy, including fail-first therapy, for special needs, vulnerable patients (including individuals living with severe mental illnesses) as discriminatory. For certain medical conditions, including illnesses such as schizophrenia, bipolar disorder and major depression, treatment decisions are relatively individualized, that is, the drug that works for one individual patient, does necessarily work for another.

In the case of severe mental illness, a strong evidence base exists to support this conclusion that medications to treat these illnesses are not "interchangeable." For example, in a recent study, "Evidence-Based Mental Health Treatments and Services: Examples to Inform Public Policy," Dr. Lehman and colleagues recommended that a wide array of effective treatments should be available within a community, because even when treatments are equally effective in general for the entire population, many of them are not equally effective for significant subgroups.¹ For individuals living with severe mental illnesses, "treatment choice and wide selection are essential in order to maximize treatment response and adherence to treatment." For beneficiaries with these conditions, this study concluded that less restrictive formularies may be important to maximizing quality of care. For other medical conditions, the choice of drugs may be less critical. Providing treatment choice and a wide selection of therapies for those with severe mental illness are key factors that are essential to balancing the costs of providing care with the benefits to individual patients.

NAMI would also like to urge caution with respect to reliance on the practices of commercial plans as benchmarks. The reality is that the needs of enrollees in these plans are typically very different from those of Medicare beneficiaries. NAMI is especially concerned by statements in the Guidelines that seem to equate widespread use of a formulary or cost management technique with best practice, which may not be the case. In addition, greater specificity is needed in several areas addressed in these Guidelines, including the requirements for pharmacy and therapeutics committees.

Defining “Medical Necessity” & “Best Practices”

The Guidelines make clear that a primary goal in reviewing formularies will be to ensure access to “medically necessary” medications by using “best practices” in commercial plans and state Medicaid programs as benchmarks against which to compare the proposed formularies of Medicare drug plans. At the same time, the Guidelines appear to lack a specific definition as to how these terms will be applied to drug plans.

Most importantly, the Guidelines do not set forth what test CMS will use to assure that beneficiaries have access to all “medically necessary” drugs, including those not on the formularies of the drug plans and Medicare Advantage plans that will be offering the new Medicare drug benefit. In NAMI’s view, CMS should not just rely on the plans’ definitions of “medical necessity,” given the financial incentives these private plans will have to limit access to off-formulary medications. NAMI would instead recommend the establishment of a uniform definition of medical necessity along the lines of the medical necessity standard for Medicare Parts A and B that limits coverage to those services or items that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”²

Likewise, the term “best practices” is used throughout the Guidelines and appears to be defined as a formulary and benefit management techniques widely in use. At the same time, widespread use does not necessarily indicate the effectiveness of practices in assuring access to medically necessary medications. In NAMI’s view, “best practices” should instead be defined as those policies that result in the best outcomes for patients in terms of reduction of symptoms, minimal complications from drug therapies, limited side effects, decreased reliance on hospitalization, and the lowest relapse rates for individuals with mental illness. The term “best practices” should also be explicitly defined to include comprehensive coverage for mental illness treatment in accordance with well-respected treatment guidelines such as those developed by the American Psychiatric Association found at www.psych.org/psych_pract/treatg/pg/prac_guide.cfm, the Texas Medication Algorithm Project (TMAP) found at www.dshs.state.tx.us/mhprograms/TMAP.shtm, and the Schizophrenia Patient Outcomes Research Team Treatment (PORT) Recommendations found at www.ahcpr.gov/clinic/schzrec.htm.

In addition, NAMI would also recommend that the definition of “best practices” be limited to benefit management techniques that take into account the medical history of individual patients and are triggered by certain prescriber behaviors as in Missouri’s “Smart Prior Authorization” program. This widely recognized model is directed toward instances of polypharmacy and prescribing patterns that exceed manufacturer and Food and Drug Administration recommendations. Under this approach, the medical history of the individual patient is examined to determine whether restricting access to certain medications is appropriate. More importantly, it also focuses on bringing provider prescribing behavior into line with best practice treatment guidelines, instead of putting the burden on vulnerable beneficiaries to overcome burdensome obstacles to accessing the medications they need.

“Best practices” are also often referred to as evidence-based practices. However, both terms should not be defined based only on clinical research data, as the evaluations being conducted by the Oregon Center for Evidence-based Policy tend to do. Instead, such practices should take into account how different therapies affect people in real world settings. Clinical trials generally do not include individuals with co-morbid conditions, but we know that people with mental illness have high rates of co-occurring disorders which greatly affect the efficacy and appropriateness of different medications. A preferable approach to assessing drug therapies is outlined in a paper by Dr. Thomas Mellman, entitled “Evidence-based Pharmacologic Treatment for People with Serious Mental Illness: A Focus on Guidelines and Algorithms”³ that incorporates scientific evidence as well as observational data and practical experience and references provider and other expert opinion.

To ensure that plans incorporate these best practices into their formularies and benefit designs before submitting their proposals for CMS review, NAMI recommends that CMS integrate into these Guidelines specific reference to

the best practices, including those listed above, that will be used to evaluate plan formularies and benefit designs. CMS should also establish a process for continually reviewing best practices as well as evaluating the experience of Part D plans to determine how their plan review and evaluation processes should be amended as new therapies become available, additional information is gathered about current therapies, and medical practice changes. CMS should also update its Guidelines at least annually to incorporate this new information.

Pharmacy and Therapeutics (P&T) Committees

NAMI has a number of concerns regarding the list of requirements that CMS plans to use to assess the P&T Committees established by drug plans and Medicare Advantage plans. The third requirement on this list states that P&T committees must include at least one practicing pharmacist and one practicing physician, each of whom has expertise in the care of elderly or disabled persons. However, best practice clearly dictates that there should be more than one expert in the care of elderly people, and more than one expert in the care of disabled individuals on these plans' P&T committees in light of the fact that both groups are comprised of individuals with such diverse needs.

In fact, the MMA clearly states that at least one such pharmacist, and at least one physician, with such expertise needs to be included on each P&T Committee – a standard that operates as a floor upon which CMS, with its emphasis on “best practices,” should build. Moreover, this requirement on the CMS list is inconsistent with the first requirement on this list that states that committee members must represent clinical specialties that adequately cover needs of plan beneficiaries. In this regard, NAMI recommends that CMS require that P&T Committees include a practicing psychiatrist with recent clinical experience. In light of the fact that it may not be possible for each P&T Committee to have experts in every field, CMS should require P&T committees to have formalized contractual relationships to advise each P&T Committee in decision-making with respect to areas where the P&T committee does not have adequate clinical expertise.

The list of P&T Committee requirements in the Guidelines also includes a provision requiring that only one pharmacist and one physician be independent. We recognize that the MMA states that “[s]uch (P&T) Committee shall include at least one practicing physician and at least one practicing pharmacist each of whom – is independent.” However, 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 in setting a minimum requirement of at least one independent physician and pharmacist. CMS should therefore build upon this minimum to ensure the integrity of the P&T Committees that will play such a critical role in determining the formularies for the Medicare drug benefit.

The Formulary Review Guidelines state that P&T Committees will have a “key role in defining policies for utilization management activities” but then in the list of requirements CMS merely states that P&T Committees must review practices and policies of utilization management for clinical appropriateness. The Guidelines should clarify that P&T Committees must have decision-making authority over a plan’s practices and policies of utilization management. Specifically, these Committees must be authorized to modify prior authorization review processes and other restrictive policies including co-payment tiering schemes, as necessary to ensure appropriate coverage. P&T Committees can provide important checks on the incentives governing individual drug plans by bringing research findings and clinical experience to bear on decisions that will restrict access to certain medications. However, they should be empowered to make such policy decisions. Moreover, the list of requirements should specifically state that P&T Committee decisions are binding on drug plans and Medicare Advantage plans.

P&T Committees must also be charged with a strong mission to promote and protect the health of beneficiaries and with ensuring that the interests of enrollees, taking into account the unique needs and co-morbidities commonly associated with aging populations and people with disabilities served by Medicare, are protected by all formulary and benefit design decisions made by the Part D plan. Their responsibilities must include permission to modify prior authorization review processes and other restrictive policies, including cost-sharing schemes, as necessary to ensure appropriate coverage. P&T Committees should also 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 that are older, have complex medical problems, and a high degree of co-morbid conditions. Cost should not be a factor in these considerations except that the P&T committee should be responsible for ensuring that adequate access is provided for the most clinically efficacious drugs in the preferred co-pay tier for all classes of covered drugs. CMS should also impose sanctions against P&T committee members when P&T committee decisions are in gross violation of this charge.

The list of requirements states that P&T Committees must review each new chemical entity within 90 days. NAMI is concerned that this is too long given the particular needs of Medicare beneficiaries, many of whom have severe disabilities or life-threatening or chronic conditions for which there is no effective treatment. A private insurance standard is simply inappropriate for this population. Medicare beneficiaries should have immediate access to new treatments once they receive approval by the Food and Drug Administration.

P&T Committees should be required to seek the meaningful input of beneficiaries as they consider medications to treat different conditions and disorders, and private drug plans and Medicare Advantage plans should be required to have advisory committees representing beneficiaries and living with disabilities and chronic illnesses. Moreover, NAMI recommends that the final regulations ensure that the processes used by P&T committees to develop formularies for the Medicare Part D benefit are open to enrollees and the public. CMS needs to ensure 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 prior to the adoption or revision of plan formularies. The final rule should also specify that meetings of P&T Committees are open to the public and actively engaged in seeking the input of enrollee populations such as seniors and people with disabilities.

Review of the Formulary Classification Systems

NAMI is encouraged by the emphasis CMS has given to the importance of preventing discrimination through formulary classification systems. At the same time, NAMI is concerned about the potential for the best practices of commercial plans to be the focus of scrutiny from CMS. It is important to note that enrollees in commercial plans are very different from Medicare beneficiaries who are older, experience more chronic illness, and thus often need multiple prescription medications. As a result, Medicare beneficiaries have higher risks of drug-related complications including adverse drug interactions.

Drugs included on the formularies for commercial plans may not be as effective, or may not be safe for older patients or individuals with multiple co-morbidities. Classification systems used by commercial plans may limit coverage to medications that may only be appropriate for younger, healthier people. NAMI is encouraged by CMS's reference to Medicaid preferred drug lists as another benchmark for evaluating Medicare formularies. Most states that have established preferred drug lists (PDLs) have recognized the special characteristics of medications to treat mental illness and have exempted these medications from restrictions applied to other types of prescription drugs.

NAMI supports statements in the Guidelines recognizing that these formularies may have to include more than two drugs per class to avoid discrimination in certain cases in which additional drugs have "unique and important therapeutic advantages in terms of safety and efficacy". This is particularly the case with respect to psychiatric medications that vary widely even among medications to treat the same condition and these drugs thus tend not to be interchangeable (see above). Even those medications with the same mechanism of action, 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.⁴ 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."⁵ In addition, each SSRI has a distinct profile of its own particular side effects, and these medications vary widely in how long they remain in the body.

Furthermore, research demonstrates that different antipsychotic medications (including atypicals) affect separate portions of the brain and affect the brain in very different ways.⁶ 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.⁷ 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 stated 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."

Medications to treat mental illness generally have such important differences, and as a result, are not interchangeable. Therefore, limiting access to two or three within each class of medications would discriminate against beneficiaries with mental illness by not providing access to medically necessary medications for those individuals while providing adequate access to medically needed medications to those for whose conditions the medications are more interchangeable.

NAMI had numerous concerns regarding the draft model guidelines for drug classification systems developed by the U.S. Pharmacopeia (USP) released earlier this year. This list of therapeutic classes grouped older mental illness medications that are recognized as inferior in terms of their efficacy and dangerous properties with newer therapies that are more effective and impose much more manageable side effects. Because these newer drugs are more expensive, grouping them together with the older medications would encourage Medicare drug plans to cover only the older, less expensive drugs. NAMI was therefore encouraged by statements in the Formulary Review Guidelines indicating that CMS will consider other classifications systems in addition to USP's guidelines in assessing the adequacy of plans' formularies. NAMI would particularly recommend that CMS look to the classification system used for the Medicare Discount Drug Card.

NAMI is especially encouraged by statements in the Guidelines indicating that CMS will review the tier placement and cost-sharing requirements of plans to ensure that they do not discourage enrollment by particular groups. Clearly, simply including a drug on a formulary may not be adequate to assure non-discrimination. CMS must closely review tier placement. The Guidelines further state that best practices in existing formularies and Medicaid PDLs only put drugs on higher co-pay tiers if a therapeutically equivalent drug is in a more "preferable" position. However, this practice may not ensure adequate access to medications to treat mental illness and we urge CMS to keep the general non-interchangeability of certain types of mental health medications in mind in assessing tiering practices.

Review of Formulary Medication Lists

The Guidelines state that CMS intends to use a variety of benchmarks to confirm sufficient breadth (number and choices) of drugs in each class necessary to treat all disease states in a non-discriminatory way. As part of this review, the Guidelines note that CMS will refer to State Medicaid PDLs. NAMI urges CMS to look to the PDLs in Indiana and Vermont as examples of Medicaid formularies that provide strong coverage of mental health medications.

The Guidelines indicate CMS intends to use commercial formularies in widespread use and Medicaid PDLs as benchmarks. Further the Guidelines state that a "possible benchmark" will be the availability and tier position of commonly prescribed drugs, particularly the top 25-50 drugs for the Medicare population. Coverage of commonly prescribed medications are appropriate to inform CMS's review of plan formularies and would be helpful in addressing concerns about the differences in the populations served by commercial plans, and their use as benchmarks given the higher medication needs, higher incidence of co-occurring disorders and chronic illnesses and special health care needs.

NAMI strongly supports statements in the Guidelines declaring that CMS will use widely accepted treatment guidelines as benchmarks for assessing whether appropriate access is provided for certain conditions, including mental illness. In NAMI's view, this approach will not place an undue burden on plans since these drugs are usually placed in favorable positions on commonly used formularies. For example, most of the states that have established PDLs in their Medicaid programs have exempted mental health medications from access restrictions.

NAMI agrees with CMS in declaring that "[i]n some cases, widespread industry practices and widely used treatment guidelines require all or substantially all drugs in a particular class to be covered" and would point out that this is especially true for mental health. This is also the case for many Medicaid PDLs regarding medications to treat mental illness.

In response to CMS's request for recommendations regarding the treatment guidelines they should consider, NAMI would urge CMS to use the following treatment guidelines as benchmarks for ensuring that the Medicare plans offer adequate coverage of mental health medications in their formularies: the Texas Medication Algorithm Project

(TMAP) found at www.dshs.state.tx.us/mhprograms/TMAP.shtm, the American Psychiatric Association guidelines found at www.psych.org/psych_pract/treatg/pg/prac_guide.cfm, and the Schizophrenia Patient Outcomes Research Team Treatment (PORT) Recommendations found at www.ahcpr.gov/clinic/schzrec.htm.

Application of the Non-Discrimination Standard in the MMA

The Guidelines in several places state that as long as a proposed formulary is the same as one in “widespread use” or by a plan with a large number of enrollees (e.g., FEHBP, retiree plans, and Medicaid), then they will consider it non-discriminatory.⁸ These statements seem to indicate that approval would be awarded without regard to whether or not this classification system meets the MMA requirement, as stated on p. 7 of the Guidelines, that “CMS review Part D formularies to ensure that beneficiaries have access to a broad range of medically appropriate drugs to treat all disease states and to ensure that the formulary design does not discriminate or substantially discourage enrollment by certain groups”.

In NAMI's view, simply adhering to a classification system or formulary that has already been applied to a large number of beneficiaries does not ensure it does not discriminate by unfairly failing to address the needs of certain beneficiaries. Comparisons between proposed formularies and these pre-existing and widely used classification systems is an important standard for CMS to establish. At the same time, CMS needs to give additional consideration to other compelling factors such as treatment guidelines, other best practices, and how the most commonly used medications for this population are treated. In addition, CMS should also look at the number of exceptions requests by beneficiaries in plans with these classification systems and drug lists in place, as well as rates of hospitalization to assess the appropriateness of these classification systems and formularies. In addition, CMS should clarify what qualifies as “widespread use”.

The Guidelines also state that CMS intends to use a series of checks to ensure that proposed formularies provide “the kind of” non-discriminatory access available in existing drug plans (p. 7). But, these additional checks, e.g., treatment guidelines, should be used to enhance the standards encompassed in the benchmark plans CMS has identified, instead of being used as another way to ensure that proposed formularies are similar to existing benchmark plans.

The Guidelines also note that CMS intends to monitor changes to approved formularies on an ongoing basis and initiate discussion when necessary to assure that approved formularies remain non-discriminatory. NAMI recommends that CMS not only monitor changes, but also initiate discussions and conduct comprehensive reviews if a plan has made numerous changes to its formulary over a three month period. Plans should be required to update their formularies based on experience data that indicate significant numbers of appeals and exceptions requests and complaints.

Review of Benefit Management Techniques

NAMI strongly support CMS's plans to review the use of utilization management techniques by Medicare prescription drug plans and Medicare Advantage plans to ensure appropriate access to medications in a timely manner. In assessing these plans' use of benefit management tools, the Guidelines state that CMS will again look to the use of these techniques in existing plans (private sector, Medicaid, FEHBP) to ensure non-discrimination. NAMI would again point out that most states with PDLs have exempted medications to treat mental illness from access restrictions under their Medicaid programs. Thus, NAMI would urge CMS to require Part D plans to follow this example and exempt mental health medications from restrictive utilization management techniques.

NAMI would also commend to CMS the Missouri “Smart Prior Authorization” program as a best practice and model approach to utilization management of mental health medications. Under this “Smart Prior Authorization” program, review is triggered by certain prescribing behaviors by providers including instances of polypharmacy and prescribing of dosages that far exceed Food and Drug Administration recommendations. Under this approach the medical history of the individual consumer is examined to determine whether restricting access to certain medications is appropriate. It also focuses on bringing provider prescribing behavior into line with best practice treatment guidelines instead of putting the burden on vulnerable beneficiaries to overcome burdensome obstacles to accessing the medications they need. At least 15 other states are adopting this approach in their Medicaid programs.

CMS itself cited this Missouri program as a model program in a brief for Medicaid directors entitled “Psychiatric Medications: Addressing Costs without Restricting Access”.⁹ In this report, CMS encourages state Medicaid directors to implement several types of innovative alternatives to restrictive formularies and prior authorization requirements for mental health medications that increase the risk of multiple prescriptions, reduced compliance, and poor outcomes.¹⁰

The innovative alternatives cited 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.¹¹ 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”.¹²

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.¹³

Since CMS has encouraged the use of these alternative cost management techniques for psychiatric medications in state Medicaid programs, it surely makes sense to urge Medicare drug plans and Medicare Advantage plans to implement the same techniques with regard to utilization management of psychiatric medications in the new Medicare drug benefit.

CMS states in the Guidelines that they will review plans’ use of drug utilization review tools and techniques including concurrent review and prospective and/or retrospective utilization review to assure appropriate access to medically necessary therapies and guard against inappropriate or dangerous utilization. As described above, Missouri and a number of other states are using data in this way in their Medicaid programs to identify instances of polypharmacy and other outlier treatment practices regarding mental health medications and to bring providers engaging in those practices back in line with best practice treatment guidelines.

State Medicaid programs are not all models of best practice. Where more standard prior authorization requirements and similar restrictions on access have been applied to psychiatric medications under Medicaid, discriminatory practices against mental health consumers have been found. For example, an independent survey following application of a prior authorization requirement to prescription medications under Michigan’s Medicaid program found that anti-depressants and pain medications were the classes of pharmaceuticals most often involved in prior authorization difficulties. Further, a study by the Kaiser Family Foundation found that Michigan’s preferred drug list was particularly restrictive regarding psychiatric medications.¹⁴ However, subsequently, Michigan rolled back many of its policies, and coverage of medications to treat mental illness, in particular, have become much less restrictive than when the program was initially implemented.

NAMI strongly recommends that CMS should ensure that management techniques used by Part D bar any requirement or incentive for pharmacists to engage in therapeutic substitution. Medications to treat mental illness differ significantly in how they affect brain chemistry and mental illnesses themselves are highly variable in terms of symptoms and effects on patients. 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. Physicians must retain the ultimate authority to decide which specific medication a Medicare beneficiary will receive.

CMS should also prohibit limits on the frequency of dispensing, maximum daily dosage, or limits on the number of prescriptions filled. Prohibiting such limits would be consistent comments from Dr. Mark McClellan during his confirmation hearing in the Senate Finance Committee related to his current position as CMS Administrator. In

response to a specific question submitted by Senator Baucus, Dr. McClellan stated that, “beneficiaries 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 of a drug.”

Finally, NAMI would recommend that all information regarding any utilization management processes must be readily available to beneficiaries and providers in clear, plain language that is easy to understand and available in written form or on the Internet.

Special Concerns Regarding Dual Eligibles

NAMI strongly recommends that prescription drug plans and Medicare Advantage plans be required to give special consideration to individuals transitioning from Medicaid into Part D. Individuals with mental illness that have been stabilized on a more costly or non-formulary drug or that have already gone through a step therapy or fail-first system should automatically receive coverage for the medically necessary drug at the lowest co-pay level without having to go through the exceptions process. 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 an individual patient'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, and their treatment typically costs about 50 percent more than it would have if they had been allowed to continue taking a medication that has already been deemed appropriate.¹⁵ Michael Hogan, former Chair of President Bush’s New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, advised in a June 10, 2004 letter to Dr. Mark McClellan that “[a]ppropriate continuity of care provisions for psychiatric medications for dual eligibles are critical and needs to be considered in the development of [the Medicare Part D] 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.” Dr. Hogan also stated that the exceptions process is not an appropriate means of ensuring access to medically necessary off-formulary medications for this population. As he pointed out, “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.”

Review of Appeals and Exceptions Procedures

The Guidelines state that CMS intends to protect beneficiary rights relating to appeals and exceptions through standards in the final regulations regarding the Medicare drug benefit and by reviewing the processes established by plans to ensure timely access to challenges of coverage decisions. CMS should regularly review how these processes work and should set forth triggers for special review if plan data submitted to CMS indicate high numbers of exceptions and appeals being filed by enrollees. These triggers for review should not be tied to high numbers of utilization management decisions being overturned because, at least as envisioned under CMS’s proposed regulations for Part D. It is likely that it will take a long time and many levels of appeal before beneficiaries are able to receive a genuine independent review.

NAMI is encouraged by CMS’s statement that the final rule for the Medicare drug benefit will reflect best practices regarding timeframes for exceptions and appeals and that they are developing notice requirements to ensure beneficiaries understand their rights. NAMI – and many other stakeholders representing beneficiaries – expressed strong concerns in comments on the proposed rule that the grievance and appeals processes as outlined in the proposed regulations were overly complex, drawn-out, and inaccessible to beneficiaries.

NAMI strongly supports CMS’s statements that they will require standardized reporting by plans on denials, reconsiderations and appeals and exceptions processing and will integrate this data into CMS oversight. It is equally important that CMS assure that plans make appropriate use of data related to excessive rates of overturned utilization management decisions. CMS should not just rely on plans to do the right thing with this data and should review it closely to identify plans with high numbers of exceptions requests and appeals and require those plans to

modify their formularies and benefit management techniques to ensure their enrollees are receiving the medications they need.

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2. Social Security Act, Sec. 1862(a)(1)(A).
3. Mellman, T., et al. “Evidence-based Pharmacologic Treatment for People with Serious Mental Illness: A Focus on Guidelines and Algorithms”, *Psychiatric Services*, (May 2001), Vol. 52, No. 5.
4. 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.
5. *Id.*, p. 10.
6. Horn, S. “Unintended Costs and Outcomes: The Fiscal Case for Open Access”, *Drug Benefit Trends*, (pending December 2003), Vol. 15, Supplement 1.
7. American Psychiatric Association, “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, (2004), p. 5.
8. For example, on page 8 of the Guidelines, CMS states that “[i]f we find that the proposed classification system is in use for many [Medicare] beneficiaries, we will approve the classification system.”
9. U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Report to State Medicaid Directors, “Psychiatric Medications: Addressing Costs without Restricting Access”, (August 20, 2004).
10. *Id.* p. 2
11. *Id.* p. 4
12. *Id.* p. 10
13. *Id.*, p. 8
14. For additional background information, see A Case Study on Michigan’s Medicaid Prescription Drug Benefit from the Kaiser Commission on Medicaid and the Uninsured, available at <http://www.kff.org/medicaid/4083-index.cfm>.
15. Hensely, PL and Numberg, HG, “Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls”, *Pharmacoeconomics*, (2001), Vol. 19, No. 10, pp. 973-982.