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March 5, 2014

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

**RE: CMS-4159-P: “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” (RIN 0938-AR37)**

Dear Ms. Tavenner,

As an association representing mental health and addiction treatment organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on the proposed rule (CMS-4159-P) titled “Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs” as published in the January 10, 2014, *Federal Register*.

#### **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 mental health and addiction treatment organizations, including more than 700 psychiatric hospitals, addiction treatment facilities, 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, and outpatient services.

#### **COMMENTS**

We write to express our concern about the 2015 proposed elimination of the category of antidepressants (and the proposed elimination in 2016 of the category of antipsychotics) as protected categories within the Part D benefit. We believe that the change will make it more difficult for some of the most vulnerable Part D beneficiaries to receive the medications necessary for them to live successfully in the community.

Many beneficiaries with mental illness diagnoses (approximately 56%) are covered by Part D by virtue of their disability status. They are younger, poorer, and “dually eligible” for both Medicare and Medicaid benefits. They are beneficiaries who can be expected to live long lives in the community and do not fit into a definition of “typical patient” to which CMS refers in the proposed rule. Several times within the proposed rule, the use of antipsychotics with elderly persons with dementia is identified as an

overutilization of drugs within the antipsychotic class. While this is of concern, it does not account for the majority of psychotropic drugs used in Part D plans for this population.

The people our members serve have long durations of illness, often with the need for medication over their lifespan. Unfortunately, psychiatric drugs are not interchangeable (even within classes). Drugs that were once effective for an individual can lose effectiveness and need to be replaced by others. People have very different responses to different antidepressants and antipsychotics. A given drug often needs to be replaced by another which works more effectively. Prescribers must take into account factors such as a patient's gender, age, co-occurring psychiatric conditions, and co-occurring medical conditions when making decisions about specific medications. Beneficiaries need access to the full range of choices.

One criterion used to identify the need for protected classes is that access to all drugs in the category is required within 7 days for a typical individual treated with those drugs. If persons with mental illness are left untreated, or inadequately treated, particularly during times of crisis, they put themselves at much higher risk for needing care at a higher, more expensive level. Likewise, if patients are suddenly unable to obtain the medications on which they have been stabilized or need a change in medication, a patient may well be at jeopardy of "hospitalization or significant disability" if not treated within 7 days.

We support the responsibility of the Centers for Medicare and Medicaid Services (CMS) to protect the Medicare dollar. We think appropriate use of antidepressants and antipsychotics is the way to best protect the dollar—not restricting access to medications in a way that makes it impossible for beneficiaries to obtain the drugs which they need to adequately treat their illness and keep them from unnecessarily utilizing more expensive levels of care.

Persons with psychiatric diagnoses often have significant difficulties understanding the role of medication in their treatment regimens. Helping patients accept and remain motivated to continue to take life-saving medication can be a great challenge. Medications can have significant side effects that vary from one person to another. Finding a combination of medications that best work to stabilize a patient's condition can be very challenging. Non-compliance with medication is a frequent reason for hospitalization or deterioration in the patient's condition. If Part D policies are greatly restricted, providers might be forced to use medications that are not effective for particular patients, have lost their effectiveness, or have unacceptable side effects.

If medications proven to be best suited for particular patients are not available under their Part D plan, they either cannot use them or need to pay for them personally. Given the high proportion of low-income and/or dually eligible beneficiaries in this population, that is not a feasible alternative.

We are not convinced that an adequate argument has been made that there would be significant savings by discontinuing the protections on the antidepressant and antipsychotic categories. In addition, cost-saving alone is not an adequate reason for changing a policy that has historically been effective. The impact of not being able to secure required drugs on people's lives, including needing to access higher levels of care, is a very important factor in the cost equation.

There is much discussion about the inadequacy and complexity of the existing exceptions, appeals, and grievances process. Navigating the unfamiliar appeals policy during an acute exacerbation of a psychiatric illness is an unrealistic burden for most people. Breaks in medication adherence, even for a few days, can make the difference between a person staying stable or deteriorating and needing a higher level of care. The people we serve cannot afford to wait to see if these processes will work for them or not. Their depression and psychosis do not wait.

## CONCLUSION

**NAPHS recommends that the proposal to remove antidepressants and, in 2016, antipsychotics from protected classes within Medicare's Voluntary Prescription Drug Benefit Program (Part D) be withdrawn.** We recommend there be no changes to the protected drug class designation for these categories.

Thank you for your consideration of our comments. We look forward to working with CMS and the Department of Health and Human Services to ensure that Medicare beneficiaries have access to the appropriate psychotropic medications required to treat their specific disorders.

Sincerely,

/s/

Mark Covall  
President/CEO