FEDERAL AIDS POLICY PARTNERSHIP
HIV HEALTH CARE ACCESS WORK GROUP

March 11, 2019

U.S. Department of Health and Human Services
Room L001
330 C Street SW, Washington, DC 20024
Attention HIV/Viral Hepatitis RFI

Re: Comments to RFI regarding National HIV/AIDS Strategy (NHAS)

To Whom It May Concern:

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 appreciate the opportunity to provide comments on the Request for Information (RFI): Improving Efficiency, Effectiveness, Coordination, and Accountability of HIV and Viral Hepatitis Prevention, Care, and Treatment Programs. Our comments below are focused on the National HIV/AIDS Strategy.

Given the health systems emphasis of our coalition, we have focused our comments around section three of the RFI, providing comments as to the current NHAS goals and federal action steps as well as actions that the federal government can take moving forward to improve the coordination of funding and delivery of HIV services.

Meeting the goals of the NHAS will require a commitment to policies, funding mechanisms, and service delivery strategies that recognize the co-morbidities and social determinants of health that impact HIV prevention, care, and treatment. It will also require greater coordination with broader healthcare financing and delivery systems to ensure we are leveraging resources effectively and efficiently. A coordinated approach is particularly important given that Medicaid and Medicare provide the majority of funding for HIV care in the United States.

We urge HHS to consider the following:

MEDICAID

The Medicaid program is a critical source of health coverage for people living with HIV. More than 40 percent of people living with HIV in care count on the Medicaid program for the

healthcare and treatment that keeps them healthy and productive.[1] Ensuring uninterrupted access to effective HIV care and treatment is important to the health of people living with HIV and to public health.[2] Effective partnership with CMS – for instance on the HIV Affinity Group – has been an important part of implementation of the NHAS and has helped to forge effective partnerships between state health department HIV programs and their Medicaid programs across a variety of data and coverage projects. We urge HHS to continue those partnerships and to continue to offer technical assistance and federal support of Medicaid and health department collaboration.

In contrast to the progress that the HIV Affinity Group made in ensuring state Medicaid programs are responsive to HIV prevention and care efforts, we are concerned that the 1115 waivers that have been approved or that are pending with CMS will thwart the access to care and prevention goals of the NHAS and we urge closer review of waiver applications to ensure they are not at odds with both the NHAS and the Administration's initiative to end new HIV infections by 2030. Work requirements, increased cost-sharing, and limits on benefits or eligibility all have the potential to cause harmful disruptions in access to HIV prevention, care, and treatment with disastrous individual and public health ramifications.

MEDICARE

Medicare is also a critical source of HIV care, treatment, and prevention services, and will become more important as individuals living with HIV age into the program. The population on Medicare include 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. A commitment to working with Medicare to ensure both a smooth transition for individuals who are newly eligible for the program and to ensure that the services offered under Medicare are consistent with HIV treatment guidelines is critical to meeting the access to care goals of the NHAS. This is particularly true given recent Administration actions to roll back important utilization management protections for the HIV class in Medicare Part D.

It will also be important to ensure that Medicare issues a coverage determination as soon as possible after the U.S. Preventive Services Task Force (USPSTF) finalizes its recommendation for

---

[1] Jennifer Kates and Lindsey Dawson, Kaiser Family Foundation, Insurance Coverage Changes for People with HIV Under the ACA (2017), available at https://www.kff.org/health-reform/issue-brief/insurance-coverage-changes-for-people-with-hiv-under-the-aca/.

[2] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services, available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGLpdf.

pre-exposure prophylaxis (PrEP).[3] A swift process for Medicare to mirror the USPSTF guidelines will be important to ensure consistent expanded access to PrEP across all payers.

PRIVATE INSURANCE

The CMS Center for Consumer Information and Insurance Oversight (CCIIO) is also a critical partner in meeting the goals of the NHAS. This partnership will be particularly important once the USPSTF recommendation for PrEP is finalized. We urge HHS to coordinate implementation of the recommendation across federal programs and to work with CCIIO to develop appropriate sub-regulatory guidance to guide private insurance practices.

It will also be important to continue to work with CCIIO to ensure access to affordable, comprehensive private insurance coverage for people living with HIV. Regulations in recent years – particularly those expanding access to short-term limited duration insurance plans and Association Health Plans – risk segmenting the private insurance market, making coverage more expensive for people who need it most. Creating a larger non-ACA compliant market also creates a risk that people living with HIV and other chronic conditions will end up in a plan that will not be able to meet their care and treatment needs.[4] Finally, we believe that robust enforcement of ACA non-discrimination requirements is needed to ensure access to culturally competent care that is consistent with the HIV treatment guidelines. This includes enforcement of the protections included in section 1557 of the ACA and its implementing regulations. Formulary designs in particular must be monitored to ensure that utilization management techniques, co-pay accumulator policies, and adverse tiering are not used to dissuade people living with HIV from signing up for and using coverage. To date, HHS has not taken any action in response to complaints the insurers are engaging in discriminatory benefit designs in violation of section 1557.

PRIMARY CARE

Primary care providers – and community health centers in particular – are essential partners for HIV care and prevention services. Because community health centers may be a significant partner in the Administration's plan to end new HIV infections by 2030, we believe that the HRSA Bureau of Primary Health Care (BPHC) must be meaningfully included in any updates to the NHAS. Because the ability and willingness of community health centers to provide HIV prevention and care services is currently variable across the country, we urge federal partners to support collaborative models, using the expertise and community connections of state and local HIV providers and health departments, particularly with regard to linkage to care. AIDS

---

[3] USPSTF, Draft Recommendation Statement: Prevention of Human Immunodeficiency Virus Infection, Pre-exposure Prophylaxis, available at https://www.uspreventiveservicestaskforce.org/Page/Document/draft-recommendation-statement/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.

[4] Lindsey Dawson and Jennifer Kates, Kaiser Family Foundation, Short-term Limited Duration Plans and HIV (2018), available at https://www.kff.org/hivaids/issue-brief/short-term-limited-duration-plans-and-hiv/.

Education and Training Centers and CDC capacity building assistance providers may be important resources as community health centers increase their capacity to provide culturally competent HIV care and prevention services.

DRUG PRICING, COVERAGE, AND ACCESS

We appreciate the need to reduce drug prices in order to reduce out-of-pocket costs for beneficiaries and expand access to effective medications, and we welcome innovative solutions to this issue. We urge HHS to engage the HIV community as drug pricing and access policies are considered. Any drug pricing proposal must ensure access to clinically appropriate care and treatment, particularly for vulnerable populations. This is particularly true for the HIV class of drugs. Compared to many other classes of drugs, lower-cost multiple-source innovator and non-innovator ("generic") antiretroviral drug options are limited and therefore not suitable for population-level cost-containment measures. Individualized therapy that requires access to a variety of higher-cost single-source innovator ("brand") products is still central to best practices toward maximized safety and virologic suppression outcomes.

Formulary exclusions are not an appropriate means to achieve lower drug pricing and will ultimately harm consumers and drive up downstream healthcare costs when people go without necessary medications. Additionally, ADAPs, as payers of last resort, would likely be forced to provide access to high-cost prescription drugs that are excluded by plans, ultimately shifting costs away from commercial payers and on to a federally funded, safety net program. We urge HHS to consider alternative regulatory approaches that shield against WAC price increases unmoored to inflation rates and that safeguard against exclusions of critical drugs and biologics. These alternative approaches could include value-based assessments supported by CMS and/or the Agency for Healthcare Research and Quality.

Thank you for the opportunity to comment on this important RFI and for your commitment to the goals of the NHAS. Please contact Amy Killelea with the National Alliance of State and Territorial AIDS Directors at akillelea@nastad.org or Phil Waters at pwaters@law.harvard.edu with the Center for Health Law and Policy Innovation if we can be of assistance.

Respectfully submitted by:

ADAP Educational Initiative | AIDS Alabama | AIDS Action Baltimore AIDS Alliance for Women, Infants, Children, Youth & Families | AIDS Foundation of Chicago | AIDS Research Consortium of Atlanta | AIDS United | American Academy of HIV Medicine | APLA Health AIDS Resource Center of Wisconsin | Bailey House, Inc. | Black AIDS Institute | Communities Advocating Emergency AIDS Relief (CAEAR) | Community Access National Network (CANN) | Georgia AIDS Coalition | Harm Reduction Coalition | HealthHIV | HIV Medicine Association | Housing Works | Human Rights Campaign | Legal Council for Health Justice | 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 | St. Louis Efforts for AIDS | The AIDS Institute | Treatment Access Expansion Project | Thrive Alabama