FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

February 22, 2021

The Honorable Xavier Becerra
Secretary Designee
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW Washington, D.C. 20201

RE: Medicare Part D Payment Modernization Model – Six Protected Classes

Dear Secretary Designee Becerra,

We are writing on behalf of the HIV Health Care Access Working Group (HHCAWG) – a coalition of over 100 national and community-based HIV service organizations representing HIV medical providers, public health professionals, advocates, and people living with HIV who are all committed to ensuring access to critical HIV and hepatitis C-related healthcare and support services. We strongly oppose recent changes in the CMS Center for Medicare and Medicaid Innovation (CMMI) Part D Payment Modernization (PDM) Model announced on January 19, 2021 under the prior administration, allowing for broad new formulary restrictions beginning in calendar year 2022. **We urge you to rescind these formulary changes**, which circumvent current law and enable plans to significantly restrict prescription drug coverage to one drug per class for all drugs covered under Part D under the guise of giving plans more flexibility.

The new Part D demonstration would also allow plans sponsors to begin restricting prescription drugs for five protected classes (anticonvulsants, antidepressants, antineoplastics, antipsychotics, and immunospressants) beginning in 2022, and for antiretroviral drugs in 2023. These changes not only undermine long-standing Medicare beneficiary protections, but also pose a direct threat to the health of those living with HIV. HHCAWG supports current Medicare policy that requires plan sponsors to include on their formularies at least two drugs per class, and to cover all or substantially all drugs within the six protected classes. This policy has ensured access to life-saving and life-extending medications for thousands of Medicare beneficiaries living with HIV, improving health outcomes among this vulnerable population.

HIV Treatment and the Six Protected Class Policy
We oppose eliminating existing protections in the Medicare Part D program for antiretroviral medications as one of the six protected classes. HIV treatment is a complex, highly individualized therapy that requires access to a variety and combination of medications to maximize virologic suppression and minimize harmful drug interactions or side effects. The HIV prevention and treatment landscape and standard of care have experienced critical advances: many of the newer antiretrovirals achieve more rapid and durable suppression of HIV, 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 to start individuals with HIV on treatment soon after diagnosis with the most effective, best-tolerated regimen to optimize individual health outcomes and public health by stopping HIV transmission. Restricting antiretrovirals will undoubtedly have a ripple effect: disruptions to care,

decreased rates of viral suppression, increased rates of new infections and more drug resistant strains of HIV. These harmful consequences would also be counterproductive to the intent of the demonstration project by ultimately increasing costs to the healthcare system through more emergency room visits and hospitalizations.[1]

The six protected class policy is also a critical protection for some of the most vulnerable Medicare beneficiaries because it ensures full access to a broad range of therapies which is particularly important for the treatment of comorbidities. People with serious mental illness and substance use disorders need access to antipsychotics and antidepressants, and also have high rates of co-occurring HIV-AIDS infections. 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."[2] 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.

Additionally, the six protected class policy has prevented people living with HIV from facing burdensome step therapy and prior authorizations in order to access treatment. These types of utilization management techniques are particularly inappropriate given the populations who depend on the Medicare program, including individuals who are either low-income and disabled or over the age of 65. These patients are likely to have been living with HIV for many years and necessarily have more complex treatment options because of co-morbid conditions and the development of resistance to some antiretroviral medications. Individualized treatment decisions are critical to ensure appropriate care and treatment for this vulnerable population. Rolling back this important protection for HIV medications is inconsistent with the federal HIV treatment guidelines[3] cited in the regulation itself (currently at 42 CFR §423.120(b)(2)(vi)(C).

Finally, the six protected classes policy is important in combating potential discriminatory treatment towards people living with HIV by part D plans sponsors. This policy protects beneficiaries from discriminatory plan designs that would discourage the enrollment of those most in need of the benefits Part D was established to provide. In these ways, the six protected class policy has been an important success of Part D. Congress has specifically sought to maintain these protections in a bipartisan manner on multiple occasions. Similar changes proposed by the Obama and Trump Administrations were reversed after Congress, patient groups and other stakeholders voiced opposition.

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[1] Studies have found that even when step therapy and prior authorization reduced pharmacy costs, emergency room and hospitalization costs increased. See, e.g., Rashad I. Carlton, "Review of Outcomes Associated with Formulary Restrictions: Focus on Step Therapy," 2 American Journal of Pharmacy Benefits 50, 56–7 (2010).

[2] 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

[3] Department of Health and Human Services, Federal HIV/AIDS Practice Guidelines, http://aidsinfo.nih.gov/guidelines.

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Two Drug Per Class Requirement
The Part D demonstration allows for plans to reduce the number of drugs covered per class to a single drug. When Congress created Part D, it required plan formularies to include *at least two drugs* per class for drugs outside of the six protected classes, in order to ensure that Medicare beneficiaries have access to the treatment options that meet their specific medical needs. This again is critically important when treating cobormidities. While the policy affords beneficiaries a minimum number of treatment options, plans continue to have the flexibility to encourage the use of lower cost drugs through a variety of utilization management tools. This balance of beneficiary protections and plan flexibility has been in place since the inception of Part D and, again, has contributed to its success.

A one-size-fits-all approach simply does not work for patients who require personalized medicine. Limiting access to the most clinically appropriate medications could have significant repurcussions on out-of-pocket costs for beneficiaries and on Medicare and Medicaid program costs. These higher costs would result from the destabilization of patients' conditions, and increased physician visits and hospitalizations that occur when patients do not have access to prescribed medications. Waiving the two drug per class requirement in the PMD Model would effectively eliminate a key component of the Part D benefit. Additionally, AIDS Drug Assistance Programs (ADAPs), as payers of last resort, may be forced to provide access to the prescription drugs excluded by Part D plans, ultimately shifting costs away from commercial payers and on to a federally funded, safety net program.

The changes announced on January 19 would roll back patient protections for Medicare beneficiaries, weaken the Part D program, and go against medical best practices for the treatment of HIV. The changes move in the wrong direction for particularly vulnerable Medicare beneficiaries, and in direct opposition to what Congress intended when it established the statutory two drugs per class requirement and the six protected classes. We again request that you rescind these policy changes to the PDM model.

We appreciate your consideration of our serious concerns the changes to the PDM model for CY 2022 announced January 19 will have for Medicare beneficiaries living with HIV. We urge you to rescind those policy changes proposed by the prior administration. Please reach out to HHCAWG co-chairs Rachel Klein, rklein@taimail.org, Phil Waters, pwaters@law.harvard.edu, or Aisha Davis, adavis@aidschicago.org, if you have any questions or if we can be of any assistance.

Sincerely,

AHF
AIDS Action Baltimore
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation Chicago
AIDS United
American Academy of HIV Medicine
APLA Health
Center for Health Law and Policy Innovation
Community Access National Network – CANN
Community Education Group
Community Research Initiative, Inc. (CRI)
Georgia Equality
HealthHIV
HIV+Hepatitis Policy Institute
HIV Dental Alliance

HIV Medicine Association
iHealth
NASTAD
NMAC
Positive Health Solutions of the University of Illinois
Positive Women's Network-USA
Prevention Access Campaign
Rural Health Service Providers Network
San Francisco AIDS Foundation
SisterLove, Inc.
The AIDS Institute
Vivent Health

cc: Elizabeth Richter, Acting Administrator, Centers for Medicaid and Medicare Services