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April 27, 2005

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

Dear Dr. McClellan:

We met with members of your staff on March 10, 2005 to discuss our concerns regarding the transition of prescription drug coverage for Medicare/Medicaid dual eligibles with mental illness from Medicaid to Medicare. We greatly appreciate their time and consideration of our views. Our discussion focused on the high rate of mental illness among dual eligibles and special protections needed to ensure that these individuals do not suffer gaps in coverage or forced switching of medications when they are enrolled into the new Medicare Part D benefit in 2006.

In addition, we were greatly encouraged by Abby Block's recent comments about CMS oversight of Part D drug plans, comments she made in representing CMS on March 14th at a conference held by the National Council for Community Behavioral Healthcare and on March 25th on a teleconference call with the National Association of State Mental Health Program Directors. Ms. Block assured us that beneficiaries in Part D plans will have access to a full array of psychiatric medications when they are medically necessary and that, in the transition from Medicaid to Medicare, dual eligibles stabilized on medications for mental illnesses will not need to switch. She asserted that CMS's review processes – through close scrutiny of how drug plans will handle formularies, utilization management, step therapy, drug transition issues, and medical review of non-formulary drug requests – will ensure that plans' procedures will safeguard against disruptions in treatment.

Nonetheless, having more specific information about the standards CMS will employ in reviewing drug plans' bids would heighten our sense of confidence that beneficiaries will not experience disruptions, and we would welcome further explanation of these standards by CMS. In addition, we hope that you will adopt further requirements to foster continuity of care for beneficiaries transitioning into the new benefit.

The transition into Part D will be particularly difficult for many individuals with mental illnesses. Thus, we urge you to require plans to provide transition supplies of non-formulary mental health medications until that beneficiary has had the opportunity to

complete all levels of the exception and appeals process. We also believe that these medications should be provided to beneficiaries: 1) at the lowest co-pay level; and 2) without being subject to any prior authorization or other restrictive requirements.

Mental health medications differ significantly in their effects on individual consumers. For example, while the different types of selective serotonin reuptake inhibitors (SSRIs) may be similar, in that they block the reuptake of serotonin by binding to and inhibiting the serotonin transporter, each medication is structurally different. Therefore, each one binds to a specific set of receptors, proteins, and enzymes associated with nerve cells that use serotonin.[1] In addition, each SSRI has a distinct profile of side effects, and varies widely in how long it takes to clear the patient's system. Other psychotropic medications, including other anti-depressants and anti-psychotics, also have unique characteristics and effects on consumers.

Physicians must take many different factors into account in prescribing mental health medications, including past treatment history, likely responses to side effects (which can be debilitating), other medications currently being taken, any co-morbidities (which are common among individuals with mental illness), and overdose safety, given the heightened risk of suicide. Formulary restrictions and utilization management techniques that force dual eligibles with mental illnesses to switch medications against the recommendations of their treating physicians will prove highly detrimental to the health and recovery of many of these beneficiaries.

Moreover, abrupt changes in psychiatric medications bring the risk of serious adverse drug interactions, and each failed trial results in suffering and the possible worsening of a person's condition. People who switch from one SSRI to another, for example, tend to remain in treatment 50 percent longer than those who remain on the same medication, and their treatment typically costs about 50 percent more than it would, had they been allowed to continue taking a medication that had already been deemed appropriate.[2]

Consequently, the current best practice for transition plans in states establishing Medicaid preferred drug lists includes continued coverage of antipsychotics and antidepressants for mental health consumers whose conditions have been stabilized on these medications. States have implemented these continuity-of-care provisions, either through legislation (e.g., New Hampshire) or through less formal administrative means (e.g., West Virginia). Furthermore, most states that have implemented preferred drug lists have simply exempted mental health medications from them.

The guidance recently issued by CMS regarding the transition processes that Medicare drug plans must have in place, however, falls far short of these best practices. Instead, it merely encourages plans to provide a temporary, 30-day supply of off-formulary

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[1] 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.

[2] 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.

medication while affected enrollees are expected to work with their physicians to switch to on-formulary medication or complete an exception request. This approach assumes that switching to alternative medications is a simple and harmless proposition, but nothing could be farther from the truth for individuals facing mental illness.

The recommended 30-day timeframe for transition medication may not allow enrollees enough time to even get an appointment with their physician. It is unrealistic to expect that the enrollee will also have time after the appointment to file an exception request, receive a final determination on it, then pursue and complete an appeal from a denial, all within 30 days. Especially in the early stages of this new and complex drug benefit, physicians will be overwhelmed with requests for assistance in this regard, as will the entire exceptions and appeals process. It will be impossible for dual eligibles with severe mental illnesses to navigate this complicated exceptions and appeals process, especially if they are not provided with the medications they need throughout the entire process.

Moreover, allowing beneficiaries only 30 days of medication while they pursue exceptions requests and appeals is inconsistent with CMS's own determination in the final Part D regulation that plans must provide 60 days' notice or a 60-day supply of relevant medication before making a change to their formularies. The 60-day period anticipates time for enrollees to pursue exceptions and appeals, despite that it is not necessarily a sufficient time span. Why would individuals newly enrolled into this complex benefit need less time?

As we stated above, current best practices dictate continued coverage of mental health medications, especially where: 1) dual eligibles with mental illnesses have been stabilized on the medications; and 2) the medications have lengthy periods of administration prior to onset of clinical effect. Consumers often need three to six weeks before they can become accustomed to the side effects and may begin to notice the therapeutic effects of anti-depressants and anti-psychotics. Forcing consumers to switch medications in the midst of this process may force them to re-experience debilitating side effects before a drug's effectiveness can even be determined. This prolonged adjustment period from drug switching will cause many patients to become discouraged and opt out of medication as a treatment choice.

We urge CMS, at the very least, to revise its transition process guidance to require that plans provide a transition supply of any mental health medications for the entire period that the beneficiary requires to complete the administrative remedies process, which includes filing an exception request and receiving a final appellate determination, if pursued after denial of that request. If a beneficiary does not file an exception request within a given period, then it may be reasonable to restrict the transition medications to a specific timeframe.

Furthermore, upon issuing the first transition supply of mental health medications to a dual eligible, CMS should require the plan to notify the prescribing physician that this medication is not on the formulary and that his or her patient will have to obtain an exception, in order to secure continued coverage. This notification would help ensure

that dual eligibles faced with mental illness actually take advantage of the exceptions and appeals process which will be bewildering and daunting for many.

We look forward to working with you to incorporate these protections for dual eligibles with mental illness into CMS's transition process guidance.

Sincerely,

American Psychiatric Association
National Alliance for the Mentally Ill
National Association of State Mental Health Program Directors
National Council for Community Behavioral Healthcare
National Mental Health Association
Treatment Effectiveness Now

cc Abby Block, CMS
Julie Goon, CMS
Leah Kegler, CMS