July 16, 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: RIN 0991-ZA49 HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar,

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 health care and support services. We appreciate the opportunity to respond to the Department of Health and Human Services' (HHS) request for information on its Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (the Blueprint).

We commend HHS on its commitment to enhancing affordability and accessibility of prescription drugs. Affordability and accessibility of drugs is a particularly burdensome problem for individuals living with HIV or Hepatitis C (HCV). When individuals with diseases like HIV or HCV cannot access affordable medications, the health of individuals with these conditions is jeopardized and public health is affected. Effectively treating HIV and HCV is critical to stopping transmission in the community. In both scenarios, health care costs are likely to rise due to increased health care utilization by people with deteriorating conditions and increases in the number of individuals newly diagnosed with a complex, chronic condition.

To ensure that people living with HIV or HCV are able to access the drugs they rely upon, we urge HHS to consider two recommendations:

I. Maintain protections under Medicare Part D for certain drug classes and the minimum inclusion of at least two drugs per therapeutic class.
II. Reject proposals to use closed formularies in the Medicaid program.

I. HHS should maintain Medicare Part D protected classes and the inclusion of at least two drugs per protected class.

Medicare Part D plans are required to cover at least two drugs in each therapeutic class.[1] Similarly, Part D plans must cover all or substantially all drugs in six protected classes: immunosuppressants, anti-depressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastic.[2] The Blueprint contemplates removing and/or altering both of these requirements.

Doing so would allow plans to limit the number of drugs in Part D plan formularies. As a result, beneficiaries may only be able to access one medication for their conditions. This means that beneficiaries living with HIV would no longer be assured that Medicare Part D will cover the specific antiretroviral drug that is working for them. This especially concerning given that about one quarter of people living with HIV in care get their health insurance coverage through Medicare and generally individuals with Medicare coverage have been living longer with HIV and may have fewer treatment options .[3] Because of this, it is imperative to ensure Medicare beneficiaries maintain access to the HIV medications recommended by their medical providers.

However, we are concerned by the rising costs of HIV treatment. For the HIV drug classes – it remains critical that people with HIV have access to the medications recommended in the HHS Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV (HHS HIV Treatment Guidelines) and that the decision regarding the most appropriate treatment option needs to be determined by the Medicare beneficiary with HIV and his or her medical provider. We continue to urge coverage of all of the antiretrovirals but support efforts to lower HIV treatment costs particularly as more generic antiretrovirals become available and in accordance with the HHS HIV Treatment Guidelines. An insufficient number of generic HIV medications are available to weaken the HIV class protections, which for the HIV medications also largely bars the application of utilization management in accordance with the HHS HIV Treatment Guidelines.

The protected classes policy recognizes that people with complex conditions like HIV and serious mental illnesses like depression, bipolar disorder and schizophrenia may need access to the full range of medication options to be effectively treated.. The protected classes policy also was intended to ensure that beneficiaries with chronic conditions transitioning to Part D could continue taking the medications that were working for them.[4,5] While we recognize greater flexibility could facilitate lower prices, a minimum of two drugs per antiretroviral drug class will not provide sufficient options to meet the medical needs of Medicare beneficiaries with HIV.

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[1] 42 C.F.R §423.120(b)(2)(i)
[2] 42 U.S.C. 1395w-104(b)(3)(G)(iv)
[3] Kaiser Family Foundation analysis of the 5% sample (see endnote 2) and CDC. (2014) *Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV — United States, 2011*. MMWR. 63(47);1113-1117, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6347a5.htm?s_cid=mm6347a5_w.
[4] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents Living with HIV. Department of Health and Human Services. Available at http://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf.
[5] THE PEW CHARITABLE TRUSTS, *Policy Proposals: Revising Medicare Protected Classes Policy* (March, 2018), http://www.pewtrusts.org/-/media/assets/2018/03/dsri_policy_proposal_revising_medicares_protected_classes_policy.pdf

Additionally, restricting access to the most effective medications increases costs for the health care system. When individuals cannot access the medications they need, they incur other medical expenses as a result of their unmanaged illness. A recent literature review of over 90 studies confirms that restricting access to drugs is associated reduced medication adherence.[6] When conditions are not properly managed, beneficiaries may need additional health care services that Medicare pays for, like inpatient hospital stays and doctors' visits. A review of nearly 60 studies found that limiting the number of covered drugs often increases costs elsewhere in the health care system, offsetting any pharmaceutical savings achieved by drug restrictions.[7] As a result, Part D plans should not be permitted to limit the number of covered drugs further than already allowed because doing so could actually drive up costs in other parts of the health care system.

Ensuring strong protections to protect Medicare beneficiaries from being forced to stop their current treatment regimen is critical. Treatment interruptions can cause beneficiaries to experience disease progression or aggravated symptoms. Switching medications for people living with HIV is complicated and must be directed by a medical provider rather than determined by coverage limitations. Federal guidelines advise against interruptions of antiretroviral treatment, as HIV drug regiments are not interchangeable.[8] The Blueprint's proposals to modify the protected classes and the requirement to include at least two drugs per therapeutic class makes it more likely beneficiaries would have to switch medications if their current medication is no longer covered.

Not only do the Blueprint's proposed policies pose medical risks to beneficiaries, they will likely also cause stress, confusion, and uncertainty for providers and beneficiaries. Physicians choose which drugs to prescribe their HIV patients based on a wide range of factors, including co-occurring illnesses, medical history, and previous treatment tolerance.[9] Limiting physicians' abilities to prescribe the best drugs for their patients interferes with the clinical care decision-making process. Moreover, individuals often attempt many treatments before they find one that works. As such, many Medicare beneficiaries have relied upon their treatment regimens for years, even decades. It is essential that Medicare Part D plans cover all drugs in the protected classes and two drugs per therapeutic class so that beneficiaries may access the particular medicine that works best for them.

Reduced access to treatment also harms communities by posing significant risks to public health. Individuals who cannot access treatment risk transmitting HIV.[10] When an individual with HIV is

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[8] *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf.
[9] *Id.*
[10] *Id.*

effectively treated achieving sustained suppression of the virus, transmission of the virus can be stopped. [11]

II. HHS should reject proposals to use closed formularies in the Medicaid program

a. Closed formularies negatively impacts individual health, especially for individuals living with HIV

The Blueprint proposes five new Medicaid demonstration projects where state Medicaid programs could determine their own drug formularies. This means that state Medicaid programs participating in these demonstration projects would not be subject to the requirements of the Medicaid Drug Rebate Program, which requires an open formulary. As such, states would be able to choose the drugs that would be covered in their Medicaid programs.

Allowing states to design their own formularies could severely limit access to drugs, particularly high-cost single-tablet regimens. Limited drug access is harmful to individuals who rely upon high-cost drugs because of their chronic, complex conditions that require individualized care. Limiting access to such drugs would particularly harm people living with HIV or HCV. More than 40 percent of people living with HIV in care rely on Medicaid to receive their health services.[12] And, about 3.5 million people are living with HCV[13], many of whom have low incomes or other characteristics that make them eligible for Medicaid. We urge HHS to reference the Bulletin released by the Centers for Medicare and Medicaid Services (CMS), Health Resources and Services Administration (HRSA), and the Centers for Disease Control and Prevention (CDC), "Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries."[14] The Bulletin highlights the standard of care for HIV treatment and pre-exposure prophylaxis (PrEP), referencing the HHS Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents and the CDC PrEP Guidelines.

As discussed above, people living with HIV require access to a variety of drugs to ensure that the particular drug that works for them is covered. When an individual's treatment is interrupted, the person who has HIV may experience a worsening of their condition. This applies to people living with HCV as well. Moreover, the risk of HIV and HCV transmission increases when treatment is interrupted. These realities are amplified in the Medicaid population, which is comprised of

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[11] *Dear Colleague, Information from CDC's Division of HIV/AIDS Prevention*, CENTERS FOR DISEASE CONTROL AND PREVENTION, available at https://www.cdc.gov/hiv/library/dcl/dcl/092717.html
[12] Jennifer Kates and Lindsey Dawson. *Insurance Coverage Changes for People with HIV Under the ACA*. THE HENRY J KAISER FAMILY FOUNDATION (February 2017).
[13] *New Hepatitis C Infections Nearly Tripled Over Five Years*. THE CENTERS FOR DISEASE CONTROL AND PREVENTION (May 11, 2017), https://www.cdc.gov/media/releases/2017/p-hepatitis-c-infections-tripled.html
[14] Joint HHS, CMCS, HRSA, and CDC Informational Bulletin, Opportunities to Improve HIV Prevention and Care Delivery to Medicaid and CHIP Beneficiaries (December 2016), available at https://www.medicaid.gov/federal-policy-guidance/downloads/cib120116.pdf.

individuals who have low incomes and therefore have few, if any, alternative options for treatment. With such a large number of people living with complex, chronic conditions like HIV and HCV relying on Medicaid, it is essential that Medicaid maintains adequate drug access to prevent transmission and increased medical costs associated with limited drug formularies.

The Blueprint states that the proposed demonstration projects would include an appeals process that would "protect beneficiary access to non-covered drugs based on medical need."[15] However, an appeals process would not prevent an interruption in treatment. A beneficiary may lose access to the drugs they rely upon during the weeks or months it could take to successfully appeal. Moreover, there is no guarantee that an appeal decision would recognize the intricate medical decision-making that goes into establishing an HIV treatment regimen. Therefore, the better policy option is to maintain beneficiaries' access to medications through the existing open formulary requirement that also allows states to manage drug coverage through a variety of utilization management techniques.

b. Closed formularies do not save money

The Blueprint's proposal to allow state Medicaid programs to establish closed formularies would not save money. First, evidence shows that formulary restrictions in Medicaid are associated with only negligible savings.[16] And, any savings produced by the limitations "appear[ed] to be more than offset by the higher medical costs associated with worse adherence and poorer health outcomes."[17] In fact, the study found that "restrictive formulary policies in Medicaid led to over $350 million in prison costs per year."[18] These staggering results came from a policy that merely restricted formularies. A fully closed formulary would therefore likely result in even higher costs and poorer health outcomes.

Second, a closed formulary would not increase state Medicaid programs' negotiating power in a meaningful way because states already have options for controlling drug costs. Many states have policies that incentivize manufacturers to offer competitive rebates. For example, in Massachusetts, MassHealth uses a tiered formulary system[19] that provides significant incentives to manufactures that offer competitive rebates. Across the country, 37 state Medicaid programs have taken some kind of action to control prescription drug costs.[20] State Medicaid programs should not have the

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[15] *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.* 83 Fed. Reg. 22,693 (May 16, 2018), https://www.gpo.gov/fdsys/pkg/FR-2018-05-16/pdf/2018-10435.pdf

[16] Seth A. Seabury et al., *Formulary Restrictions on Atypical Antipsychotics: Impact on Costs for Patients with Schizophrenia and Bipolar Disorder in Medicaid* 20 AM. J. MANAGED CARE e52, e58 (2014).

[17] *Id.* at e58.

[18] *Id.*

[19] *Pharmacy Manual,* COMMONWEALTH OF MASSACHUSETTS MASSHEALTH PROVIDER MANUAL SERIES. 406 et seq. (Aug. 12, 2016), https://www.mass.gov/files/documents/2017/11/10/regs-pharmacy.pdf; *Introduction to MassHealth Drug List*, EXECUTIVE OFFICE OF HEALTH AND HUMAN SERVICES (June 18, 2018), https://masshealthdruglist.ehs.state.ma.us/MHDL/pubintro.do?category=Introduction+to+MassHealth+Drug+List

[20] THE HENRY J. KAISER FAMILY FOUNDATION. *States Reporting Any Prescription Drug Cost Containment Action* (State Fiscal Years 2003-2017), https://www.kff.org/medicaid/state-indicator/states-reporting-any-prescription-drug-cost-containment-action-2/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D

ability to implement closed formularies that would harm beneficiaries, especially when it is unlikely that closed formularies would achieve cost savings.

c. Closed formularies are unlawful

The Blueprint "call[s] for new Medicaid demonstration authority" for the proposed demonstration projects that could allow for closed formularies.[21] HHS cannot legally approve such demonstration projects. Section 1927(d)(4) of the Social Security Act, codified at 42 U.S.C. § 1396r–8(d)(4), establishes rigid requirements for drug coverage in a state's formulary under the rebate program. Section 1396r-8(d)(4)(B) makes it clear that states must cover all of the drugs of manufacturers participating in the rebate program. Section 1396r-8(d)(4)(C) provides only one exception where a state may exclude a drug: when the drug "does not have a significant, clinically meaningful therapeutic advantage." As discussed above, the Blueprint's proposal suggest that states could exclude drugs without any clinical justification, and could even exclude drugs that have significant therapeutic advantages for beneficiaries, violating section 1927(d)(4) of the Social Security Act.

Similarly, Section 1115 of the Social Security Act would not permit the type of closed formularies the Blueprint's proposals could allow for. Section 1115 of the Social Security Act, codified at 42 U.S.C. § 1315, permits waivers of only certain specified sections of section 1927(d)(4), which do not include any part of the rebate provisions. The D.C. Circuit made this clear in *PhRMA v. Thompson*: "Although the Act authorizes the Secretary to waive certain Medicaid requirements for such demonstration projects, it does not authorize him to waive any requirements of section 1396r–8's rebate provision . . ."[22]

Moreover, the Blueprint's proposal that would allow closed formularies rests entirely on an economic justification of cost-cutting, which does not qualify as an "experimental, pilot, or demonstration project" as required by section 1115 of the Social Security Act, codified at 42 U.S.C. § 1315(a). As the Ninth Circuit explained: "The Secretary's obligation under § 1315 to 'make some judgment that the project has a research or a demonstration value' cannot be satisfied by '[a] simple benefits cut, which might save money, but has no research or experimental goal.'"[23] The Blueprint does not address any experimental goal for the proposed demonstration projects. It merely states that the demonstration projects would "provide states with new tools to control drug costs and tailor drug coverage decisions to state needs."[24] Because the Blueprint does not state any goal outside of cost containment, its proposed demonstration projects are unlawful and should not be implemented.

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[21] *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.* 83 Fed. Reg. 22,693 (May 16, 2018), https://www.gpo.gov/fdsys/pkg/FR-2018-05-16/pdf/2018-10435.pdf
[22] 251 F.3d 219, 222 (D.C. Cir. 2001).
[23] *Newton-Nations v. Betlach*, 660 F.3d 370, 381 (9th Cir. 2011) (citing *Beno v. Shahala*, 30 F.3d 1057, 1069 (9th Cir. 1994)).
[24] *HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.* 83 Fed. Reg. 22,694 (May 16, 2018), https://www.gpo.gov/fdsys/pkg/FR-2018-05-16/pdf/2018-10435.pdf

The HIV Health Care Access Working Group thanks you for the opportunity to provide input on the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. For all of the reasons discussed above, we urge you to reject any proposals that would negatively impact access to affordable care and treatment for individuals living with HIV.

Contact Robert Greenwald with the Treatment Access Expansion Project at rgreenwa@law.harvard.edu, Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@NASTAD.org, or Andrea Weddle with the HIV Medicine Association at aweddle@hivma.org with any questions regarding how people living with HIV would be affected by the Blueprint proposals discussed above. Thank you for your time and consideration.

Respectfully submitted by the undersigned organizations,

ADAP Advocacy Association
ADAP Educational Initiative
AIDS Action Baltimore
AIDS Alabama
AIDS Alliance for Women, Infants, Children, Youth & Families
AIDS Foundation of Chicago
AIDS Research Consortium of Atlanta
AIDS Resource Center of Wisconsin
AIDS United
American Academy of HIV Medicine
APLA Health
Bailey House, Inc.
Careteam Plus Family Health and Specialty Care
Communities Advocating Emergency AIDS Relief (CAEAR)
Community Access National Network (CANN)
Georgia AIDS Coalition
Harm Reduction Coalition
HealthHIV
HIV Medicine Association
Housing Works
Legal Council for Health Justice
Los Angeles LBGT Center
Michigan Positive Action Coalition
Minnesota AIDS Project
National Alliance of State and Territorial AIDS Directors
National Latino AIDS Action Network
NMAC
Positive Women's Network – USA

Project Inform
Rocky Mountain CARES
San Francisco AIDS Foundation
SisterLove
Southern AIDS Coalition
Southern HIV/AIDS Strategy Initiative
The AIDS Institute
Thrive Alabama
Treatment Access Expansion Project
Treatment Action Group
Whitman-Walker Health