



April 15, 2019

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, SW, Room 600E
Washington DC 20201

Mr. Russell Vought
Acting Director
Office of Management and Budget
725 17th Street NW
Washington, DC 20503

Dear Secretary Azar:

The undersigned clinical providers and pharmacists are writing to express our concern about recently proposed changes to the six protected classes in Medicare Part D that could lead to increased utilization management and reduced access to medicines for serious and life-threatening conditions.

Traditionally, Part D plans are required to cover all or substantially all medications in six classes and categories: antidepressants, antipsychotics, anticonvulsants, immunosuppressants, antiretrovirals, and antineoplastics. Given the conditions treated by these products, the “protected classes” policy protects some of the most vulnerable Medicare beneficiaries, including those suffering from conditions such as HIV, who we care for and treat on a daily basis. Access to the full range of treatment options is critical for successful management of patients with HIV, for both new, treatment naïve patients, as well as those who are stable on their anti-viral regimens.

CMS recently proposed exceptions to this policy that would allow insurers to use more aggressive utilization management for these classes of products, and even to exclude certain products from formulary altogether. As providers and pharmacists, we are deeply concerned about giving insurers the ability to exclude new generation products from formulary and thus denying patients access to the latest science. We are particularly concerned that the proposed rule would allow widespread use of prior authorization and step therapy for stable patients.

As providers and pharmacists, we know how difficult it can be to find a treatment in one of these six protected classes that works for a patient. Often a patient is only stable after a long period of trying different therapies to find one that is effective and has manageable or no side effects. In other cases, one medicine is appropriate due to a patient’s condition and comorbidities. A carve out for stable patients will not be sufficient as there are other clinical considerations that must be taken into account. Antiviral regimens are prescribed based on individual clinical and psychosocial factors that we determine during our assessments.

Further, the existence of the Part D exceptions and appeals process gives us little comfort. These processes are opaque and burdensome to providers and pharmacists, who should instead be focused on delivering clinical care. These processes create delays to treatment that are unacceptable to patients currently protected by the six-protected classes policy. Additionally, Medicare Payment Advisory Commission staff has stated that “CMS has found that several plan sponsors fail to comply with regulations” governing the exceptions and appeals process. In HIV, delaying and in some cases blocking patients’ access to tailored treatment is deleterious to not only the patients’ individual health, but also to the broader public health in terms of transmissibility of the virus.

For these reasons, we strongly oppose the Administration’s proposal to weaken the protected classes policy and urge this proposal to be withdrawn.

Sincerely,

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