



July 16, 2018

Via Electronic Filing: <http://www.regulations.gov>

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

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

The American Academy of HIV Medicine welcomes the opportunity to comment on some of the issues raised by the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. The Academy is an independent organization of HIV specialists and HIV care providers dedicated to promoting excellence in HIV care and to ensuring optimal care for those living with HIV.

While we are sensitive to the challenges faced by policy makers and the financial burdens on coverage entities, programs and payers, we -- as HIV care providers -- necessarily focus our concern on ensuring that people living with HIV have access to the medications they need. One vital mechanism to ensuring this access is the designation of six classes of drugs as “protected classes” for Medicare purposes. The inclusion of antiretroviral medications as one of the six protected classes is literally life-saving to many of our patients.

Established in 2005, the Medicare Protected Classes Policy dictates that six key classes of critically needed drugs be protected from budgetary fluctuations and subsequent policy restrictions to ensure that they remain accessible. This “protected classes” policy has continuously enjoyed strong bipartisan support in Congress. It has also cost less than was originally estimated by the Congressional Budget Office (CBO).

At present, the six protected classes are still mandatorily included in all Medicare Part D plan formularies. They are antidepressants, antipsychotics, anticonvulsants, antineoplastics, antiretrovirals and immunosuppressants.

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The administration's currently proposed "HHS Blueprint to Lower Drug Prices and Reduce Out of Pocket Costs" which proposes to allow flexibility in how drugs within a given class are covered and how utilization of them is managed. **The American Academy of HIV Medicine strongly opposes any policies that weaken or disrupt any access to antiretroviral drugs**, as well as to drugs in the other five protected classes. These six specialized classes were created in recognition of the complexity of the treatment required by these conditions, and the necessity of access to uninterrupted therapy in order achieve medical benefit from this treatment. .

The current Blueprint also proposes various mechanisms that could compromise our ability to get the appropriate antiretroviral drugs into patients consistently over time, which is essential to maintaining viral suppression. Among these are:

Prior Authorizations Procedures often slow or impede a patient's access prescribed medicine by requiring that insurers assign special approval for it before the pharmacy fills the prescription. Prior authorization is increasingly being used as a tool by insurers to slow or stop the use of high-cost medications, even when they are the standard of care for that condition. The six protected classes of drugs are currently exempt from Prior Authorization. Even a short delay in getting an antiretroviral medications can trigger the occurrence of viral resistance which can then render the medication ineffective for that patient. Resistance to that whole class of medications can even occur if consistent use is interrupted – thus reducing the number of options for effectively suppressing the person's HIV. **AAHIVM strongly opposes the imposition of prior authorization requirements on people living with HIV** as well as those people using medications in the other five protected classes.

Deciding whether a drug should be "allowed to be included in the protected classes" based on whether its manufacturer has increased its prices recently or provided a discount to Medicare is unsound medicine. Someone who has had HIV for decades, for example, may well have a narrow range of drugs to which he or she is not yet acquired resistance. Ethically, those remaining drugs must be available within the protected class formulary, regardless of pricing behaviors of the drug's manufacturer. **AAHIVM strongly opposes the use of a manufacturer's marketing patterns – or any such non-medical criteria – as a factor in decisions regarding which drugs are available in the protected classes' formularies.**

Allowing Part D plan formularies to provide only one drug per category and class, rather than two, is another Blueprint recommendation. There is a significant need for access to multiple drugs within one class due to the unique chemical reactions and pharmacological effects of the various drugs. **AAHIVM strongly urges that Part D plan formularies be required to include multiple drugs per category to ensure that people in the six protected classes have access to treatments appropriate for their complex conditions.** We urge CMS, both at the before and during the plan year, to monitor formularies regularly to ensure that they are providing access to the drugs and classes of drugs needed within the six protected classes.

Antiretroviral drugs, without exaggeration, are what turned HIV from an unstoppable death sentence into a manageable disease with which the human body can coexist for a nearly normal lifespans.

These are not the only concerns raised by the Blueprint draft but we chose to bring these to your attention because of damage they could cause for people living with HIV and others in the protected classes identified over a decade ago. We accept that the proposals in the Blueprint are still exploratory and we appreciate this opportunity to address these issues above and bring them to your attention.

If you have any questions regarding the above comments, please contact Anna Forbes, Public Policy Director of the American Academy of HIV Medicine, at (202) 659 0699, ext. 18, or at anna@aahivm.org.

Sincerely,

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Chairperson
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