National Mental Health Association

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Comments of the National Mental Health Association
on the
Draft Model Guidelines for the Medicare Prescription Drug Benefit
Developed by the U.S. Pharmacopeia Expert Committee

We appreciate the opportunity to comment on the draft Medicare Prescription Drug Benefit Model Guidelines developed by the Expert Committee of the U.S. Pharmacopeia. These guidelines will play a critical role in the implementation of the new Medicare drug benefit. This drug benefit is long overdue as prescription medications have become, over the years, some of the most efficacious treatments for many illnesses and conditions, including mental illness. We strongly believe that Medicare beneficiaries deserve and need comprehensive drug coverage that will ensure them access to the medications they need.

The National Mental Health Association

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

Mental Illness in the Medicare Population

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 seniors show signs of depression when they visit their primary care physician. But we know that most are not receiving the care they need because seniors have the highest rate of suicide in the country, accounting for 20 percent of all suicide deaths. Beneficiaries with disabilities also frequently experience mental illness and studies have shown that 40% of those who qualify for Medicare based on their disabled status have a diagnosed mental illness or substance abuse disorder. 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. We must ensure that these very vulnerable beneficiaries receive coverage for the medications they need under the new Medicare drug benefit and are not harmed or made worse off when their drug coverage is switched from Medicaid to Medicare at the end of 2005.

The Classification System: A Step Backward

Unfortunately, the draft guidelines developed by USP would likely cause harmful disruption in care for dual eligibles as well as inadequate drug coverage for other beneficiaries with mental illness. In general, the proposed classification of mental health drugs would group older 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 health plans offering the Medicare drug benefit to cover only the older, less expensive drugs. Such an outcome is fundamentally inconsistent with Congress' core goal of assuring beneficiaries access to the drugs they need. Yet in proposing so few categories and classes, and creating groupings of highly diverse agents, USP's draft guidelines would allow health plans' economic incentives to override consumer needs and standards of care. Indeed, the proposed guidelines appear to ignore much of what has been learned about pharmacological treatment of mental illness. As discussed more fully below, one sees no evidence, for example, that the development of these guidelines took account of the serious side-effects of many psychotropic medications, the variability of individual responses to these agents, and the reality that these medications are NOT therapeutically interchangeable. From the vantage point of an association focused on the needs of those with or at risk of mental illness, it is difficult to imagine Medicare beneficiaries with mental health needs finding any encouragement in these guidelines to enroll in a Medicare prescription drug plan.

Anti-Depressants

One of our primary areas of concern is the categorization of anti-depressants in which the older tricyclics are grouped with reuptake inhibitors even though they have a fundamentally different mechanism of action which is the basis USP has stated it used in grouping together medications into the pharmacologic classes in the proposed classification guidelines. Tricyclics can be the best choice for individuals who have not responded to the newer medications, but in general reuptake inhibitors, e.g., selective serotonin reuptake inhibitors (SSRIs), are the first line of treatment recommended and prescribed by psychiatrists. This should have been a primary consideration and should have dictated that tricyclics be categorized into a separate class. Major drawbacks of tricyclics are very dangerous side effects and potential lethality in overdose. An overdose of as little as a 7-day supply of a tricyclic can result in potentially fatal cardiac arrhythmias. With suicide a major risk for those suffering from depression, the lethality of tricyclics in cases of overdose must be weighed heavily by physicians in determining the most suitable medication for an individual consumer. Given the significant risks and shortcomings of tricyclics, the categorization for anti-depressants in the USP guidelines must separate out tricyclics from the newer medications to ensure that beneficiaries are not left with no other option but to take these older, less effective and potentially dangerous medications.

Moreover, reuptake inhibitors themselves have different mechanisms of actions and should not all be grouped into one class. They affect brain chemistry in distinct ways, have singular side effects, and some evidence shows that their effectiveness varies depending on the type of depression. They also differ in how long they remain in the body. In addition, the disease of depression itself is highly variable with different symptoms for different individuals. A recent poll by Consumer Reports of 3,000 members with commentary by national experts found that it is essential to have a wide choice of anti-depressants because most people need to try several before they find one that works and no one can predict which one that will be. **Physicians must weigh many factors in prescribing anti-depressants including the consumer's current mental condition, past treatment history, the likelihood of side effects, likely response to side effects, other medications currently being taken, any co-morbid illnesses, safety in overdose, and expense. This process is so complex it mandates that the full array of anti-depressants be available for beneficiaries under the new Medicare drug benefit**. However, the USP guidelines would encourage health plans to offer only two drugs out of the entire array of reuptake inhibitors and tricyclics. By grouping all reuptake inhibitors and tricyclics together into

one class, the USP has fallen far short of its stated goal of "assuring beneficiaries access to the drugs they need".

Anti-depressants, including SSRIs, are not interchangeable and thus any classification that is not broken down by individual medication will inappropriately group types of drugs that vary widely in how they affect consumers whose own symptoms also vary so greatly. However, at the very least, to rectify the overly broad classifications of anti-depressants included in the draft guidelines, USP must instead use the classifications included in the list of drug classes developed for the Medicare discount card which establishes separate classes for alpha-2 receptor antagonists (NaSSA), Monamine Oxidase (MAO) Inhibitors, Norepinephrine & Dopamine Reuptake Inhibitors (NDRIs), Serotonin-2 Antagonist/Reuptake Inhibitors (SARIs), Selective Serotonin & Norepinephrine Reuptake Inhibitors (SSRIs & SNRIs), Tricyclics & Related (Non-select Reuptake Inhibitors), and Anti-depressant Combinations. These classes more accurately reflect the wide variation among these highly specific medications and will help encourage health plans to provide adequate drug coverage for Medicare beneficiaries -- a disproportionate number of whom struggle with depression often in conjunction with other co-morbid illnesses and they desperately need mental health treatment carefully tailored to their complex needs.

Anti-Psychotics

In the classification of anti-psychotics, USP has shown some recognition of the importance of covering newer, more effective medications in establishing a separate category for atypical anti-psychotics. But, even this category is overly broad. Newer, atypical anti-psychotics have been shown to be more effective and display fewer side effects. Older medications are not as effective (for instance, they do not alleviate the symptoms of apathy and withdrawal) but even worse are the pervasive, uncomfortable, and sometimes disabling and dangerous side effects evident in an estimated 40 percent of patients (e.g., muscle spasms resulting in abnormal and usually painful body positions, tremors and muscle rigidity, involuntary repetitive movements often of the face, mouth, or hands, and painful muscular restlessness requiring the person to move constantly.) Nonetheless, even within the proposed class of atypicals, anti-psychotics are even less interchangeable than SSRIs. Research shows that different antipsychotic medications (including atypicals) affect separate portions of the brain and affect the brain in very different ways. There are two or more distinct types of atypical anti-psychotics that each have different chemical structures, mechanisms of action, and clinical outcomes. As a result, they have varied clinical and side effects. In addition, the signs and symptoms of schizophrenia vary greatly among individual consumers. Moreover, some of these newer, more effective atypicals have the unfortunate side effect of increasing the risk of diabetes**. With the very troubling side-effects common in both older and new-generation anti-psychotics, it is extremely important that beneficiaries have access to the full array of these medications.** As with anti-depressants, any classification that is not broken down by individual anti-psychotic medications will group together medications that have very different effects on the brain and on the well-being of individual mental health consumers.

Failure to Address Specific Illnesses

Despite the fact that the USP states that it adopted a disease-based approach in developing these proposed guidelines and included many categories clearly linked to specific diseases, the guidelines fail to include separate therapeutic categories to address either anxiety or attention deficit-hyperactivity disorder (ADHD). Treatments for anxiety presumably are intended to be covered, in part, under the therapeutic category entitled Sedatives/Hypnotics. However, this broad category is not broken down into any classes, and thus plans would only have to cover two of these drugs in order to be in compliance with the USP's guidelines. This approach would clearly encourage coverage of older drugs within this class which are both addictive and very dangerous in cases of overdose. It is important to have coverage for an anti-anxiety medication that is not sedating. In

addition, several of the reuptake inhibitors are effective in treating anxiety, but would physicians have to diagnose patients with depression before they could receive these drugs? Medications to treat ADHD presumably are intended to be covered by the category entitled Central Nervous System Stimulants, but this is not clear. In addition, this categorization would deny coverage of newer non-stimulant treatments for this disorder. USP has indicated that they left out some categories and classes in order to avoid duplication, but this approach risks confusing health plans into thinking that they may not need to cover drugs for certain illnesses, like anxiety and ADHD. We urge USP to include separate therapeutic categories for both anti-anxiety agents and treatments for ADHD and to provide greater specification within these classes to promote coverage of non-sedating treatments and reuptake inhibitors for anxiety as well as newer, non-stimulant treatments for ADHD.

The USP-proposed guidelines include one broad category for "Bipolar Agents" which we presume is meant to cover treatments for bipolar disorder, but no classes are included to ensure coverage of the many different treatments for this complex disease. Individuals with bipolar disorder typically take a variety of medications including anti-convulsants, anti-depressants, and anti-anxiety medications. This is a devastating disease that requires individualized and comprehensive treatment. The inclusion of this broad category without further specification of the types of medications that must be covered will likely cause confusion among health plans offering the Medicare drug benefit. We urge USP to consult with experts in the treatment of bipolar disorder to establish very specific classes of medications under this category.

We are also concerned by USP's proposal to only establish one class for all anti-convulsants. Certain anti-convulsants have proven effective as off-label treatments for bipolar disorder. By only establishing one class for all anti-convulsants, of which there are over twenty, the draft guidelines again would encourage health plans offering the drug benefit to cover only the older, less efficacious medications. The older drugs are more dangerous and cannot be used when consumers have certain medical conditions.

Medicare Beneficiaries' Needs Must Not Be Compromised

USP states repeatedly that it has tried to remain sensitive to the practicalities required for the prescription drug plans to utilize the proposed guidelines and the fact that more classes of drugs would make it harder for drug plans to negotiate savings with pharmaceutical manufacturers. This concern appears to have been given equal or even greater weight than assuring beneficiaries access to the drugs they need. A drug-classification system that ultimately fails patients cannot be deemed a success simply because it maximizes negotiating opportunities. This concern with securing drug plan savings is highly inappropriate. If anything, USP should concern itself with preventing overly restrictive drug plan formularies from driving up federal government Medicare costs when beneficiaries who are denied the medications they need, find themselves instead in hospital or nursing home beds, utilizing more expensive services not covered by the drug plans but which the federal government pays for under Medicare or Medicaid.

The costs of denying adequate drug coverage have been forcefully described by Michael Hogan, former Chair of President Bush's New Freedom Commission on Mental Health and Director of the Ohio Department of Mental Health, in a recent letter urging CMS Administrator Mark McClellan to maintain the progress states have made in ensuring open access to psychotropic medications in most states' Medicaid programs for the dual eligibles when their drug coverage is transferred to Medicare. In this letter, the mental health directors state that they too have struggled to find a balance between containing the costs of drug benefits while also ensuring beneficiaries have access to all clinically appropriate treatment options. "We have come to understand through direct experience with the consequences and benefits, respectively, of the grave risks of limiting care and the clear advantages to assuring access to effective psychiatric care for this population". One of the lessons they have learned that they describe in this letter is the understanding that "most psychotropic medications, even if classified within the same therapeutic category, are not clinically interchangeable . . . each has a different set of

specific mechanisms 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." They also state, speaking from experience, that consumers "who are not adequately treated or treated with the wrong therapeutic agent tend to utilize more costly crisis intervention, inpatient hospital, and intensive case management services." They also claim that these consumers will be less adherent to prescribed medications from that point forward – even when given a more clinically appropriate treatment.

The proposed guidelines for coverage of mental health medications are troubling in many respects and our overriding concern is that the overly broad categorization of these medications will encourage health plans offering the Medicare drug benefit to cover only older, less expensive and usually less effective, medications. The Centers for Medicare and Medicaid Services (CMS) has very recently stated that newer psychiatric medications, including SSRIs and atypical anti-psychotics, are more efficacious and that limiting access can have a negative effect on quality. Centers for Medicare and Medicaid Services, Technical Assistance Paper for State Medicaid Directors, "Psychiatric Medications: Addressing Costs without Restricting Access", August 20, 2004. We urge the USP to revisit these categories with the following recommendation of the President's New Freedom Commission on Mental Health in mind, that "[a]ny effort to strengthen or improve Medicare and Medicaid programs should offer beneficiaries options to effectively use the most up-to-date treatments and services." New Freedom Commission on Mental Health, *Achieving the Promise: Transforming Mental Health Care in American. Final Report*, p. 26. With these guidelines the USP has failed to achieve its stated goal of assuring beneficiaries access to the drugs they need, and we urge revision of these guidelines to address the concerns we have outlined above.