



**NACBHD**  
National Association of County  
Behavioral Health and  
Developmental Disability  
Directors

Mark McClellan, M.D.  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Dr. McClellan:

On behalf of the National Association of County Behavioral Health and Developmental Disability Directors (NACBHD), I am pleased to submit comments and recommendations in response to the draft Guidelines for Reviewing Prescription Drug Plan Formularies and Procedures issued by the Centers for Medicare & Medicaid Services (CMS) on February 24, 2006. NACBHD appreciates your agency's effort to protect the most vulnerable in our communities.

### ***Who We Are***

The National Association of County Behavioral Health and Developmental Disability Directors (NACBHD) is comprised of county/city governments and county sponsored authorities responsible for the management and delivery of behavioral health and developmental disability services. NACBHD is the only behavioral health and developmental disability services affiliate of the National Association of Counties (NACo).

In 1999, county/city governments and county sponsored behavioral health and developmental disability authorities contributed over \$15 billion dollars to ensure services. County/city governments and county sponsored behavioral health authorities in 22 states either directly or indirectly provide mental health services to 70% of the US population. In 18 states, county/city governments and county sponsored behavioral health authorities ensure delivery of substance abuse services to 60% of the US population. Local authorities are also responsible in 15 states for the delivery of developmental disability services that reach over 50% of the US population.

Given that the NACBHD membership is in direct contact with those impacted by implementation of the Medicare Modernization Part D, it is our hope that CMS will do what it can to incorporate the following comments and recommendations. Although not directly on topic of this correspondence, please note that our members and local governments filled in the "gap" as transition began on January 1, 2006. If not for the actions of the NACBHD membership and local government authorities, many of the most vulnerable would have gone without the medications they need to stay healthy and in communities.

## ***Comments and Recommendations***

Overall, NACBHD recognizes the hard work of the staff of the Centers for Medicare and Medicaid Services (CMS) during the roll-out of Part D. CMS staff has done an excellent job in keeping the community aware of federal policy making and of resources to assist with transition. Further, the staff has been most responsive to requests for support and information. Given this, NACBHD is confident that its comments and recommendations as well as those of the advocacy community will be considered and implemented where possible.

### **All or Substantially All**

NACBHD is most encouraged that CMS proposes to continue the policy that requires plans to cover “all or substantially all” drugs in the six approved classes. However, NACBHD recommends that CMS consider that the policy of “all or substantially all” (AoSA) be defined to include the full range of drugs in these classes and in a dosage that is necessary and effective based upon individual need and response. Unfortunately, our members have reported that limitations on dosage and form have been imposed on beneficiaries. There have also been numerous reports of patients who are unable to continue on the medications that they were stable on prior the start of Part D. It is our hope that these patients will be able to gain access to their medications without the barriers that the plans are creating. It is also our hope that the AoSA category expand, including other mental health diagnoses but are not limited to, bipolar disorder, anxiety disorder, dementia, and substance use disorders.

The proposed limitation on the inclusion of new medications is of concern to NACBHD. Our members believe that such limitation is inappropriate for those with behavioral health and developmental disabilities given the scientific discoveries that are improving function and quality of life. Further, NACBHD does not believe that the “exceptions” process will facilitate beneficiary access as these processes are not yet effective and have created excessively long waiting times for resolution.

NACBHD also supports and encourages CMS to modify the “all or substantially all” policy to encompass all dosages and forms, including “extended release” medications.

### **Formulary Review**

NACBHD is aware of the efforts that CMS has made to ensure that plans provide required formularies and to facilitate access related to placement on tiers (e.g. cost sharing impacts). While CMS has provided strong oversight and careful evaluation, NACBHD supports further development in this area. For example, many in the field are reporting that plans have placed the newer most effective medications (with the fewest side effects) on the highest cost tiers. This is obviously a barrier to those with mental health needs and few resources available to meet the increased costs. As we all are

aware, these newer antipsychotic medications have greatly improved quality of life for those with serious mental illnesses.

### **Utilization/Benefits Management**

Plans have the ability to manage utilization through various mechanisms such as prior authorization, step therapy, and quantity limitations. NACBHD urges CMS to ensure that utilization management tools are appropriately used and do not create additional barriers to access—as was experienced by many during Part D start up. There are many pharmacy benefit management techniques that are not appropriate for persons with serious mental illnesses because of their clinical vulnerability. Restrictive UM practices, such as step therapy and others, can actually cause delays in successful treatment that require many weeks to reach therapeutic effectiveness thus limiting likelihood of effective care. This and other complications for patients can actually discourage enrollment in Part D.

### **P&T Committees**

NACBHD is encouraged that CMS will continue to review the work of the P&T Committees. However, NACBHD does propose the following as opportunities to strengthen the role that P&T Committees can play in ensuring access. For example, NACBHD supports the new requirement of review of new medications within 90 days of release onto the market and that justification for not meeting this timeline should be provided to CMS. CMS should also require P&T Committees to document reasons for removing a drug from a plan formulary.

### **Define a “Medical Necessity” Standard**

CMS should clarify the “medical necessary” standard, as set forth at 42 CFR 423.578 (b) (5) to define documentation expectations and to ensure uniform application of this standard across all Part D plans. Lacking this clarified definition, some plans could (and are) adopt very restrictive standards thus limiting access under the exceptions process.

### **Transition Guidance**

NACBHD is encouraged that CMS has extended the transition period through March 31, 2006—especially given the uneven application of “continuity of care” requirements on the part of some of the plans (not all of which may have been intended). “Continuity of Care” is crucial for those with serious mental illnesses. Any delay in medication can be disastrous. NACBHD also agrees with the advocacy community and with CMS in that “continuity of care” must also be imposed when a dually eligible individual is stable on a medication—whether or not the plan uses utilization management tools like prior authorization or step therapy.

NACBHD also encourages CMS to consider these “continuity of care” requirements as some dually eligibles may be reassigned to new plans that meet the “below benchmark level” criteria for 2007.

The National Association of County Behavioral Health and Developmental Disability Directors (NACBHD) is most appreciative of the opportunity to comment on these critical guidelines. We hope that you use our association to assist with further policy developments.

Thank you for your time and consideration.

Sincerely,

Melissa M Staats, MA MSW  
President and CEO