

United States Senate

WASHINGTON, DC 20510

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-4180P - 83 Fed. Reg. 62152 (November 30, 2018)

Dear Administrator Verma:

We write to request that the Centers for Medicare & Medicaid Services (CMS) maintain the six protected classes policy in Medicare Part D that ensures the most medically complex patients have access to life-saving and life-sustaining medications.

Congress created the Medicare Part D program to provide robust, outpatient prescription drug coverage for Medicare beneficiaries. The six protected classes policy has been part of the Part D program since the program launched and has enjoyed strong bipartisan support. The proposed rule would allow Part D plans to limit access to critical medicines to patients in need of immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastic medicines, by permitting prior authorization or step therapy. We urge CMS to reconsider this proposal that would risk the health of our most vulnerable beneficiaries.

While we applaud the Administration's commitment to making pharmaceuticals more affordable, we have concerns that undermining the protected class status of medications could have much larger consequences in the long-term. For example, the U.S. government spends more than \$20 billion annually to prevent HIV and care for those infected. As you know, modern medicine reduces the risk of contracting HIV from another person by up to 97 percent, if the correct medication is taken directly as prescribed. However, if a patient is required to first try drugs that are older, less expensive, and ineffective, we fear decades of HIV prevention work could be undone.

The President's 2019 State of the Union speech announced a bold initiative to end the HIV epidemic within the next decade. This is a laudable goal and we are eager to work together towards this effort. However, the November 30, 2018 proposal on Part D protected classes undermines this effort, by preventing HIV patients from receiving critical medications needed to end the HIV epidemic.

These concerns are not limited to just HIV patients. Cancer patients often need highly personalized therapies and cannot afford treatment interruptions caused by insurers second guessing their doctors. Patients with schizophrenia and depression often struggle to find a medicine that works for them and could risk relapse if forced to switch to alternatives. Epilepsy patients often find that only one treatment works for them, and any disruptions in treatment could increase the likelihood of seizures. Organ transplant patients have complex medical needs and should not be required to jump through hoops in order to prevent transplant rejection.

Patients who are stable on a medicine that is currently protected should not be forced to unnecessarily jeopardize their health. Moreover, the proposal would result in very few Part D plans offering the specific types of therapies these patients need.

Thank you for your attention to this critical issue. It is our hope that CMS will reconsider its position on this important issue. We stand ready to work with the Administration to lower prescription drug costs for all beneficiaries, including its most vulnerable.