



March 5, 2014

**Board of Directors**

Michael Maples, L.P.C., L.M.F.T.  
President  
*Texas*

Scot L. Adams, Ph.D  
Vice President  
*Nebraska*

Lisa Clements, Ph.D.  
Secretary  
*Colorado*

Terri White, M.S.W.  
Treasurer  
*Oklahoma*

Kevin Huckshorn, Ph.D., R.N., M.S.N.,  
C.A.D.C., I.C.R.C.  
Past President  
*Delaware*

Patricia Rehmer, M.S.N.  
At-Large Member  
*Connecticut*

Lynda Zeller  
At-Large Member  
*Michigan*

Tracy J. Plouck  
Mid-Western Regional  
Representative  
*Ohio*

Craig Stenning  
Northeastern Regional  
Representative  
*Rhode Island*

Doug Varney  
Southern Regional  
Representative  
*Tennessee*

Cory Nelson, M.P.A.  
Western Regional  
Representative  
*Arizona*

Robert W. Glover, Ph.D.  
Executive Director  
*NASMHPD*

Marilyn Tavenner, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244

**Re: Proposed Regulations: Medicare Program; Contract Year 2015  
Policy and Technical Changes to the Medicare Advantage and the  
Medicare Prescription Drug Benefit Programs (CMS-4159-P)**

Dear Administrator Tavenner:

The National Association of State Mental Health Program Directors (NASMHPD) appreciates the opportunity to respond to the proposed Medicare regulations, published January 10, 2014, governing Policy and Technical Changes to the Medicare Advantage and Prescription Drug Benefit Programs for Contract Year 2015.

NASMHPD is the only member organization representing the state executives responsible for the \$37 billion public mental health service delivery system serving 7.2 million people annually in all 50 states, 4 territories, and the District of Columbia. NASMHPD operates under a cooperative agreement with the National Governors Association.

While we are very supportive of the efforts by the Centers for Medicare and Medicaid Services (CMS) to ensure cost-effective utilization of Part D drugs, we must express some reservations regarding the proposals to summarily eliminate the Part D protected drug category designation for antidepressants in CY2015 and antipsychotics in CY2016. The reasons for our concerns are outlined below, with a suggested alternative approach to achieving effective drug and cost utilization.

**Public Mental Health Policy Requires A Balancing of Best Practice,  
Sensitivity to Individual Patient Variability, and Cost-Effective Stewardship**

As careful custodians of state and federal funds ourselves, NASMHPD's members recognize the importance of maximizing the cost-effective utilization of public funds in administering public mental health programs, particularly those programs designed to afford essential healthcare coverage to seniors and individuals with disabilities who often lack the resources to gain ready access to affordable care.

Effective public mental health program policy involves several balancing acts:

- (1) providing "all" maximally effective services within the context of limited resources;
- (2) articulating clear practice standards in the context of scientific uncertainty;
- (3) effectively guiding good practice without interference in clinical decision-making; and
- (4) harmonizing the often conflicting objectives of multiple stakeholders, including patients, providers, pharmaceutical manufacturers, and state political and fiscal officials.

Our states' Medicaid programs long ago acknowledged by implementation the need for reasonable and timely prior authorization procedures while safeguarding patient health and safety. In the pharmacy realm, this stewardship approach took the form of implementing appropriate preferred drug lists (PDLs) designed to prevent waste and avoid fraud and overutilization while at the same time ensuring that medically necessary drugs are available and accessible in a timely manner.

While an open formulary with unrestricted access to all antidepressant and antipsychotic medications will almost always be clinically desirable because it allows unfettered clinical decision-making without additional administrative burden, it has the disadvantage of reducing the government's ability to limit cost and encourage evidence-based best practice. Our states' experience with Medicaid PDLs has driven home the importance of ensuring that the entities negotiating drug prices and rebates with pharmaceutical manufacturers—whether they be state Medicaid programs, pharmaceutical benefit managers, or Medicare Part D prescription drug plans—have the ability to leverage program parameters in negotiating reduced pharmaceutical costs and avoiding inappropriate and/or excessive utilization.

At the same time, with regard to the Part D program, we believe that the factors still exist that led CMS in 2005 and Congress in 2008 to recognize that some drug classifications deserve particular protection from over-broad utilization controls. While we acknowledge that generic equivalents and therapeutic equivalents for specific antidepressants and antipsychotics have become more available over the last decade, treatment with mental health medications—more so than any other treatment—must be individualized to promote optimal patient outcomes. The particular variability of individual patient responses to specific antidepressants and antipsychotics—not only on first administration but also subsequently, over time—demand a unique perspective on utilization controls that treatments for physical ailments and conditions may not necessitate.

Any prescribed treatment with antidepressants or antipsychotics must be effective, safe, and tolerated by the patient as optimally as possible. The appropriateness of any treatment should be informed by best evidence and constantly evolve in response to new information, both with regard to the individual patient's health, vulnerabilities, and preferences and with regard to clinical and scientific findings and the market availability of the treatment. Treatment with mental health drugs must provide unique value in terms of the patient's improved quality of life and ability to achieve increased independence. Only once these criteria have been met should issues of cost guide medication selection.

There is no best medication or best dose for all patients. Treatment of any individual patient with an antidepressant or antipsychotic medication requires balancing efficacy and tolerability. The choice of a antidepressant or antipsychotic and its dosage, and subsequent decisions about

changes in treatment, require careful initial consideration and ongoing, shared decision-making between the patient and the prescribing provider.

**Continue to Protect the Antidepressant and Antipsychotic Categories,  
Within the Context of Effective Utilization Controls that Protect the Member**

Given the significant individual patient variability in responses to treatment, all marketed antidepressant and antipsychotic medications should be readily available and accessible under the Medicare Part D program to members who require them for treatment. Within that context and where appropriate, reasonable and transparent prior authorization and step therapy procedures that safeguard appropriate use but also ensure timely availability and accessibility should be permitted, within the bounds of the limitations currently permitted for protected drug classifications under 42 CFR 423.120(b)(2)(vi)(A).

Where two mental health drugs are found by the Food and Drug Administration (FDA) to be therapeutically equivalent, the entity administering utilization controls should be authorized to require a prescribing provider to show through prior authorization that the effects of the two drugs on the specific patient vary, due to accompanying side effects or adverse drug interactions, or as demonstrable through past health outcomes for that individual patient. Similarly, as these regulations propose, point-of-sale safety edits should be permitted where those edits are based on labeled maximum daily dosages and frequencies or black box warnings mandated by the FDA. Controls are also appropriate on any off-label use that is not clearly supported by peer-reviewed medical or pharmaceutical research published in nationally recognized medically- or pharmaceutically-related professional publications.

With that said, a member should have to face few, if any, obstacles under the Part D program to getting an effective and safe antidepressant or antipsychotic medication on which he or she is currently stable. To assure this, the following program designs should be but in place:

- If a mental health medication is known or proven to be safe and effective for a patient moving into the Part D program, he or she should remain “grandfathered” on that medication for a clinically reasonable period to minimize risk of relapse and support continuity of care.
- Part D mental health medication re-authorization procedures should be simple and flexible, and re-authorization should be for a clinically reasonable period.
- Part D members should not be forced to switch medications due solely to changes in program or plan formulary policy or prior authorization procedures, or a change in the identity of the utilization control entity or payer responsible for the benefit.

If the required switching of a Part D member to another antidepressant or antipsychotic medication is found to be appropriate on its face, a transition period should be mandated during which outcomes and metabolic and motor side effects are closely monitored by the prescribing provider and the entity administering utilization controls. If negative outcomes or side effects result from the switch to another medication, program regulations should mandate that access to the original medication be reinstated immediately. In particular, switching antipsychotic medications in schizophrenia carries significant risk and should be undertaken and monitored carefully.

March 5, 2014

Page 4 of 4

At the same time, continuation of any mental health drug in the absence of evidence of the desired benefit and/or in the presence of significant adverse effects is also inappropriate. In those cases, careful and informed switching to a suitable alternative medication may and should be considered.

In conclusion, NASMHPD recognizes and appreciates the factors that drive the need to loosen restrictions on utilization controls inherent in the categorization of the antidepressant and antipsychotic drug categories as “protected.” However, we suggest that, instead of eliminating the designation of those categories as protected, CMS reconsider what the “protected” designation means, authorizing meaningful and reasonable utilization controls for antidepressants and antipsychotics within the context of protecting Part D member health and safety.

If you should have further questions about NASMHPD’s comments, please contact NASMHPD’s Director of Policy and Health Care Reform, Stuart Gordon at [stuart.gordon@nasmhpd.org](mailto:stuart.gordon@nasmhpd.org) or by telephone at 703-739-9333.

Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert W. Glover". The signature is fluid and cursive, with a long horizontal stroke at the end.

Robert W. Glover, Ph.D.  
Executive Director