National Mental Health Association

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December 29, 2004

Mark McClellan, M.D. Ph.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Draft Guidelines on Formulary Review for the Medicare Prescription Drug Benefit

Dear Administrator McClellan:

The National Mental Health Association (NMHA) appreciates this opportunity to comment on the Center for Medicare and Medicaid Services' (CMS') draft Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures (Guidelines). Prescription medications have become some of the most efficacious treatments for many illnesses and conditions, including mental illness. We strongly believe that Medicare beneficiaries deserve and need comprehensive drug coverage that will ensure them access to all necessary medications, and we appreciate this opportunity to provide input on how CMS should evaluate Medicare Part D plan formularies and benefit management techniques.

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

Many Medicare beneficiaries face mental illness, often alone and without medications that have proven widely effective and that would likely ease their symptoms and lead to recovery. Research has shown that some 37% of older adults show signs of depression when they visit

their primary care physician,[1] but we know that most are not receiving the care they need. In fact, older adults have the highest rate of suicide of any age group in the country.[2] It is estimated that only half of older adults who acknowledge mental health problems actually are treated by either mental health professionals or primary care physicians.[3] Beneficiaries who qualify for Medicare based on their disability status also frequently experience mental illness, and studies have shown that over half of all under-65 beneficiaries with disabilities have problems with mental functioning.[4] We are particularly concerned about the impact of the new Medicare drug benefit on those beneficiaries who currently have drug coverage through their state Medicaid programs, i.e., the dual eligibles. There is a high rate of mental illness among this segment of Medicare beneficiaries: according to Medpac, 38% of dual eligibles have cognitive or mental impairments.[5] We must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new Medicare drug benefit and are not made worse off when their drug coverage is switched from Medicaid to Medicare at the end of 2005.

We are generally encouraged by the Guidelines and are particularly supportive of the deference CMS indicates it will show to widely accepted treatment guidelines for psychological disorders in conducting these reviews. We also support indications by CMS that close review will be conducted of not just formulary lists but also benefit management tools and cost-sharing requirements to guard against discriminatory practices. A number of other aspects of these Formulary Review Guidelines are also very encouraging including CMS's statements that the statutory requirement of two drugs per class will be viewed as a minimum and not an absolute standard and that standardized reporting by plans on denials, reconsiderations, and appeals and exceptions processing will be required and that this data will be integrated into CMS management and oversight activities.

However, we have concerns regarding the reliance by CMS on the practices of commercial plans as benchmarks because the needs of enrollees in these plans are very different from those of Medicare beneficiaries. We are also 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, and we have a number of concerns regarding the requirements for pharmacy and therapeutics committees.

General Comments Regarding Terminology

CMS indicates in these Guidelines 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. Several of these key terms, which are used in numerous places throughout the Guidelines, need further definition.

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[1] U.S. Department of Health and Human Services, Administration on Aging. *Older Adults and Mental Health: Issues and Opportunities*, January, 2001, p. 9.
[2] Id., p. 3.
[3] Id., p. 11.
[4] The Henry J. Kaiser Family Foundation, *The Faces of Medicare: Medicare and the Under-65 Disabled*, July 1999.
[5] Medpac, *Report to Congress: New Approaches in Medicare*, June 2004, p. 72.

It is unclear, for instance, what test CMS will use to assure that beneficiaries have access to all "medically necessary" drugs including those not on the formularies of the private drug plans and Medicare Advantage plans that will be offering the new Medicare drug benefit. CMS should not just rely on the plans' definitions of "medical necessity" given the financial incentives of these private plans to limit access to off-formulary medications as much as possible. Instead, CMS should establish a federal 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."[6]

The term "best practices" is used throughout CMS's draft Guidelines and in some instances seems to be defined as formularies and benefit management techniques that are widely used. However, widespread use does not necessarily indicate the effectiveness of practices in assuring access to medically necessary medications. "Best practices" should instead be defined as those policies that result in the best outcomes for consumers in terms of the most reduction in symptoms, the least complications from drug therapies, the least side effects, the least hospitalization, and the lowest relapse rates for people with mental illness. The term "best practices" should also be explicitly defined to include comprehensive coverage for mental health treatment in accordance with well-respected treatment guidelines including 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, "best practices" should be defined to only include benefit management techniques that take into account the medical history of individual consumers and are triggered by certain prescriber behaviors as in Missouri's "Smart Prior Authorization" program which is triggered by, for example, 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.

Best practices are often referred to as evidence-based practices but 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, and instead should include practices that 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

[6] Social Security Act, Sec. 1862(a)(1)(A).

Serious Mental Illness: A Focus on Guidelines and Algorithms"[7] 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, we urge CMS to include in the final version of 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 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 changed as new therapies become available, additional information is gathered about current therapies, and medical practice changes. CMS should update its Guidelines at least annually to incorporate this new information.

Pharmacy and Therapeutics Committee Requirements

We have a number of concerns regarding the list of requirements that CMS plans to use to assess the pharmacy and therapeutics (P&T) committee of each private drug plan and Medicare Advantage plan. The third requirement on this list states that P&T committees of these plans 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 dictate that there 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. The statute states that at least one such pharmacist and at least one physician with such expertise be included in the P&T committees and thus merely sets a floor on 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, CMS must 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 the 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 also includes a provision requiring that only one pharmacist and one physician be independent. We recognize that the Medicare Modernization Act (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 build upon this minimum to ensure the

[7] Mellman, Thomas 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

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 profit-seeking motives of private drug plans by bringing research findings and clinical experience to bear on decisions that will restrict access to certain medications, but they must be empowered to make such policy decisions. Moreover, the list of requirements should specifically state that P&T committee decisions are binding on the drug plans and Medicare Advantage plans.

P&T committees must 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 must be charged with ensuring that each therapeutic drug class included in the formulary contains enough variety and number of agents to reflect current utilization patterns and meet the needs of the Medicare beneficiaries who are older, have complex medical problems, and a high degree of 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, but this length of time 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 not appropriate 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 consumer input from affected enrollee populations as they consider medications to treat different conditions and disorders, and private drug plans and Medicare Advantage plans should be required to have consumer advisory committees.

The final rule must 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 must require that P&T committees hold public hearings with notice to the public well in advance and provide an opportunity for consumers and family members to be heard prior to the adoption or revision of

plan formularies. The final rule should specify that meetings of the P&T committee should be open to the public. Further, plans should be required to seek input in the P&T committee process from affected enrollee populations, including elderly populations and a diverse range of individuals with disabilities.

Review of the Formulary Classification Systems

We are encouraged by the emphasis CMS gives to the importance of preventing discrimination through classification systems but are concerned by statements in the Guidelines that best practices of commercial plans will be a focal point of evaluations in this regard. We urge CMS to keep in mind that enrollees in commercial plans are very different from Medicare beneficiaries who are older, have more health problems and chronic conditions, 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 individuals 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. We are encouraged by CMS's reference to Medicaid preferred drug lists as another benchmark for evaluating Medicare formularies because most states that have established preferred drug lists (PDLs) have recognized the special characteristics of mental health medications and have exempted those medications from restrictions applied to other types of prescription drugs.

We appreciate 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 true with regard to mental health medications which vary widely even among medications to treat the same condition and these drugs thus tend not to be interchangeable. 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.[8] 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."[9] 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 shows that different antipsychotic medications (including atypicals) affect separate portions of the brain and affect the brain in very different ways.[10] There are two or more distinct types of atypical anti-psychotics that each has different chemical structures,

[8] 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.
[9] Id., p. 10.
[10] Horn, S. (pending December 2003). Unintended Costs and Outcomes: The Fiscal Case for Open Access. *Drug Benefit Trends*, Vol. 15, Supplement 1.

mechanisms of action, and clinical outcomes. As a result, these medications have varied clinical and side effects.[11] 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." Since mental health medications generally have such important differences and thus tend not to be interchangeable, 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.

We had numerous concerns regarding the draft model guidelines for drug classification systems developed by the U.S. Pharmacopeia (USP) which grouped older mental health medications that are far 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 will encourage plans offering the Medicare drug benefit to cover only the older, less expensive drugs. Thus we were encouraged 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. We particularly recommend that CMS look to the classification system used for the Medicare Discount Drug Card.

CMS requests comments on requiring at least one drug from the third column on USPs proposed classification system. Although better than just using the first two columns, simply incorporating the third column would not solve our concerns with this classification system and would be a minimal improvement.

We are heartened 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. We agree that just including a drug on a formulary may not be adequate to assure non-discrimination and urge CMS to closely will review tier placement. CMS states 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 mental health medications 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

CMS indicates it will 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.

[11] American Psychiatric Association (2004), *Maximizing Pharmacotherapy in the Treatment of Severe and Persistent Mental Illness: The Case for Maintaining Open Access to Medically Indicated Medications for Schizophrenia,* White Paper, p. 5.

The Guidelines state that CMS will refer to State Medicaid preferred drug lists (PDLs). We urge 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 will definitely use commercial formularies in widespread use and Medicaid PDLs as benchmarks and then says they are just considering as a "possible benchmark" looking at the availability and tier position of commonly prescribed drugs particularly the top 25-50 drugs for the Medicare population. Coverage of commonly prescribed medications should definitely inform CMS's review of plan formularies and help address the problem that the commercial plans they will be using as benchmarks cover a very different population from the Medicare population that has higher medication needs, more co-occurring disorders, more chronic illnesses, and more people with disabilities who have special health care needs.

We strongly support CMS's statements in the Guidelines that they will use widely accepted treatment guidelines as benchmarks for assessing whether appropriate access is provided for certain conditions including behavioral health and psychological disorders. We agree that this approach will not place an undue burden on the 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.

We concur with CMS's finding 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. We would add that this is also true for many Medicaid PDLs regarding mental health medications.

In response to CMS's request for recommendations regarding the treatment guidelines they should consider, we 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.

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.[12] 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". Just because a classification system or formulary has

[12] 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."

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 may be a good start, but CMS must give equal or preferably more weight to other factors including 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 and rates of hospitalization to assess the appropriateness of these classification systems and formularies. In addition, CMS should clarify what qualifies as "widespread use".

Furthermore, the Guidelines state that CMS will use a series of checks to insure 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

CMS states it will monitor changes to approved formularies on an ongoing basis and initiate discussion when necessary to assure that approved formularies remain non-discriminatory. CMS should not only monitor changes and initiate discussions but should also conduct comprehensive reviews if a plan has made numerous changes to its formulary over a three month period that were not necessary to ensure the safety of the plan's enrollees. 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

We 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. We would like to point out that most states with PDLs have exempted mental health drugs from access restrictions under their Medicaid programs. Thus, we urge CMS to require Part D plans to follow this example and exempt mental health medications from restrictive utilization management techniques.

We also urge CMS to adopt Missouri's "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".[13] 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.[14] The innovative alternatives discussed by CMS in this report include a physician educational intervention and outlier management program in Pennsylvania designed to align physician prescribing practices with best practice guidelines. At the end of the first year of operations, key findings include reduced polypharmacy, reduced multiple prescribers, reduced therapeutic duplication of atypical anti-psychotics, and reduced per consumer costs.[15] 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".[16]

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.[17]

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 mental health 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.

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

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 mental health medications under Medicaid, discriminatory practices against mental health consumers have been found. For example, a 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 (see report attached) and a study by the Kaiser Family Foundation found that Michigan's preferred drug list was particularly restrictive regarding mental health medications[18] However, subsequently, Michigan rolled back many of its policies, and coverage of mental health drugs, in particular, has become much less restrictive than when the program was initially implemented.

In its review of Part D plans' benefit management techniques, CMS should prohibit plans from requiring or encouraging pharmacists to engage in therapeutic substitution. Mental health medications differ significantly in how they affect brain chemistry and mental illnesses themselves are highly variable in terms of symptoms and effects on consumers. Physicians have to carefully tailor drug therapies to each individual to take into account current medical condition, past treatment history, likely response to side effects, other medications currently being taken, expense, any co-morbid illnesses, and safety in overdose given heightened risk of suicide. 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 Senator Baucus' question number 27, 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."

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.

Plans must be required to give special consideration to individuals transitioning from Medicaid or other insurance sources, including another Part D plan. Individuals with mental illness who have been stabilized on a more costly or non-formulary drug or who 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 a person's condition. People who switch from one SSRI to another, for example, tend to

[18] *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.

remain in treatment 50 percent longer than those who don't, and their treatment typically costs about 50 percent more than it would have if they'd been allowed to continue taking a medication that has already been deemed appropriate.[19] 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 will protect beneficiary rights relating to appeals and exceptions through standards in the final regulations regarding the Medicare drug benefit and by reviewing processes plans use to provide timely access to these avenues for challenging coverage decisions. CMS should regularly review how these processes play out and should establish triggers for special review if plan data submitted to CMS indicates high numbers of exceptions and appeals being filed by enrollees. These triggers for review must 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 will take a long time and many levels of appeal before beneficiaries will receive truly independent review of their cases.

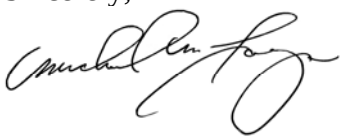
We are heartened by CMS's statement that the final rule for the Medicare drug benefit will reflect best practices regarding timeframes for exceptions and appeals and that they are developing notice requirements to ensure beneficiaries understand their rights. We expressed strong concerns in our comments 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.

We strongly support 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. CMS says this will assure plans make appropriate use of the data such as addressing excessive rates of overturned utilization management decisions. But CMS should not just rely on plans to do the right thing with this data. CMS should review it closely and 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.

[19] Hensely, PL and Nurnberg, H.G. (2001), *Formulary Restriction of Selective Serotonin Reuptake Inhibitors for Depression: Potential Pitfalls*, Pharmacoeconomics, Vol. 19, No. 10, pp. 973-982.

We appreciate CMS' consideration of these comments and would welcome the opportunity to discuss these issues further. Please contact Kirsten Beronio at (202) 675-8413 if you have any questions.

Sincerely,



Michael M. Faenza, MSSW
President and CEO