July 10, 2018

Office of the Secretary
Department of Health and Human Services
200 Independence Ave. SW
Room 600E
Washington, DC 20201

Submitted via regulations.gov

Re: RIN 0991-ZA49: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs
II. B. Better Negotiation; "Providing plans full flexibility to manage high cost drugs that do not provide Part D plans with rebates or negotiated fixed prices, including in the protected classes.

Dear Secretary Azar:

The undersigned organizations write today in response to RIN 0991-ZA49 and on behalf of our constituents living with and affected by HIV/AIDS in the US South.

The Southern AIDS Coalition (SAC) is a non-partisan coalition of government, community, and business leaders working alongside thousands of individual members to prevent new infections and build a better South for people living with HIV. For more than fifteen years, the coalition has promoted accessible and high-quality systems of HIV prevention and care across sixteen southern states and the District of Columbia.

The Southern HIV/AIDS Strategy Initiative (SASI) is an initiative of the Duke Health Justice Clinic and works with a broad-based Steering Committee of HIV advocates and a Duke research team to create data-driven policy solutions to ending AIDS in the US South. SASI develops research-based policy and strategy recommendations aimed at securing a federal commitment to fully implement the National HIV/AIDS Strategy in the US South.

Overview of SAC and SASI's Position

We applaud the efforts of HHS to lower drug prices and reduce out-of-pocket costs. These goals are particularly important for people living with chronic diseases who rely on medications for their survival. It is critical, however, that people living with HIV have uninterrupted access to their HIV medications for their own health and to prevent the spread of HIV to others. We therefore urge HHS to (1) maintain antiretrovirals as a protected class on the Medicare Part D

formulary; and (2) provide access to antiretrovirals without pre-authorization or other utilization barriers within Medicare Part D.

Background Information

We are making progress in the fight against HIV/AIDS. Nationally, new HIV infections declined 8% from 2010 to 2015.[1] Progress has been uneven, however, and although Southern states account for 38% of the US population, in 2015 the South accounted for 51% of all HIV diagnoses and 46% of all persons living with HIV in the US. According to the CDC, in some Southern states, people living with HIV are 3 times as likely to die as those living with HIV in some other states. Of the total deaths attributed directly to HIV in 2014, 53 percent were in the South. [2]

Because of HIV treatment advances, people diagnosed with HIV are living longer, healthier lives. At the end of 2014, 428,724 people aged 50 or over were living with diagnosed HIV in the US which represented 45% of all people living with HIV in the US.[3]

People living with HIV are increasingly dependent on Medicare for their health coverage. According to the Kaiser Family Foundation, the number of Medicare beneficiaries with HIV has tripled since the 1990s with approximately a quarter of people living with HIV getting their health insurance coverage through Medicare.[4]

History of Protected Classes in Medicare Part D

In 2005, CMS adopted a policy requiring part D plans to cover all or substantially all drugs in six protected classes, including antiretrovirals. Further, Part D plans could not impose step therapy or prior authorization requirements for these drugs. In 2008, Congress passed legislation that specified two criteria that CMS must use to identifying additional classes of clinical concern:

1. restricted access to the drugs in the class would have major or life-threatening clinical consequences for individuals with a disease or disorder treated by drugs in such class; and
2. there is a significant need for such individuals to have access to multiple drugs within a class due to unique chemical actions and pharmacological effects of the drugs within a class.[5]

[1] Centers for Disease Control, Estimated HIV incidence and prevalence in the United States, 2010-2015. *HIV Surveillance Supplemental Report* 2018;23(1).
[2] CDC: HIV Surveillance Report 2016 Vol. 28.
[3] CDC: HIV Among People Aged 50 or Over; CDC: AtlasPlus.
[4] Kaiser Family Foundation, Medicare and HIV, October 14, 2016.
[5] Medicare Improvements for Patients and Providers Act (MIPPA)

In the Affordable Care Act, Congress re-affirmed the two-part test established under MIPPA and provided that the six existing protected classes would remain intact until such time as the HHS Secretary establishes formal criteria to identify classes of clinical concern.

The Medicare Prescription Drug Benefit Manual, last updated in January of 2016, contains a provision requiring Medicare Part D plans to include "all or substantially all drugs in the ….antiretroviral…class.." One stated rationale for this policy is to "..mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations." The Manual explicitly states that "Part D sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes…" Further, for "HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models."[6] A review in 2013 of the protected classes by CMS concluded that antiretrovirals met the criteria for inclusion in the protected classes and should remain protected.[7]

Importance of Broad and Uninterrupted Access to Antiretrovirals by People Living with HIV.

We urge HHS to (1) maintain antiretrovirals as a protected class on the Medicare Part D formulary; and (2) provide access to antiretrovirals without pre-authorization or other utilization barriers within Medicare Part D. Formulary limitations and utilization management tools can pose barriers to viral suppression, and thus increase costs.

The treatment of HIV disease is complex and requires that providers have the full panoply of antiretroviral medications available to treat the disease. This is particularly true in an aging population. As the 2013 CMS review panel found, antiretroviral medications are not interchangeable. We agree with CMS's conclusion that the "…need to adjust specific combination antiretroviral therapy in real time is complex and must consider, among other things, viral sensitivity to the drugs, drug interactions, pregnancy status (if applicable), and potentially the patient's pharmacogenomics profile of the cytochrome P450 system."[8] It is fortunate that providers have access to robust, long-standing, and frequently updated HIV Treatment Guidelines. These guidelines emphasize the importance of adherence, and outline different regimens for patients with different characteristics.[9] The choice of an HIV treatment regimen should always depend on a person's individual needs, as determined by his or her provider and in accordance with the HIV Treatment Guidelines. Maintaining protected status for antiretrovirals on the Medicare Part D formulary is crucial so that providers can navigate the HIV Treatment Guidelines to determine what is best for each patient.

[6] Medicare Prescription Drug Benefit Manual, Chapter 6, 30.2.4,
[7] Center for Medicare Protected Classes Review Panel, December 2013.
[8] See footnote 7.
[9] https://aidsinfo.nih.gov/guidelines, last updated May 2018.

People living with HIV comprise a vulnerable population for whom access to medications affects both the individual and the public health. HIV treatment failure for even a short time can result in drug resistance and viral mutations that limit future therapeutic options and can cause irreversible damage to the immune system. According to the American Academy of HIV Medicine (AAHIVM), "Decreased health, co-morbid conditions, and hospitalizations also result from disruptions in access to necessary medication."[10] Providers and their patients must be able to select the HIV treatment regimen that will most effectively suppress the virus.

Not only does unfettered access to effective HIV treatment result in positive health benefits for the person living with HIV, effective treatment also has profound public health benefits. The CDC summarized the scientific evidence of these benefits as follows: "People living with HIV who take HIV medicine as prescribed and get and keep an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative sexual partners." Medication interruptions can increase a person's viral load and the risk of transmitting the virus to others. According to the CDC, stopping HIV medication can result in viral load increases within even a few days.[11]

Prior authorization requirements for HIV medications cause unnecessary delays for already vulnerable patients in accessing life-saving HIV medication. People run out of medication while waiting for prior authorization approval. As discussed above, these medication interruptions can have serious and permanent consequences to a person's individual health and to the health of the public. Prior authorization requirements also add countless hours to the work of medical providers, pharmacists and their staffs as they navigate the bureaucracy to seek appropriate approval for HIV medications. Several studies cited by the American Academy of HIV Medicine cite the added cost incurred by clinics as a result of prior authorization requirements with no improved outcomes for patients.[12]

Similarly, the imposition of step therapy protocols restrict access to the optimal HIV treatment regimen for some people living with HIV and may permanently limit their future treatment options. HIV treatment failure can result in drug resistance to an entire class of antiretroviral medications limiting future therapeutic options and causing irreversible damage to the immune system. Providers must have the flexibility to navigate the HIV Treatment Guidelines and provide individually tailored treatment for each patient living with HIV without being required to choose from a limited number of antiretrovirals, or jump through prior authorization and/or step therapy hoops.

We urge HHS to (1) Maintain antiretrovirals as a protected class in the Medicare Part D formulary, and (2) Provide access to antiretrovirals without utilization barriers such as prior authorization or step therapy requirements within Medicare Part D.

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[10] American Academy of HIV Medicine: Prior Authorization,
[11] CDC, Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV, December 2017.
[12] See footnote 10.

Sincerely,

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