Depression and Bipolar Support Alliance

March 7, 2014

The Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Comments on Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Proposed Rule (CMS–4159–P)

Dear Administrator Tavenner:

The Depression and Bipolar Support Alliance (DBSA) thanks you and your colleagues for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule, "Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" (the Proposed Rule).

DBSA is a national mental health advocacy organization created by and for people who live with mood disorders. DBSA provides empowering wellness-oriented services, resources, and tools in our 800 local peer support groups, online, in audio and video casts, and in printed materials. DBSA's 300 chapters across the nation—along with our programs, communications, resources, and tools—reach two million people each year.

DBSA is not an organization comprised primarily of clinical professionals, health care administrators, or family members of people with mental health conditions, although some of each of these groups certainly number among our constituents. Instead, DBSA is made up almost entirely of people who personally experience depression or bipolar disorder. From this first-person perspective, and based on a longtime commitment to ensuring access to appropriate, quality care, we strongly urge CMS to withdraw the Proposed Rule. DBSA has serious issues with the Proposed Rule's provisions that weaken treatment of mental health conditions, such as mood disorders, as one of the "six protected classes" of Medicare Part D.

Not all of us who live with a mood disorder require a pharmacologic intervention, but many of us do. Regardless, DBSA advocates for the rights of individuals to choose the most appropriate treatments based on our own needs and concerns and the advice and guidance of our clinicians.

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Specifically, maintenance of protected access to antidepressants and antipsychotics is important to DBSA because:

1. First and foremost, depression and bipolar disorder can be life-threatening conditions. People with untreated or inadequately treated depression and bipolar disorder are exposed to the very real possibility of suicide. Individuals with mood disorders are also exposed to risk of co-occurring physical and/or other mental health conditions, all of which can shorten their lives. Treatments for mental health symptoms—including antidepressants and antipsychotics—can reduce and even eliminate these risks, and, for this life vs. death reason, we believe they should retain protected class status.

2. Beyond the fundamental and serious issue of mood disorders' potential for mortality—which we feel should be sufficient for maintenance of protected class status on its own—by removing antidepressants, and ultimately also antipsychotics, from protected class status, CMS is suggesting that they do not need to be prescribed within seven days to avoid hospitalization. For an individual experiencing crippling or suicidal depression, or dealing with delusions or hallucinations related to psychosis, that wait time seems highly problematic, to say the least.

3. Depression and bipolar disorder are among the most co-morbid conditions in healthcare. This means that people who are prescribed medications for mental health symptoms are very likely to be taking additional medications for other, co-occurring conditions. Therefore, allowance for the chemical interactions among compounds is essential, which any limitation of antidepressant or antipsychotic options would largely prohibit.

4. Elimination of antidepressants and antipsychotics from the protected classes would not only jeopardize individuals' timely access to appropriate medication, but it could also result in negative health outcomes, actually resulting in increased costs to other parts of the Medicare program, whether through increased hospitalizations and physician visits related to mental health issues or the same increased usage related to worsened co-occurring physical conditions. So to remove the best chance for first-line success in treatment—the protection of being able to follow our doctors' direction and advice—seems not only misguided in terms of harm to our health, but also with regard to the bottom line.

5. The CMS policy is focused on the "typical" individual. Yet mental health conditions are hugely complex, and there is nothing "typical" about living with or treating mood disorders.

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a. It is common for people living with mental health conditions to work closely with their physicians, trying several different medications before finding those that provide successful outcomes.

b. Treatment of depression and bipolar disorder is not a one-size-fits-all endeavor. People with mood symptoms are often faced with unsuccessful treatment regimens that only increase relapse rates and lessen chances of remission.

c. Mental health conditions are unique in that, with each additional unsuccessful course of therapy, there are both a progressively lower likelihood of remission and higher relapse rates.

6. Experience and tolerance of the side effects of antidepressants and antipsychotics also vary immensely from medication to medication, person to person. Side effects can of course be a barrier to adherence if they are disruptive to people's lives. Given the life-and-death nature of these conditions, anything that stands in the way of adherence to a treatment that mitigates mood symptoms is immensely harmful; indeed, it could be lethal. So access to an array of options that not only work differently, but may also have different side effect profiles and therefore be variously tolerable, is essential for the people taking these drugs.

7. The appeals process that CMS has in place to deal with access issues for unprotected medications is inadequate. Individuals managing already complex conditions that require access to a variety of drugs should not have previously guaranteed treatments replaced by arduous, bureaucratic, and questionably effective appeals.

Ultimately, if the CMS rule to remove antidepressants, and eventually antipsychotics, from Medicare Part D's protected class status is approved, there will be severe human, economic, and societal consequences for not only people with mental health conditions, but also our families, friends, and communities.

Over the past several decades, significant and important progress has been made to help those of us with mental health conditions. Increased understanding and new therapies and treatments—pharmacologic and otherwise—mean that prosperous, meaningful lives can and should be possible for all people affected by mental health conditions.

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We at DBSA strongly feel that the CMS rule is a step in the wrong direction, potentially vitiating the work of many years—the efforts of thousands of Americans who live with and are concerned about mental health issues.

DBSA urgently requests that CMS withdraw the Proposed Rule.

Sincerely,

Allen Doederlein
President
Depression and Bipolar Support Alliance (DBSA)

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