August 17, 2026

Senator Ron Wyden
Ranking Member
Senate Finance Committee Minority
Washington, DC 20510

Re: Request for Information: Commonsense Policy Options to Lower Drug Prices for Patients

Dear Ranking Member Wyden,

On behalf of the Partnership for Part D Access, we appreciate the opportunity to offer recommendations on how the Senate Finance Committee can lower out-of-pocket costs for prescription drugs and bolster biopharmaceutical innovation, while continuing to ensure that patients with life-threatening conditions maintain access to the life-saving drugs they require. We urge the Committee to uphold Congress's commitment to defending Medicare's six protected classes (6PC) policy and avoid considering policies that infringe on the guarantees it provides to Medicare Part D beneficiaries. We also recommend that Congress oppose the Center for Medicare and Medicaid Services (CMS)' Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model, which, if enacted, could increase the out-of-pocket costs that Medicare Part D beneficiaries pay for select critical medications and disincentivize future biopharmaceutical innovations.

1. Protecting the Six Protected Classes

Congress established the 6PC policy to ensure that seniors and people with disabilities can access the full range of medications for serious conditions, including cancer, HIV, neurological disorders like epilepsy and Parkinson's, mental illness, and organ transplant rejection. The treatments for these conditions are rarely interchangeable. Patients may spend years working with their clinicians to find the right medication regimen. Once stabilized, uninterrupted access is essential to maintain patient well-being and avoid dangerous, costly health episodes.

Congress reaffirmed the importance of the original protected classes in Section 3307 of the Affordable Care Act, which codified in law the six protected classes and categories by name, and expanded coverage to include "all" drugs within these six classes until and unless the Department of Health and Human Services (HHS) establishes different criteria through the rulemaking process. In 2019, the first Trump Administration attempted to roll back these

important patient protections but faced significant congressional opposition, including letters and repeated challenges to former HHS Secretary Alex Azar during congressional appearances. Ultimately, the proposed changes to the six protected classes were withdrawn.

Despite Congress's longstanding commitment to upholding the 6PC policy in statute, beneficiaries still experience significant barriers to accessing their preferred 6PC medications. For example, in the first quarter (Q1) of 2026, Medicare patients attempting to fill brand prescriptions in the Part D protected classes were initially rejected 58% of the time.[1] Furthermore, initial rejection rates across protected classes ranged from 47% (antiretrovirals) to 73% (anticonvulsants) in Q1 2026, and within protected classes, initial rejection rates also varied by brand by up to 77 percentage points (antidepressants).[2] These figures highlight that despite the special coverage protections afforded to these drugs, each class is not protected equally, and within classes, there is differential coverage across products.

Still, the 6PC policy has resulted in meaningful gains for patients, including increased life expectancy for people living with HIV and ensuring cancer patients' access to medications remains uninterrupted.[3] [4] The Partnership believes that the 6PC policy must be upheld in its entirety and would be concerned about any policy changes, whether the GUARD Model or otherwise, that could erode access.

2. Opposing the GUARD Model

While the GUARD Model is framed as an effort to reduce out-of-pocket costs to patients, CMS's own analysis shows that, rather than decreasing financial burdens for patients, the model would result in an estimated $3.6 billion increase in cost sharing for beneficiaries over the model years.[5] The agency states in the proposed model that "we do not expect the GUARD rebates to be visible to beneficiaries at the point of sale." In other words, the model would not translate into lower costs for the program or its beneficiaries.

CMS attributes this increase to projected higher point-of-sale drug prices in the pilot's initial year, as well as increases in beneficiary premiums, which have already increased due to other Part D policy changes currently in effect. Taken together, CMS's own economic analysis

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[1] Ehrenberg, R. (Aug. 13, 2026). Protected Classes are Not Immune to Payer Control. IQVIA. https://www.iqvia.com/locations/united-states/blogs/2026/08/protected-classes-are-not-immune-to-payer-control.

[2] Ibid.

[3] Mental Health America. Position Statements: Access to Medication. https://mhanational.org/positionstatements/access-to-medications/.

[4] Cancer Action Network. (Jul. 20, 2018). Six Protected Classes Explained. https://www.fightcancer.org/sites/default/files/Medicare%20Six%20Protected%20Classes%20Fact%20Sheet%2007202018.pdf.

[5] Centers for Medicare & Medicaid Services. (Dec. 23, 2025). Table CS: Impacts to Medicare Part D enrollees ($ billions), in Guarding U.S. Medicare Against Rising Drug Costs (GUARD) Model. Federal Register, (90 Fed. Reg. 60411) (Proposed rule). https://www.govinfo.gov/content/pkg/FR-2025-12-23/pdf/2025-23705.pdf.

demonstrates that the GUARD Model, in practice, would increase the financial burden on Medicare beneficiaries, directly contradicting the model's stated goals.

Furthermore, we are concerned that the GUARD Model will disincentivize the scientific innovation that patients rely on by destabilizing the health care marketplace. When policies reduce incentives to innovate, fewer new therapies get developed and fewer reach patients. This is especially true for high-risk/high-reward research and development efforts necessary to develop medicines that fall within the 6PC. That means people wait longer for better options, have fewer choices when current treatments do not work, and miss out on next-generation therapies that could improve or extend their lives, or cure them of their illness.

Conclusion

The Partnership for Part D Access supports efforts to improve pharmaceutical affordability. However, reforms must strengthen access, not weaken it. Policies designed to lower prices must be carefully evaluated to ensure they achieve their intended goals rather than shifting costs elsewhere or creating unintended consequences that hinder beneficiary access to critical medicines. The 6PC policy has longstanding bipartisan support, and we ask that Congress ensure any proposed policies preserve this critical safeguard for vulnerable patients.

We appreciate the opportunity to provide feedback on this issue through this comment and welcome continued discussion with you. Should you have any questions for us, please reach out to Margaret French at mfrench@vennstrategies.com.

Sincerely,
The Partnership for Part D Access