United States Senate
WASHINGTON, DC 20510

March 29, 2019

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar,

We write to you today to express concern about the recently proposed changes to the Medicare Part D Six Protected Classes policy in the November 2018 CMS-4180P - 83 Fed. Reg. 62152 and to request that you reconsider allowing prior authorization and step therapy for the prescription drugs in the six protected classes.

When Congress created the prescription drug benefit in Medicare, the goal of the new program was to ensure that Medicare beneficiaries had access to the necessary and lifesaving drugs they needed. During the implementation of Part D, it became apparent that some additional protections were required for certain classes of prescription drugs. In 2008, Congress established the Six Protected Classes in Medicare Part D as part of the Medicare Improvements for Patients and Providers Act (MIPPA)[1]. MIPPA codified the requirement that plan sponsors must offer all or substantially all drugs in the Six Protected Classes as well as consider the impact that restrictions on the classes would have on beneficiaries and the need for broader access to medications for a particular condition. Congressional commitment to the Six Protected Classes was confirmed by the Affordable Care Act's codification of the six classes.

In the November 2018 rule, the Administration proposed to allow plans to use prior authorization and step therapy for prescription drugs in the Six Protected Classes. As you mentioned in remarks given before the American Medical Association, these tools can be harmful to beneficiaries who are particularly at risk for interruption of their drug regimen such as those with a mental illness, epilepsy, or HIV. Interruption of a beneficiary's medical regimen due to a plan sponsor utilizing step therapy or delaying access to medication after diagnosis can lead to setbacks for the beneficiary or treatment noncompliance, which ultimately can lead to higher health care costs elsewhere in Medicare.

[1] Medicare Improvements for Patients and Providers Act (MIPPA) of 2010. Pub. L. 110-275. 122 Stat. 2494.

Medicare Part D rules already allow plan sponsors to exclude brand-name drugs from their formularies if a generic equivalent exists. Between 80 and 90% of prescriptions filled in the Six Protected Classes, other than antiretrovirals, are for generics[2]. For those drugs without a generic equivalent, we recommend the Administration work to expedite approval of generics to ensure access to lower cost alternatives. According to the Medicare Payment Advisory Commission (MedPAC), there have not been as significant price increases for protected class drugs with a generic equivalent as there have been for other Part D drugs[3].

Any changes to the Medicare Part D Six Protected Classes should consider both Congressional intent for the Six Protected Classes and the potential harm to beneficiaries whose drug regimens are interrupted or delayed from the use of step therapy or prior authorization. We look forward to working with you to continue to improve Medicare Part D and ensure beneficiaries continue to receive uninterrupted access to medications where no alternative therapies exist.

Sincerely,

ROBERT MENENDEZ
UNITED STATES SENATOR

DEBBIE STABENOW
UNITED STATES SENATOR

MARGARET WOOD HASSAN
UNITED STATES SENATOR

ROBERT P. CASEY, JR
UNITED STATES SENATOR

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UNITED STATES SENATOR

[2] Medicare Payment Advisory Commission, Report to Congress: Medicare Payment Policy *March 2016), pg. 394
[3] Medicare Payment Advisory Commission, "Improving Medicare Part D" (2016), pg. 191
http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf?sfvrsn=0