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July 16, 2018

The Honorable Alex M. Azar, II
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Re: RIN 0991-ZA49 HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (CMS-2018-0075; 83 FR 22692)

Dear Secretary Azar,

We are writing on behalf of AIDS United's Public Policy Council (PPC) – the largest and longest-running national coalition of community-based HIV/AIDS organizations that, in service of AIDS United's singular mission to end the HIV epidemic, provides diverse, collaborative perspectives and analysis on regulatory and legislative priorities to federal policymakers.

PPC member organizations cover jurisdictions that include more than two-thirds of people living with HIV in the United States. We appreciate the opportunity to respond to and provide feedback on policies under consideration in the Department of Health and Human Services' (HHS) request for information on its Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (Blueprint).

We are encouraged by the steps HHS is taking to reduce out-of-pocket costs at pharmacies and other settings, thereby improving affordability and accessibility of prescription drug medications which are crucially important for the health outcomes of people living with HIV. Since people living with HIV who have an undetectable viral load as a result of successful antiretroviral treatment are unable to transmit the virus to others,[1] any compromise to affordability and accessibility of prescription drugs places the health of people living with HIV at risk, affects public health, inflates health care costs, and unduly burdens already-strained precious safety net resources.

To ensure people living with HIV can access the prescription drugs on which they rely and to move toward an end to the HIV epidemic, we implore HHS to consider the following recommendations:

I. Preserve protections under Medicare Part D for certain drug classes.
II. Reject proposals limiting the benefits, intent, and structure of the 340B Drug Discount Program.

I. Preserve protections under Medicare Part D for certain drug classes.

[1] *10 Things to Know About HIV Suppression*, National Institute of Allergy and Infectious Diseases at the National Institutes of Health, https://www.niaid.nih.gov/news-events/10-things-know-about-hiv-suppression.

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As HHS considers various Medicare Part D proposals in the Blueprint, we appreciate the opportunity to reinforce our unwavering support for the requirements that all Medicare Part D plans must cover at least two drugs in each therapeutic class[2] and that Part D plans must cover all drugs in six protected classes: immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.[3] The Blueprint proposes altering and/or altogether removing both of these requirements.

Promulgating these changes would allow plans to limit the number of drugs covered under Part D plans. Limiting covered drugs could restrict beneficiaries' access to only one medication for their condition(s), meaning that beneficiaries living with HIV would no longer be assured that Medicare Part D would cover the specific antiretroviral drug that is working for them.

These protected classes were established to ensure that people have unfettered access to prescription drug medication necessary for the treatment of certain serious, chronic illnesses including HIV. HHS must ensure access to drugs within the protected classes and craft policy solutions that guarantee people living with chronic illnesses – including but not limited to HIV – can obtain treatments chosen with their physician at affordable costs.

II. Reject proposals limiting the benefits, intent, and structure of the 340B Drug Discount Program.

Created under President George H. W. Bush, the 340B Drug Discount Program (Program) requires pharmaceutical manufacturers to enter into an agreement with the federal government whereby the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers called "covered entities" that serve the nation's most vulnerable populations. Covered entities include Community Health Centers, Ryan White clinics, and disproportionate share/safety net hospitals.

During its 26-year existence, the Program has been an indispensable resource for HIV service organizations, with savings generated from drug discounts enabling more Americans living with and at risk for HIV to benefit from lifesaving treatment, preventive healthcare, and chronic disease management. As a direct result of the Program, access to care has dramatically expanded across the U.S. as covered entities have been able to increase healthcare services in their communities, offering more healthcare delivery locations, hours of operation, expert providers, added services, and healthcare workers. Savings from the Program have also enabled increases in the healthcare expertise needed to properly treat and manage HIV across the country.

Ultimately, the purpose of the Program as defined by Congress is "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." The Program fulfills this purpose very well and is performing as intended. AIDS United and its Public Policy

[2] 42 C.F.R §423.120(b)(2)(i)
[3] 42 U.S.C. 1395w-104(b)(3)(G)(iv)

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Council urge HHS not to change the Program in ways that run counter to its intended purpose, especially in ways that will result in fewer services for people living with and affected by HIV.

Over the past several years, Congress has held hearings concerning the future of the Program in which some pharmaceutical industry organizations and members of Congress have claimed that the Program is not working as was originally intended. In part, they claim that the program is contributing to the rise in prescription drug prices. This is simply untrue. In reality, the Program has been shown to represent only 2.2% of total drug spending.[4] Drug prices continue to rise for many reasons, none of which are directly attributable to covered entities participating in the Program.

New legislation has been introduced that would place a moratorium on certain new 340B hospitals and outpatient locations and mandate significant new reporting requirements; it is widely speculated that forthcoming proposed regulations from HHS regarding the Program include similar changes in addition to shifts in the definition of a "patient." AIDS United may support legislation or regulatory proposals for increased transparency and oversight of the Program; however, any legislation should not focus solely on narrow classes of charity care and individual patients but rather provide a wider understanding of the care and services 340B covered entities provide with the savings from the Program. Additionally, increased oversight must also include transparency regarding drug pricing.

Although much of the current scrutiny surrounding the Program is focused specifically on disproportionate share/safety net hospitals, AIDS United is concerned that legislative and regulatory proposals subtly seek to change the purpose of the program to specify that benefits of the program go to providing discounted drugs to a narrow class of low-income patients rather than to stretch scarce resources for needed services. Changing the purpose of the Program shrinks the health services available to underserved populations, including for people living with HIV, precisely the opposite the program's original intent. We also note that disproportionate share/safety net hospitals are a critical component of care for many needs of people living with HIV.

We again note simply that the Program in its current form is doing exactly what it was designed to do, and we urge HHS not to make changes that will result in unintended consequences and fewer services for people living with and affected by HIV.

AIDS United's Public Policy Council thanks you for the opportunity to provide input on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. In order to end the HIV epidemic, access to affordable care and treatment for people living with HIV must be protected, and HHS must reject proposals that would diminish or reverse that access.

Please contact Carl Baloney, Director of Government Affairs for AIDS United, at cbaloney@aidsunited.org or Alex Smith, Senior Policy Manager for AIDS United, at

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[4] *Report to the Congress: Overview of the 340B Drug Pricing Program*, Medicare Payment Advisory Commission, http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf.

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asmith@aidsunited.org with any questions on how people living with HIV would be affected by the Blueprint proposals discussed above. Thank you for your time and consideration.

Respectfully submitted,

AIDS United
AIDS Action Committee, Boston, MA
AIDS Alabama, Birmingham, AL
AIDS Foundation of Chicago, Chicago, IL
AIDS Resource Center of Wisconsin, Milwaukee, WI
Amida Care, New York City, NY
APLA Health, Los Angeles, CA
BOOM!Health, Bronx, NY
Cascade AIDS Project, Portland, OR
CrescentCare, New Orleans, LA
Equitas Health, Columbus, OH
The Fenway Institute, Boston, MA
God's Love We Deliver, New York, NY
Harlem United, New York, NY
Harm Reduction Coalition, Oakland, CA
Hispanic Health Network, New York, NY
Howard Brown Health, Chicago, IL
Housing Works, New York, NY
Justice Resource Institute, Boston, MA
JustUs Health, St. Paul, MN
Latino Commission on AIDS, New York, NY
Legacy Community Health, Houston, TX
Los Angeles LGBT Center, Los Angeles, CA
My Brother's Keeper, Ridgeland, MS
National Alliance for HIV Education and Workforce Development, Washington, DC
National Black Justice Coalition, Washington, DC
Prism Health North Texas, Dallas, TX
Project Inform, San Francisco, CA
Rocky Mountain CARES, Denver, CO
San Francisco AIDS Foundation, San Francisco, CA
Thrive Alabama, Huntsville, AL
Urban Coalition for HIV/AIDS Prevention Services, Washington, DC
Whitman-Walker Health, Washington, DC
The Women's Collective, Washington, DC