



March 16, 2006

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Executive Director
NASMHPD

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

Dear Dr. McClellan:

On behalf of the National Association of State Mental Health Program Directors (NASMHPD), I am writing to offer our appreciation for the recently issued guidances on formulary and transition policies for prescription drug plans and Medicare Advantage (MA) plans for the Medicare Part D program for 2007. We are very supportive of both guidances and see them as critical protections for ensuring that all Medicare beneficiaries with mental illness – especially those dually eligible for both Medicare and Medicaid – are able to make a smooth transition to Part D and maintain access to the specific medications prescribed to them over the long-term. NASMHPD strongly supports renewal of both of these protections for 2007 and it is our hope that CMS will work toward making both a permanent part of the regulatory standards in place for Part D so that they will not have to be renewed on an annual basis.

In response to CMS's announcement of renewal of both guidances for 2007, NASMHPD would like to offer a few comments. In regards to the "Transition Guidance," NASMHPD strongly supports the principle of "continuity of care" requiring PDPs and MA plans to refill any and all medications prescribed to enrollees who are currently stable on a drug within the 6 protected classes. This guidance is most critical to those with mental illness who, without coverage of medications, even for brief periods of time, can have a life-threatening recurrent episode of symptoms.

The extension of this protection through March 31, 2006, has been extremely helpful to many dual eligibles in the first months of this benefit and we would encourage making it permanent. If in the initial coverage period, Part D plans are allowed to impose coverage restrictions such as prior authorization requirements, dosage limitations, and formulary exclusions, we fear some enrollees may

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destabilize into acute episodes of their illness. This, of course, can have human and financial costs such as hospitalization, interaction with the criminal justice system and homelessness.

Thus, if a beneficiary – especially a dual eligible – is prescribed a medication prior to enrollment and is stable on that medication, it should be deemed efficacious and covered immediately. The renewed guidance adheres to this principle and NASMHPD is grateful for its being continued for 2007.

In reference to the “Formulary Guidance,” NASMHPD strongly supports the tenet of requiring PDPs and MA plans to cover “all or substantially all” of the medications commonly prescribed to treat mental illness, including anti-psychotics, anti-depressants and anti-convulsants. NASMHPD is very appreciative that CMS has renewed this guidance for 2007. Continuation of these protections will ensure that prescription drug coverage is effective and uninterrupted for those who are most vulnerable: Medicare beneficiaries living with chronic illnesses with complicated treatment needs and high drug costs.

NASMHPD also believes that all Part D enrollees with serious mental illnesses are at-risk for discontinuing their medications when forced through extraordinary utilization management edits. We would like to suggest that enrollees with serious mental illness be exempt from prior authorization and step therapy (not just those currently stable on a drug within the 6 protected classes). Further, as an alternative to uniform imposition of restrictive policies such as prior authorization and step therapy, NASMHPD agrees with our colleagues who recommend consideration of strategies outlined by your colleagues at SAMHSA in their report “Psychotropic Medications: Addressing Costs Without Restricting Access”:

1. Identification and reduction of polypharmacy,
2. Adoption of treatment algorithms for serious mental illness, and
3. Educational interventions and outlier management programs aimed at aligning prescribing patterns with recognized best practice guidelines.

Further, NASMHPD is concerned that PDPs and MA plans are not required to cover all dosage strengths for the drugs covered within the 6 protected classes. Many enrollees with severe mental illness require certain dosage strengths well above those which are covered by many plans. This situation has caused many enrollees to be denied coverage at their prescribed level of need and forced into lengthy appeal processes because they have violated a plan’s quantity limit. Medications listed in the

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six classes represent a broad range of therapeutics, many of which require a wide range of strengths to accommodate specific therapeutic needs and dosage adjustments. NASMHPD would urge adoption of an "all or substantially all" policy pertaining to dosage strengths, similar to the policy of "all or substantially all" medications covered within the 6 protected classes.

NASMHPD thanks you for your leadership in focusing on the interests of beneficiaries with mental illnesses and the opportunity to comment on these important guidance policies. For the vulnerable Medicare beneficiaries we represent, renewal of both of the Transition and Formulary policies is very critically important. We look forward to working with you and your staff to ensure that the future Medicare Part D is a successful one.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert W. Glover", with a long horizontal flourish extending to the right.

Robert W. Glover
Executive Director