January 25, 2019

Secretary Alex Azar
Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

Re: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Secretary Azar:

The AIDS Institute, a national nonprofit organization dedicated to supporting and protecting health care access for people living with HIV, hepatitis, and other chronic and serious health conditions, appreciates the opportunity to comment on the Proposed Rule, *Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P*) published in the *Federal Register* on November 30, 2018. We applaud the Administration's efforts to lower prescription drug prices and reduce beneficiary cost-sharing in order to ensure patients have access to the medications that work to treat or prevent HIV. However, the proposed policy changes to the six "protected classes" of prescription drugs in the proposed rule would be detrimental to the most medically complex patients in Medicare Part D. **Therefore, The AIDS Institute urges the Administration to withdraw this part of the rule in order to ensure beneficiaries are able to continue to receive appropriate treatment and attain the best possible health outcomes.**

Specifically, we strongly oppose permitting prior authorization and step therapy for antiretroviral medications used to treat and prevent HIV. We also have serious concerns with the unprecedented expansion of prior authorization and step therapy for patients *stable* on their treatment regimens across the six protected classes, and other aspects of the proposed rule including the ability for an insurance plan to exclude prescription drugs from its formulary under certain circumstances.

We understand that the underlying purpose of these proposals is to increase pressure on pharmaceutical manufacturers to provide greater rebates to the plans that administer Medicare Part D programs. We find this goal surprising in light of previous Administration

comments attributing high prescription drug prices in part to the rebates that insurers and pharmacy benefit managers extract from the manufacturers. We believe that the health care system would be better served through a focus on reducing rebates to lower list prices. Prescription drug pricing is complex, and difficult to evaluate in a programmatic silo. Thus, we believe it is also important to consider the total amount of rebates and discounts HIV drug manufacturers provide, including to the 340B and the Ryan White AIDS Drug Assistance Programs. **Any effort to address drug pricing should not come at the expense of patient access and patient health. Unfortunately, we believe these proposals will do just that.**

Antiretrovirals and the "Protected Classes"

Prescription drugs in the six "protected classes" (as defined in Section 1860D-4(b)(3)(G)(iv)) are used to treat the most vulnerable of patients for whom medicines are not interchangeable due to sensitivity or resistance to a drug, the unique biochemistry of the individual, or severe side effects. It is because of this that Congress enacted protections guaranteeing access to the full range of approved prescription medications used to treat epilepsy, cancer, mental illness, HIV/AIDS, and organ transplants.

Antiretrovirals used to treat and prevent HIV represent a unique position within the six protected classes because HIV is the only infectious disease among the classes. Ensuring broad access to life-saving and life-extending antiretrovirals is not only necessary for maintaining the health and well-being of Medicare Part D beneficiaries living with or at risk of HIV, but also for the prevention of new HIV infections through consistent viral suppression as a result of treatment and access to pre-exposure prophylaxis (PrEP) used to prevent HIV.

With the tools currently available, including antiretroviral medications, we have the ability to decrease the number of new infections which can lead to the end of the HIV epidemic. Commemorating the most recent World AIDS Day, President Trump proclaimed, "through public and private American leadership, innovation, investment, and compassion -- we have ushered in a new, hopeful era of prevention and treatment…[w]e reaffirm our on-going commitment to end AIDS as a public health threat."

Leadership within the Administration is taking a strong stance and pushing for an end to the epidemic. Dr. Robert Redfield, Director of the Centers for Disease Control and Prevention, when asked about ending the AIDS epidemic in America, responded, "It's possible. I think it could be done in the next three to seven years, if we put our mind to it."[1] Dr. Anthony Fauci,

[1] Hellmann, J. US Could End AIDS Epidemic in Three to Seven Years. March 2018. The Hill. https://thehill.com/policy/healthcare/380986-new-cdc-director-says-us-could-end-aids-epidemic-in-three-to-seven-years-if

Director, National Institute of Allergy and Infectious Diseases, has stated, "If we only implemented the public health tools we have now, we could end the AIDS epidemic."[2]

Advances in prevention and treatment have resulted in declining numbers of new HIV infections and in greater viral suppression among people living with HIV. But in order to achieve this laudable goal, it is imperative that patients have access to the full range of antiretrovirals for both treatment and prevention.

Expanding, not limiting, access to HIV preventions and treatments is central to protecting the public's health and ending the HIV/AIDS epidemic. To this end, the administration is currently engaging stakeholders to update the National HIV/AIDS Strategy, which includes critical focus areas of improving treatment access and universal viral suppression.[3] Many cities, counties, and states across the country, working in concert with community-based organizations, are developing and implementing "Ending AIDS" plans. Medicare Part D plays an important role in this strategy, and finalizing this proposed rule as written would undermine efforts to end the HIV/AIDS epidemic.

HIV Care and Treatment Landscape

In 2014, there were approximately 120,000 people living with HIV on Medicare[4], and the CDC estimates that number will dramatically increase over the next two decades as approximately 600,000 people living with HIV age into the program.[5] Medicare accounts for approximately half of all federal spending on HIV care and treatment in the US.[6] As the population of people living with HIV become even more reliant on Medicare for coverage, it is even more imperative that Medicare Part D policy supports full access to appropriate and effective HIV treatment without unnecessary administrative burden.

The HIV prevention and treatment landscape and standard of care have experienced critical advances, including the advent of PrEP to prevent the acquisition of HIV. Many of the newer antiretrovirals achieve more rapid and sustained HIV suppression, have fewer side effects and can improve adherence through reduced pill burden. Based on a conclusive body of evidence, the recommended standard of care is now to start individuals with HIV on treatment as quickly as possible after diagnosis with the most effective, best-tolerated regimen to optimize individual health outcomes and public health by stopping HIV transmission. The CDC made the

[2] "AIDS epidemic could effectively end if steps taken, Fauci says" https://www.axios.com/aids-epidemic-could-end-if-steps- taken-fauci-says-682ffeb0-2156-4606-861c-e0b18e260d33.html

[3] National HIV/AIDS Strategy. https://www.hiv.gov/federal-response/national-hiv-aids-strategy/overview

[4] Kaiser Family Foundation. https://www.kff.org/hivaids/fact-sheet/medicare-and-hiv/

[5] Bloomberg Health, Law & Business. Aging HIV Population Faces High Drug Costs, Taxes Medicare. June 2018. https://news.bloomberglaw.com/health-law-and-business/aging-hiv-population-confronts-high-drug-costs-taxes-medicare

[6] Azar, A. Remarks to the National Ryan White Conference on HIV Care and Treatment. December 2018. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-to-2018-national-ryan-white-conference.html

important public health announcement that an undetectable viral load equals an un-transmittable virus. This is only achievable through uninterrupted access and adherence to medicines as prescribed by a provider in accordance to federal guidelines for treatment of HIV.[7]

There are very few lower-cost generic antiretroviral options available and none are prescribed as a front-line therapy. Individualized therapy that requires access to a variety of brand products is still central to best practices toward maximized safety and virologic suppression outcomes. Thus, it is at best questionable whether the proposed policy changes would result in any significant cost savings within the antiretroviral class, as cost-saving calculations in the proposed rule are predicated on decreased utilization of single-source drugs and increased utilization of generic products. At worst, the proposed rule could result in a dramatic rise in Medicare Part A and B, Medicaid, and public health expenses as people experience health crises due to reduced or delayed access to appropriate HIV medication.

Prior Authorization and Step Therapy Impedes HIV Treatment and Disease Management

The proposed rule would permit, for the first time, the application of utilization management for antiretrovirals in Medicare Part D. The AIDS Institute has serious concerns regarding the detrimental effects prior authorization and step therapy would have for patients newly diagnosed or stable on their on-going treatment regimen particularly since they run counter to the practice of HIV treatment and prevention. Moreover, CMS' proposal upends its long-standing, evidence-based policy which "…(I) ensures that any exception to such requirement is based upon scientific evidence and medical standards of practice (and, in the case of antiretroviral medications, is consistent with the Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents)…"

The current US government sponsored HIV treatment guidelines state that prior authorizations for HIV drugs "result in fewer prescriptions filled and increased nonadherence…. and have substantially reduced timely access to medications." Step therapy is not a clinically acceptable practice in the treatment of HIV due to the danger of developing resistance to an entire class of drugs and potential side effects.

Best practices among medical providers, validated through many clinical studies, indicate that beginning antiretroviral therapy immediately upon diagnosis shortens the time to viral suppression, thus serving as a public health approach to containing HIV transmission while treating the individual's health. Issued as part of the most recent HIV treatment guidelines, the World Health Organization "strongly recommends that rapid ART initiation should be offered to people living with HIV following confirmed diagnosis and clinical assessment" and that "same day start can improve program outcomes, especially by reducing loss to care in the pre-ART

[7] U.S. Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV; Adherence to ART: https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/30/adherence-to-art

period."[8] Delaying an individual's initiation of treatment through unnecessary bureaucracy as a result of prior authorization is likely to harm not only individual patient outcomes, but also undermine the larger public health goal of reducing the number of new HIV infections.

Each step in the HIV care continuum is critical, from initial diagnosis to linkage and retention in care to achieved viral suppression, and obstacles presented at any point throughout the continuum may contribute to poor engagement in HIV care and can substantially limit the effectiveness of efforts to improve health outcomes and to reduce HIV transmission.[9] The CDC reported that of all people living with HIV in 2015, 86 percent received a diagnosis, but only 63 percent received care and only 49 percent were retained in care.[10] Imposing hurdles to accessing HIV medications through prior authorization has been shown to result in fewer prescriptions filled and increased non-adherence, directly relating to the loss to follow up through the HIV care continuum.[11] Prior authorization for individuals who have been living with HIV for many years poses the risk of triggering viral resistance, even with a short gap in prescription access, which then renders the entire class of medications ineffective for that patient. [12]

Step therapy is not a clinically acceptable practice in the treatment of HIV due to the danger of causing irreversible disease progression or developing resistance to an entire class of drugs. Destabilizing an HIV patient's treatment regimen by requiring them to 'fail-first' will impact their viral load suppression and increase the risk of drug-resistant HIV transmission, which will be harder to treat and suppress. HIV specialists have stated that there are "many important considerations, including the person's adherence to medications, drug resistance, drug-to-drug interactions, concomitant medical conditions and side effect profiles [are] taken into account when choosing the best regimen…. it's medically crucial to have all options on the table when prescribing and to be able to start those drugs quickly, with no barriers to access."[13] These unique biological and circumstantial considerations are true when approaching every HIV patient's treatment; however, each variable becomes even more critical for those within the Medicare program due to common occurrences of comorbidities that come with aging, the

[8] World Health Organization. Guidelines for Managing Advanced HIV Disease and Rapid Initiation of Antiretroviral Therapy. July 2017. HIV Treatment Guidelines. https://www.who.int/hiv/pub/guidelines/advanced-HIV-disease/en/

[9] HIV.gov. What is the HIV Care Continuum? https://www.hiv.gov/federal-response/policies-issues/hiv-aids-care-continuum

[10] Centers for Disease Control and Prevention. Understanding the HIV Care Continuum. June 2018. https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf

[11] U.S. Department of Health and Human Services, Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/30/adherence-to-the-continuum-of-care

[12] American Academy of HIV Medicine. Prior Authorization Policy One-pager. 2016. https://aahivm.org/wp-content/uploads/2016/12/AAHIVM-policy-one-pager-Prior-Authorization-FINAL.pdf

[13] HIV Medical Providers Strongly Oppose Proposed Changes to Medicare Drug Plans "Protected Classes." POZ Magazine. January 2019. https://www.poz.com/article/hiv-medical-providers-strongly-oppose-proposed-changes-medicare-drug-plans-protected-classes

associated risk of harmful drug interactions to manage those comorbid conditions, as well as an increased likelihood of having experienced drug resistance over their lifetime. This demonstrates the importance of individualized treatment in accordance with a prescribing medical provider who is experienced and familiar with the patient's need.

Improving the speed at which an individual is engaged in healthcare through 'rapid start' of antiretroviral therapy, which combines the phases of diagnosis, linkage to care, and prescription of medication, has a high return on investment not only for the patient but for the healthcare system.[14] Moreover, delaying treatment due to prior authorization can increase health care costs if patients run out of medication or experience disease progression while waiting for approval of their medication, according to the American Academy of HIV Medicine, which represents specialized medical professionals in the field of HIV care and treatment.[15]12 aboveThe Academy is also concerned that prior authorization poses a significant burden for physicians in terms of time and money, with some estimates of physicians spending approximately twenty hours per week at minimum on prior authorization activities, and up to $31 billion each year to the US health care system.[16,17]

Prior Authorization Puts HIV Prevention At Risk

Pre-exposure prophylaxis (PrEP) is one of the most promising and effective tools in our fight against HIV, as you noted in your recent speech at the National Ryan White Conference.[18] The proposed language allowing prior authorization to be used "to confirm use is intended for a protected class indication" would also impact the use of PrEP. There is currently only one antiretroviral medication approved for the prevention of HIV, a use that is squarely within the protected class indication as it is an antiretroviral approved by the FDA for both treatment and prevention of HIV. But adding unnecessary bureaucratic hurdles to the prescribing process jeopardizes the promising role PrEP can play in preventing HIV infection in the future.

[14] "Rapid Start of ART" A Critical Goal of Ending HIV/AIDS in America. November 2018. O'Neill Institute for National & Global Health Law, Georgetown Law. http://oneill.law.georgetown.edu/news/rapid-start-of-art-a-critical-goal-toward-ending-hiv-aids-in-america/

[15] American Academy of HIV Medicine. Prior Authorization Policy One-pager. 2016. https://aahivm.org/wp-content/uploads/2016/12/AAHIVM-policy-one-pager-Prior-Authorization-FINAL.pdf

[16] The Prior Authorization Predicament. Medical Economics. July 8, 2014. http://www.medicaleconomics.com/modern-medicine-feature-articles/prior-authorization-predicament

[17] Casalino, L.P., Nicholson, S., Gans, D.N., Hammons, T., Morra, D., Karrison, T., Levinson, W. What Does it Cost Physician Practices to Interact with Health Insurance Plans? Health Affairs. August 2009. https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.28.4.w533?keytype2=tf_ipsecsha&ijkey=ab6e6c7d689c5a4949c03fc849458f04aeb59a2d

[18] Azar, A. Remarks to the National Ryan White Conference on HIV Care and Treatment. December 2018. https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-to-2018-national-ryan-white-conference.html

Additionally, recently the US Preventive Services Task Force (USPSTF) issued a draft "A" grade recommendation for PrEP for persons at high risk of HIV acquisition.[19] Once finalized, this grade will carry with it the credibility for providers to more widely prescribe the preventative drug, supporting efforts to reduce new infections of HIV. Imposing prior authorization requirements on PrEP will impede access for the vulnerable individuals at-risk for the acquisition of HIV who could easily be discouraged and therefore disengage with the healthcare system. Furthermore, any impact on access could affect adherence to PrEP, rendering its preventive qualities ineffective.

Uninterrupted Care for Stable Patients in all Six Protected Classes

Additionally, we have serious concerns regarding the unprecedented proposal to permit step therapy and prior authorization for patients *stable on existing treatments*, across all six protected classes. Many people living with HIV experience co-morbid health conditions. For example, multiple studies have found that approximately half of those living with HIV have been diagnosed with a comorbid mental health condition.[20] Ensuring that an individual with a mental health condition receives appropriate care and treatment is necessary to achieving positive health outcomes for all people, but especially for people living with HIV. When a mental health issue is controlled, patients will have an easier time treating their HIV and staying adherent to their medications.

Removing Drugs from Formulary based on Price Increases

The AIDS Institute has serious objections with the proposal to allow plans to remove medications from a formula if a manufacturer increases the list price of the drug higher than the consumer price index. If such a policy were to be implemented, Medicare Part D beneficiaries with or at risk of HIV could be harmed for something for which they had no responsibility. While it would punish the manufacturer, it would also punish the beneficiary, and in the case of HIV, interfere with proper treatment and viral suppression.

Even if CMS were to proceed with such a proposal, we question why the list price of the drug would be used rather than the after-rebate net price. While we agree that the list price does matter to patients when determining cost-sharing, what really impacts federal government spending and reinsurance is plan preferences to select higher priced drugs with a high level of

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[19] US Preventive Services Task Force. Draft Recommendation Statement for Prevention of HIV Infection: Pre-exposure Prophylaxis https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis

[20] "Public Financing and Delivery of HIV/AIDS Care: Securing the Legacy of Ryan White," Washington DC: National Academies Press, http://www.iom.edu/Reports/2004/Public-Financing-and-Delivery-of-HIVAIDS-Care-Securing-the-Legacy-of-Ryan-White.aspx
Bing, E.G, et al., "Psychiatric disorders and drug use among human immunodeficiency virus-infected adults in the United States," Archives of General Psychiatry. 2001 Aug;58(8):721-8. http://archpsyc.jamanetwork.com/article.aspx?articleid=205826; Kates, Jen, Kaiser Family Foundation, "Medicaid and HIV: A National Analysis," 2011, http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8218.pdf.

rebates. Therefore, we believe any calculation should be based on a number that at least subtracts out rebates and other discounts paid by the manufactures.

We also do not believe that the consumer price index is the correct measure. There are other indexes, including the medical price of inflation. Finally, we do not believe the plans themselves should be the ones overseeing, calculating and implementing any such procedure. For these reasons, we urge CMS not to proceed with this faulty proposal.

Including Pharmacy Price Concessions in the Negotiated Price

We support the proposal to require all pharmacy price concessions, such as fees to participate in a preferred network, to be included in the negotiated price. This will help lower patient cost-sharing since it is determined as a percentage of the negotiated price. While it is not included in the proposed rule, we look forward to future proposals by CMS that will address the issue of moving rebates to the point of sale. By doing so, you would dramatically increase patient savings.

The AIDS Institute appreciates the Administration's laudable efforts to lowering drug prices and reducing patient expenses. However, we hope you remain committed to protecting America's most vulnerable patients within the Medicare Part D six protected classes as the rule is finalized, including those who are living with or at risk of HIV. We look forward to working with you to ensure patients' access to life-saving medications are protected, while finding innovative ways to impact costs in the healthcare system.

Should you have any questions or comments, please do not hesitate to contact Carl Schmid, Deputy Executive Director at (202) 462-3042 or cschmid@theaidsinstitute.org.

Sincerely,

Michael Ruppal
Executive Director

Carl E. Schmid II
Deputy Executive Director

cc: Seema Verma/CMS
Demetrius Kouzoukas/CMS
Dr. John O'Brien/ASPE
Joe Grogan/White House
Dr. George Sigounas/HRSA
Dr. Robert Redfield/CDC
Adm. Brett Giroir/ASH