

November 15, 2021

The Honorable Ron Wyden
Chairman
Committee on Finance
United States Senate
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Wyden and Ranking Member Crapo:

As organizations advocating for patient access to needed medications, we appreciate the opportunity to provide input into the Committee's request for evidence-based policies to improve access to high quality mental health care. Our comments will focus on how the six protected classes policy aligns with the Committee's request for information related to increasing integration, coordination, and access to care.

We applaud Senators Wyden and Crapo for recognizing the importance of this issue and acting with urgency to address it. One example of a successful policy that we believe has improved access to medications that treat mental health conditions is Medicare's "six protected classes" policy. We urge the Committee to protect and reinforce the value of this policy for individuals living with mental health conditions as well as those whose conditions are often co-occurring with mental health conditions. The six protected classes policy was created to ensure that the most vulnerable patients in the country and those with the most challenging medical conditions can access the full range of treatment options recommended by their physician under Medicare Part D.

As you know, the COVID-19 pandemic has dramatically worsened the state of mental health in the United States.

Your stakeholder feedback letter from September 21st rightly highlights the drastic impacts that the pandemic has had on the state of mental health in America. In fact, considering that:

- 4 in 10 U.S. adults have now reported anxiety or symptoms of depressive disorder – representing a nearly 400 percent increase since the beginning of the pandemic;¹
- A report from the Centers for Disease Control and Prevention showing that as of June 2020, 40 percent of U.S. adults were struggling with mental health or substance abuse,² including 11 percent of adults reporting seriously considering suicide; and
- A study published in *JAMA* noting that actual deaths attributable to the COVID-19 pandemic are approximately 13 percent higher when accounting for lives lost due to COVID-19-imposed mental health issues.³

¹ Barton, T., Donnellan, J., Harootunian, L., Harris, J., Hartnett, T., Hoagland, G. W., McDonough, D., Newell, B., Bguyen, M., O'Gara, B., Parekh, A., & Werber Serafini, M. (2021, March). *Tackling America's Mental Health and Addiction Crisis Through Primary Care Integration*. Bipartisan Policy Center. Retrieved October 21, 2021, from https://bipartisanpolicy.org/download/?file=/wp-content/uploads/2021/03/BPC_Behavioral-Health-Integration-report_R01.pdf.

² Czeisler MÉ, Lane RI, Petrosky E, et al. Mental Health, Substance Use, and Suicidal Ideation During the COVID-19 Pandemic — United States, June 24–30, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1049–1057. DOI: [http://dx.doi.org/10.15585/mmwr.mm6932a1external icon](http://dx.doi.org/10.15585/mmwr.mm6932a1external%20icon)

³ Simon NM, Saxe GN, Marmar CR. Mental Health Disorders Related to COVID-19–Related Deaths. *JAMA*. 2020;324(15):1493–1494. doi:10.1001/jama.2020.19632

We believe that one critical component in the delivery of comprehensive mental health care services is ensuring adequate access to prescription medications, which are essential for many Americans' effective and successful management of their mental health condition. There are substantial benefits to protecting patients' medication access and to sustaining medication treatment regimens for those with mental health conditions. These benefits are not only essential to improving patients' lives – but they also reduce the risk of increasing overall health care costs – and are a vital element of improving our current mental health care system.

We view preserving Medicare's six protected classes policy as essential to any well-functioning mental health care delivery system because this policy provides patients with mental illnesses access to the appropriate, FDA-approved therapies prescribed by their physician to manage their condition. This policy provides additional significant protections for many other Americans living with complex chronic diseases such as cancer, HIV/AIDS, and epilepsy who suffer from disproportionately high rates of mental illness.

The policy, enacted by Congress, requires Medicare Part D plans to cover substantially all medications within six classes, which include access to therapies used to treat individuals with mental illness, among others. This includes facilitating access to prescribed antidepressants and antipsychotics. When Congress established the Medicare Part D prescription drug benefit, it recognized that certain drug classes were vital to the beneficiaries who depended on those drugs, and that their prescribers needed access to the full range of treatment options, and the importance of the protected classes policy has been reinforced an additional two times in legislation since then.^{4 5 6}

Patients with a condition in one of the protected classes have very complicated medical needs, and many of these patients must attempt a variety of therapies before coming to a decision with their physicians about what is the most appropriate treatment. For example, patients often have significant co-morbidities, requiring nuanced treatment regimens. Patients with mental health conditions often have high rates of diabetes and heart disease, which may be exacerbated by untreated mental illness.⁷ One in four individuals with cancer has clinical depression⁸ and nearly half of individuals with HIV have a mental illness.⁹ The protected classes policy shields them from arbitrary restrictions and limitations that may hinder access to important medications.

⁴ Public Law 110-275 (July 15, 2008)

⁵ 42 U.S.C. § 1395w-104(b)(3)(G)(ii)

⁶ Public Law 111-148 (March 23, 2010)

⁷ Smith, Kenneth J. et al. (February 2013), Cost-Effectiveness of Medicare Drug Plans in Schizophrenia and Bipolar Disorder, 19:2 American Journal of Managed Care 55.

⁸ American Cancer Society website. Accessed Oct. 21, 2021, Available at:

<https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/emotional-mood-changes/depression.html>.

⁹ Beckett, Megan K., Rebecca L. Collins, M. Audrey Burnam, David E. Kanouse, Eric G. Bing, Douglas L. Longshore, John Fleishman, Cathy D. Sherbourne, Andrew S. London, Barbara J. Turner, Ferd Eggan, Benedetto Vitiello, Sally C. Morton, Maria Orlando Edelen, Samuel A. Bozzette, Lucila Ortiz-Barron, Martin F. Shapiro, Laura M. Bogart, William Cunningham, Daniela Golinelli, Robin L. Beckman, David Eisenman, Chloe E. Bird, Kitty S. Chan, Allen Gifford, Geoffrey F. Joyce, Joan S. Tucker, Frank H. Galvan, Raul Caetano, Susan M. Paddock, Steve R. Mitchell, Ron D. Hays, Nell Griffith Forge, Fuan-Yue Kung, Stephanie L. Taylor, Ronald Andersen, Nanette Wenger, and Michael Stein, Mental Health and Substance Abuse Issues Among People with HIV: Lessons from HCSUS. Santa Monica, CA: RAND Corporation, 2007. https://www.rand.org/pubs/research_briefs/RB9300.html.

This policy has been a vital protection for patients and restricting access to these therapies would have major, life-threatening consequences for patients and increase the likelihood of costly hospitalizations and emergency room visits for those suffering from serious mental health conditions. Diagnosing and treating mental health conditions can be very challenging, with individual patients responding differently to available treatments. It is not uncommon for patients who are newly diagnosed with a mental health condition to undergo a lengthy trial and error process to identify an optimal treatment regimen. As such, these medications are not interchangeable.

A 2017 article¹⁰ examines the challenges in diagnosing proper treatments for people with depression, namely the fact that not all treatments work for every patient. This article underscores the importance of the six protected classes, as proposals to limit access to certain medications under the Part D program which are not interchangeable, such as antidepressants, would have a profound impact on the patients who depend on access to the full spectrum of treatment options. CMS has acknowledged this fact in the case of step therapy when there is a delay in a patient receiving a drug. CMS states “that delay may cause a worsening of conditions leading to increased medical costs.”¹¹

Policy proposals to weaken the six protected classes have been offered several times since 2014 that would ultimately make it more difficult for our nation’s most vulnerable patients to manage their disease by limiting their access to needed medications. Unfortunately, these policies would put patients’ lives in jeopardy.

These policy proposals demonstrate a misunderstanding of drug utilization across the six protected classes and are misplaced. Currently, Part D plans have many tools that they use to control costs through utilization management and rebate negotiation. For example, under current guidance issued by the Centers for Medicare and Medicaid Services (CMS), for drugs other than those relating to HIV, Part D plans may use prior authorization and step therapy to manage therapies for any beneficiary beginning treatment on a protected class drug.¹² In addition, Part D plans may utilize formulary tiering to steer patients toward lower cost drugs. These tools give Part D plans considerable flexibility to manage more expensive medications.

In fact, according to a 2021 report from Avalere Health, generic utilization among drugs in the six protected classes is extremely high.¹³ Avalere found that across the classes of drugs, generic drugs represented 93 percent of prescriptions filled in 2019 – an increase from 91 percent in 2016. This includes generic utilization rates of 92 percent for anticonvulsants, 98 percent for antidepressants, and 91 percent for antipsychotics.

¹⁰ Resnick, B. (2017, April 4). *Treating depression is guesswork. Psychiatrists are beginning to crack the code.* Vox. Retrieved October 15, 2021, from <https://www.vox.com/science-and-health/2017/4/4/15073652/precision-psychiatry-depression>.

¹¹ Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses, Proposed Rule. Centers for Medicare and Medicaid Services. November 20, 2018. <https://www.regulations.gov/document/CMS-2018-0149-0002>

¹² Medicare Prescription Drug Benefit Manual, Ch. 6 §30.2.5.

¹³ *Partnership: New report highlights access challenges for patients with complex, chronic conditions.* Partnership for Part D Access. (2021, February 25). Retrieved October 15, 2021, from <http://www.partdpartnership.org/resources/partnership-new-report-highlights-access-challenges-for-patients-with-complex-chronic-conditions>.

Fortunately, support for the six protected classes has been profound and bipartisan, particularly among Senate Finance Committee members. As you are undoubtedly aware, in 2014, all 24 Members of the Senate Finance Committee wrote to then-Administrator Marilyn Tavenner at the Centers for Medicare & Medicaid Services¹⁴ to “strongly urge the Centers for Medicare & Medicaid Services (CMS) to continue this important beneficiary protection.” We encourage the Committee to use the current opportunity to support and protect these patients, specifically by ensuring there are no changes made to erode or undermine Medicare’s six protected classes policy.

We look forward to working with you and the rest of the Committee as you take on this critical task of ensuring evidence based and comprehensive care for those living with mental health conditions. If you have any questions, please do not hesitate to reach out to Reyna Taylor at ReynaT@TheNationalCouncil.org.

Thank you for your consideration of these comments.

Signed,

The AIDS Institute
Aimed Alliance
American Foundation for Suicide Prevention
American Kidney Fund
American Psychiatric Association (APA)
American Psychoanalytic Association
American Society of Consultant Pharmacists
American Society of Nephrology
California Access Coalition
California Council of Community Behavioral Health Agencies (CBHA)
CancerCare
Cancer Support Community
College of Psychiatric and Neurologic Pharmacists
Color of Crohn’s and Chronic Illness (COCCI)
Depression and Bipolar Support Alliance
Epilepsy Foundation
HIV+Hepatitis Policy Institute
International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis)
The Kennedy Forum
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Mental Health America
The Michael J. Fox Foundation for Parkinson’s Research
National Alliance on Mental Illness
National Alliance on Mental Illness of Coastal Virginia (NAMI Coastal Virginia)
National Alliance on Mental Illness of Virginia (NAMI Virginia)
National Association of State Mental Health Program Directors

¹⁴ Available at:

http://www.partdpartnership.org/uploads/8/4/2/1/8421729/6_protected_classes_letter_6.30.16.pdf

National Council for Mental Wellbeing
NJAMHAA - New Jersey Association of Mental Health and Addiction Agencies
Partnership for Part D Access
Tourette Association of America
Transplant Recipients International Organization (TRIO)
Transplant Support Organization
TRIO-Oklahoma
US COPD Coalition
Vibrant Emotional Health