November 5, 2018

The Honorable Alex Azar
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue S.W.
Washington, D.C., 20201

Re: Protecting HIV Medication Treatment and Access in the Medicare Part D Program

Dear Secretary Azar,

As leading state and national 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 medications, we continue to hear you state the administration will be changing the rules regarding the protected drug classes under Medicare Part D. We oppose changing this rule for all classes because it would jeopardize access to effective treatment for Medicare beneficiaries living with HIV and other serious, complex chronic conditions that require timely and uninterrupted access to drug therapies. About one quarter of people living with HIV in care get their health insurance coverage through Medicare and individuals with HIV with Medicare coverage by virtue of qualifying for the program are disabled, or seniors, and have been living longer with HIV and have fewer treatment options. Because of this, it is imperative to ensure Medicare beneficiaries maintain access to the HIV medications recommended in the *Department of Health and Human Services Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV* (**DHHS HIV Treatment Guidelines**) and by their medical providers.

Ending the Epidemic: Thanks to the Ryan White HIV/AIDS Program, Medicare, Medicaid and the Affordable Care Act, more people living with HIV have access to comprehensive, high quality, affordable insurance. We have preexposure prophylaxis (PrEP), a prevention pill that is nearly 100% effective at preventing HIV infection when utilized consistently and correctly. With uninterrupted access to the appropriate antiretroviral medications and additional healthcare and support services, people living with HIV can achieve and sustain undetectable levels of the virus or "viral suppression" allowing them to stay healthy and stopping transmission of HIV. This is called "Undetectable = Untransmittable", or U=U. Modeling indicates that with improved coverage and access to HIV medications through federal programs, including Medicare Part D, we can end the HIV epidemic by 2030.

Formulary Requirements Including Protected Classes: For people living with HIV and so many others, new drug therapies have saved millions of lives and prolonged millions more. The advent of antiretroviral medications in the late '90s turned HIV from a near certain death to a more manageable disease if patients have access to quality care and medications. We know that not all medications are the same, and each person reacts differently to a particular medication. Treatment for HIV has evolved rapidly and the DHHS HIV Treatment Guidelines are widely recognized by the medical community as setting the current standard for HIV treatment. With the guidelines, doctors and patients together make careful treatment decisions about which therapies are most appropriate on a case by case basis. Some individuals may develop side effects to a particular drug, while another person may need a certain therapy to avoid a harmful interaction with a drug being taken for another health condition. Drug resistance can occur in people living with HIV, particularly those who are treatment experienced, and they must have the ability to switch to another drug without interruption.

It was for these reasons that when Medicare Part D was first implemented, CMS determined that a minimum of only two drugs in a class was simply not enough for certain patients, including those with HIV, mental illness, cancer, epilepsy, and those undergoing organ transplantation. The "six protected classes" was created so that patients could have broad access to all the drugs in these classes. Additionally, due to the way in which HIV is treated, CMS has stated that for HIV drugs plans need to follow procedures in accordance with the DHHS HIV treatment guidelines. CMS has made it clear that this means "utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models."

In the newly released version of the Guidelines it states:

> As a cost-containment strategy, some programs require that clinicians obtain prior authorizations or permission before prescribing newer or more costly treatments rather than older or less expensive drugs. Although there are data demonstrating that prior authorizations do reduce spending, **several studies have also shown that prior authorizations result in fewer prescriptions filled and increased nonadherence. Prior authorizations in HIV care specifically have been reported to cost over $40 each in provider personnel time (a hidden cost) and have substantially reduced timely access to medications.**

The current system is working for patients and we urge you to continue access to these important therapeutic areas, which Congress has recognized by codifying in law. The reason for the six protected classes was to ensure beneficiary access to all or substantially all drugs in certain therapeutic classes or categories where it is known that complete formulary access is essential to successful treatment. The reasoning behind this policy continues today.

HHS has expressed concerns that there is little negotiation between the plans and drug manufacturers. Part D plans may utilize formulary tiering to steer patients toward lower cost drugs. These tools give Part D plans considerable flexibility to manage more expensive medications, as well as leverage to negotiate rebates with manufacturers. Additionally, in all classes except antiretrovirals, Part D plans use prior authorization and step therapy to manage therapies for any beneficiary beginning treatment on a protected class drug.

We strongly oppose any changes to the protected classes. Additionally, for those drugs that do not fall into these classes, such as those used to treat hepatitis B and C, we oppose changing the minimum number of drugs a plan is required to cover in each class from two to one.

Please contact Ramon Gardenhire at rgardenhire@aidschicago.org with the AIDS Foundation of Chicago, Carl Schmid at cschmid@theaidsinstitute.org with The AIDS Institute, Robert Greenwald at rgreenwa@law.harvard.edu with the Center for Health Law and Policy Innovation, Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@nastad.org, or Andrea Weddle at aweddle@hivma.org with the HIV Medicine Association with any questions.

Respectfully submitted by the undersigned organizations:

ADAP Educational Initiative
African American Health Alliance
AIDS Action Baltimore
AIDS Alabama

AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
AIDS Project Rhode Island
AIDS Research Consortium of Atlanta
AIDS Resource Center of Wisconsin
AIDS United
American Academy of HIV Medicine
APLA Health
Association of Nurses in AIDS Care
Bailey House, Inc.
Cascade AIDS Project
Center on Halsted
Chicago House and Social Service Agency
CHOICES. Memphis Center for Reproductive Health
Christie's Place
Clare Housing
Columbia CARES, Inc.
Communities Advocating Emergency AIDS Relief (CAEAR)
Community Access National Network (CANN)
Equality California
Equality North Carolina
Equitas Health
Fenway Health
Florida Keys HIV Community Planning Partnership
Friends For Life
Georgia AIDS Coalition
Georgia AIDS Coalition
GreaterWorks! Inc.
Harlem United
Harm Reduction Coalition
HealthHIV
HIV Medicine Association
Housing Works, Inc.
Howard Brown Health Center
Human Rights Campaign
JustUs Health
Latino Commission on AIDS
Legacy Community Health
Legal Council for Health Justice
Los Angeles LGBT Center
Michigan Positive Action Coalition
Minnesota AIDS Project
Nashville CARES
National Alliance of State and Territorial AIDS Directors
National Black Justice Coalition
National Latino AIDS Action Network
National Working Positive Coalition
NMAC

North Carolina AIDS Action Network
Oklahoma AIDS Care Fund
Open Door Clinic of Greater Elgin
Pediatric AIDS Chicago Prevention Initiative
Positive Women's Network - USA
Pride Action Tank
Prism Health North Texas
Project Inform
Puerto Rico CoNCRA
Rocky Mountain CARES
Ryan White Medical Providers Coalition
San Francisco AIDS Foundation
San Francisco AIDS Foundation
SisterLove
Southern AIDS Coalition
Southern HIV/AIDS Strategy Initiative
St. Louis Efforts for AIDS
The AIDS Institute
The Center for HIV Law and Policy
Thrive Alabama
Treatment Access Expansion Project
Treatment Action Group
TruEvolution