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**VIA ELECTRONIC SUBMISSION:** [www.regulations.gov](http://www.regulations.gov)

March 13, 2009

Charlene Frizzera  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Room 445-G  
Washington, DC 20201

**RE: Medicare Program: Medicare Advantage and Prescription Drug Programs MIPPA  
Drug Formulary & Protected Classes Policies**

Dear Ms. Frizzera,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on the interim final rule with comment period titled "Medicare Program: Medicare Advantage and Prescription Drug Programs MIPPA Drug Formulary & Protected Classes Policies" as published in the January 16, 2009, *Federal Register* [CMS 4138-IFC4; RIN 0938-AP24].

We are specifically providing comments on the impact of the drug formulary and protected classes policies on the individuals who are served by our member organizations – individuals who are experiencing severe mental and addictive disorders.

#### **ABOUT NAPHS**

Founded in 1933, NAPHS advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations, including more than 600 psychiatric hospitals, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, outpatient networks, and other providers of care. Our members deliver all levels of care, including inpatient care, residential treatment, partial hospitalization services, and outpatient services. These services are paid for by all types of payers, including Medicare as well as commercial insurers, Medicaid, states, and others.

## **COMMENTS AND CONCERNS**

As medication policies are developed, we believe that it is critical to pay particular attention to the specific needs of individuals experiencing psychiatric and substance use conditions.

### **Lack of access to medication can result in serious consequences for behavioral health patients.**

Without access to their medicines, behavioral health patients are at risk of decompensation into psychiatric crisis and attendant contact with emergency rooms, homelessness, incarceration, or even suicide. Robust clinical evidence indicates that a patient's cognitive function does not fully recover after each psychiatric episode.

### **The need for stabilization in this patient population is a priority for providers, clinicians, and families.**

Patient access and adherence to psychotropic medication regimens is an essential prerequisite for a stable clinical condition. Uncontrolled symptoms make it difficult for patients to follow their comprehensive behavioral health treatment plan and are a direct contributor to serious alcoholism and substance abuse.

### **Congress originally granted the Centers for Medicare and Medicaid Services (CMS), through the *Medicare Modernization Act (MMA)*, the authority to protect certain vulnerable patient populations against discrimination with regard to Part D coverage.**

No language in MIPPA directs CMS to abandon its original mandate in MMA to prevent discrimination and ultimately ensure that beneficiaries reliant upon certain drugs would not be substantially discouraged from enrolling in certain Part D plans as well as be able to access necessary therapies once in a plan. With no changes in CMS' authority laid out in MIPPA, it follows that CMS remains responsible for protecting vulnerable patients from discrimination with regard to access regardless of the process established around the protected classes.

### **The mandated expert panel should be structured in a way that keeps the unique interests of behavioral health patient populations in mind.**

The panel should consist of three to four actively practicing physicians with documented experience in caring for Medicare patients that fall within the therapeutic areas treated by these classes of drugs and should also include three to four individuals representing patient and consumer advocacy groups. The interim final rule's inclusion of pharmacists as the only non-physician stakeholder on the panel is unbalanced, allowing for representation of one stakeholder over others. To add any significant value to the patient, all interests must be represented. Should CMS impanel pharmacists, it should follow that representatives be included from patient groups, health plans, and pharmaceutical manufacturers.

### **Exceptions and coverage changes must be clearly communicated, and ample time must be afforded for medication changes.**

Due to the uniqueness of each patient's therapy and the complications associated with switching patients from one medication to another, providers and patients must be given ample time to consider and try alternative therapies if their current medications are no longer covered as the result of an exemption of the class or a change in qualification as a class of clinical concern. CMS should select multiple methods to quickly communicate

changes to patients and providers (e.g., online resources, e-mail notifications, provider newsletters, etc.).

## **RECOMMENDATIONS**

We believe that it is important that protected classes be maintained, and we suggest that an open process be implemented to prevent barriers to access now and in the future.

- 1) We urge that the Centers for Medicare and Medicaid Services continue to protect vulnerable behavioral health patients with regard to access to medications.
- 2) We recommend that CMS construct an expert review panel that includes representatives of patient and consumer advocacy groups, health plans, and pharmaceutical manufacturers.
- 3) We recommend that CMS ensure a process for rapid communication to providers and consumers of exceptions and coverage changes.

## **CONCLUSION**

Thank you for your consideration of our comments. We look forward to continuing to work with the Department of Health and Human Services and the Centers for Medicare and Medicaid Services to ensure that Medicare beneficiaries continue to have access to the prescription medications that are essential to their recovery.

Sincerely,

Mark Covall  
President/CEO