



March 11, 2022

Submitted online via <https://docs.google.com/forms/d/e/1FAIpQLSfMq-10zZICT4pCtpwgC4CSOFV44ft8frOrsXkz0Aoj-85pyg/viewform>.

Dear Representatives Wenstrup, Joyce, and Westerman:

As a coalition advocating for patient access to needed medications, we appreciate the opportunity to provide input in the Healthy Future Task Force Treatment Subcommittee’s Request for Information (“RFI”), particularly as it relates to ensuring the continued availability of life-saving treatments. This is especially important for vulnerable patient populations.

The Partnership for Part D Access (“the Partnership”) is a collection of healthcare stakeholders, including leading patient groups and other advocacy organizations who are committed to maintaining access to critically important medications under Medicare Part D — especially the categories and classes of drugs identified for unique patient protections in Medicare’s protected classes.

We applaud you for your work in recognizing the importance of ensuring robust patient access to needed medications and innovations and are committed to working with Congress towards this shared goal. One example of a highly successful policy that we believe has demonstrated the ability to improve patient access to medications is Medicare’s “six protected classes” policy. It is our hope that the future work of the Task Force will reinforce the value of this policy and affirm its continued ability to benefit patients across the country. This policy was created to ensure that many of 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.

The six protected classes policy requires Medicare Part D plans to cover all medications within six classes: therapies used to treat cancer, epilepsy, HIV/AIDS, mental illness, organ transplant rejection, and autoimmune disorders. 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.

Notably, this policy has demonstrated robust, bipartisan support. In 2008, Congress passed the Medicare Improvements for Patients and Providers Act (“MIPPA”), which included language replacing CMS’ previous “substantially all” standard to a requirement affecting the six protected classes.¹ that “all” drugs in the protected classes be covered.²

¹ Public Law 110-275 (July 15, 2008)

² 42 U.S.C. [Section Symbol] 1395w-104(b)(3)(G)(ii).

Patients served by the six protected classes policy have very complicated medical needs. Many of these patients go through a “trial and error” process with their physicians before identifying the best, most appropriate treatment regimen. For example, patients with complex, co-occurring medical conditions or those who experience side effects from their treatment plans often require nuanced regimens overseen by their physicians.

Additionally, and of concern to us and our member organizations, many patients served by the six protected classes also experience other significant medical conditions. For example, one in four individuals with cancer has clinical depression³ and nearly half of individuals with HIV have a mental illness.⁴ Additionally, patients with mental health conditions often have high rates of diabetes and heart disease, which may be exacerbated by untreated mental illness.⁵ In this instance, the policy protects these patients against unnecessary restrictions that could jeopardize their health by limiting access to important medications.

The six protected classes policy also provides an opportunity to reduce overall healthcare expenditures. The Centers for Medicare and Medicaid Services (“CMS”) have acknowledged that delaying or impeding patient access to these drugs can increase medical expenditures. At the time, CMS said that such a delay “may cause a worsening of conditions leading to increased medical costs.”⁶

The six protected classes policy offers plans a variety of tools to manage and control costs, including – but not limited to utilization management and rebate negotiation. For example, under current guidance issued by 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.⁷ In addition, Part D plans may utilize formulary tiering to steer patients towards lower-cost drugs. These tools give Part D plans considerable flexibility to manage medication costs.

In fact, according to a 2021 report from Avalere Health, generic utilization among drugs in the six protected classes is extremely high.⁸ Avalere found that across the classes of drugs, generic drugs

³ 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>.

⁴ 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.

⁵ 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.

⁶ 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>

⁷ Medicare Prescription Drug Benefit Manual, Ch. 6 §30.2.5.

⁸ *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>.

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. For covered drugs, nearly two-thirds of all medications in the six protected classes were placed in a non-preferred or specialty category, with 89 percent of branded products categorized as non-preferred.

Fortunately, Congressional support for the six protected classes has been profound and bipartisan. We hope that the work of the Treatment Subcommittee of the Healthy Future Task Force will continue this tradition and use the current opportunity to support and protect these patients, specifically by ensuring there are no changes made to Medicare’s six protected classes policy. We view preserving Medicare’s six protected classes policy as essential to any well-functioning health care delivery system because this policy provides patients access to the appropriate, FDA-approved therapies prescribed by their physician to manage their condition.

We appreciate the opportunity to comment on the Subcommittee’s Request for Information. If you have any questions or would like to discuss this further, please feel free to contact me at ReynaT@TheNationalCouncil.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Reyna Taylor', with a stylized flourish at the end.

Reyna Taylor

Executive Director, Partnership for Part D Access

Vice President of Public Policy and Advocacy, National Council for Mental Wellbeing