March 11, 2019

Tammy Beckham, DVM, PhD
Director
Office of HIV/AIDS and Infectious Disease Policy (OHAIDP)
U.S. Department of Health and Human Services
Room L001, 330 C Street SW
Washington, DC 20024
Attention HIV/Viral Hepatitis RFI

Re: Comments on the National HIV/AIDS Strategy Update

Dear Dr. Beckham,

The AIDS Institute, a national nonprofit organization dedicated to supporting and protecting health care access for people living with HIV, hepatitis, and other chronic and serious health conditions, welcomes the opportunity to respond to the Request for Information on the next iteration of the National HIV/AIDS Strategy (NHAS). The AIDS Institute provided input on previous versions of NHAS and is pleased the Department of Health and Human Services has begun the important task of preparing a new Strategy that reflects the progress made and new challenges our nation has experienced in the fight against HIV. We congratulate the Trump Administration and HHS for its continued focus on ending the HIV epidemic in the United States and trust our comments will help inform the next NHAS, which will serve as a guiding document in achieving this difficult but achievable goal.

As you begin to draft the new Strategy, we recommend that you continue to promote the overarching vision contained in previous Strategies: “The United States will become a place where new HIV infections are rare and when they do occur, every person regardless of age, gender, race/ethnicity, sexual orientation, gender identity or socio-economic circumstance, will have unfettered access to high quality, life-extending care, free from stigma and discrimination.”

In order to achieve that vision, we support the continued inclusion of the four overall goals that were developed in previous iterations of NHAS: 1) preventing new infections, 2) increasing access to care and treatment while improving health outcomes, 3) reducing disparities, and 4) increasing government coordination will result in an impactful and thoughtful document.

In the State of the Union Address, President Trump announced a historic HHS-led initiative to end the HIV epidemic in the next 10 years. We believe the Ending the Epidemic Plan, if fully scaled and funded, coupled with the updated NHAS, will ultimately lead to a dramatic reduction in new infections, an increased number of people living with HIV engaged in care, and more people living with HIV achieving viral suppression. If we can accomplish this in a targeted, efficient and thoughtful manner, we agree that
we will be able to end the HIV epidemic in the coming decade. The AIDS Institute congratulates the administration for challenging our nation to achieve this goal and supports the Ending the Epidemic Plan. We look forward to working with federal, state and local partners, along with the Congress, to make sure this plan is crafted and implemented in a timely manner.

The AIDS Institute would like to provide the following specific recommendations for the next NHAS as you craft the Strategy.

1. **Ensure Comprehensive Access to HIV Care and Treatment:** As included in the previous NHAS vision statement, ensuring “unfettered access to high quality, life-extending care” is paramount to ending the HIV epidemic and must be a central tenet when drafting the updated strategic goals and progress indicators. The CDC reported that of all people living with HIV in the United States in 2015, 86 percent received a diagnosis, but only 63 percent received care and only 49 percent were retained in care. The AIDS Institute recommends that the NHAS prioritize increasing treatment, along with treatment retention, to maximize the number of people living with HIV who are receiving ongoing care. To do this, we suggest that CDC utilize epidemiologic data and surveillance systems to identify and re-engage those who have fallen out of care. We also suggest that NHAS should focus on setting aggressive and achievable milestones to increase viral suppression nationally, with a particular focus on decreasing disparities geographically and among target populations.

The advancement in science and medical research have provided our nation with incredibly effective tools to treat people living with HIV (PLWH). We have effective treatments, which are better tolerated and have less side effects than the treatments available 10 years ago. If someone living with HIV is engaged in care and is adherent to their medication, they can achieve viral suppression and expect to live a full life. Additionally, science has now proven that if a person achieves sustained viral suppression, they are unable to transmit HIV to another person. Since the last NHAS, the science of Undetectable = Untransmittable (U=U) has been proven by multiple studies, and The AIDS Institute commends HHS for coming to a consensus about this important science. We trust that the next NHAS will incorporate this important message.

To achieve any of the goals established by the Strategy, access to healthcare must be protected and strengthened. Health insurance made available through the Affordable Care Act (ACA) provided an unprecedented opportunity to expand access to care and treatment for people living with HIV. However, weakening of the ACA by policies such as expanding short-term limited-duration health plans and association health plans, discontinuing cost-sharing reduction payments, and permitting changes to the essential health benefits benchmark stand to jeopardize the stability of the market, weaken patient protections, and risk access to vital healthcare. While access to healthcare is crucial for testing and diagnosis, treatment and care, it is also critical for HIV prevention. Improving health insurance coverage will ensure more people at-risk for acquiring HIV will have access to the ground-breaking medication, pre-exposure prophylaxis (PrEP), to prevent HIV. We urge the administration to strengthen the ACA as a means to increase access to care and improve health outcomes for people living with HIV.

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An equally important health reform for people living with HIV, made possible by the ACA, has been Medicaid expansion. In an analysis by Kaiser Family Foundation, Medicaid expansion to non-elderly adults and those without dependents has made this health insurance program the single largest source of coverage for people living with HIV. In order to increase HIV treatment, states should expand Medicaid for their low-income population, which are disproportionately impacted by HIV.

The AIDS Institute is concerned about measures that may diminish Medicaid coverage, such as imposing community engagement requirements, which will threaten access to prevention, care, and treatment services. Maintaining a strong Medicaid program will help to reduce HIV-related disparities and health inequities while ensuring vulnerable populations who access their healthcare through this source will be able to continue to effectively manage their health.

Access to HIV care and treatment through insurance coverage and benefits is important in order to achieve the goals of NHAS, and nothing is more critical to that end than broad, unhindered access to innovative medications that treat HIV and prevent HIV infection. As the update to the Strategy is developed, we urge the administration to consider ways to mitigate burdensome insurance plan benefit design trends, with high deductibles and high co-insurance shifting the bulk of cost-sharing responsibilities to patients who pay more out-of-pocket when they pick up their prescription at the pharmacy.

In 2019, the maximum out-of-pocket limit on health insurance plans for an individual is $7,900 and $15,800 for a family, with the average deductible for a silver-level qualified health plan being $4,375. Plans have also expanded the number of formulary tiers placing specialty medications, like those used to treat chronic conditions such as HIV, often on the highest tiers. The highest tiers are associated with steep cost-sharing, which can reach upwards of 50 percent co-insurance. IQVIA-conducted research shows that when patient cost-sharing exceeds $250, 69 percent of new prescriptions are not filled or are abandoned at the pharmacy. These amounts, combined with high copayments and co-insurance, are simply too high for many patients to afford. Adherence is of the utmost importance for HIV treatment to prevent disease progression and drug resistance.

Many patients living with HIV rely on manufacturer and other copay assistance programs to afford their medications and remain adherent to their treatment regimen. Copay assistance programs help patients access their medications by reducing the cost burden for the individual and helping them meet their deductible and maximum out-of-pocket spending limit. When health care isn’t affordable, access is meaningless. NHAS should incorporate and encourage policies that remove barriers, which impede patient access to health care and prescription drugs.

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Medicare also plays a strong role in achieving NHAS goals, in particular through the program’s prescription drug benefit, Part D. The administration recently proposed changes to the “six protected classes” prescription drug policy within Part D, which include antiretrovirals for the treatment and prevention of HIV. Ensuring broad formulary access to antiretrovirals is particularly important because these medications are not interchangeable due to sensitivity or resistance to a drug, the unique biochemistry of the individual, or side effects. The administration proposed permitting, for the first time, prior authorization and step therapy as utilization management techniques to curb costs within the Medicare Part D program. However, these efforts to address drug rebates would come at the expense of patients, causing detrimental effects for those newly diagnosed or stable on their on-going treatment regimen. Step therapy and prior authorization run counter to decades of medical best practices and the Department of Health and Human Services Treatment Guidelines for HIV Infected Adults and Adolescents. Delaying an individual’s initiation of treatment through unnecessary bureaucracy as a result of prior authorization is likely to harm not only individual patient outcomes, but also undermine the larger public health goal of reducing the number of new HIV infections.

We encourage you to carefully consider the implications policy changes to health insurance and prescription drug coverage have on patient access, and the downstream effects on achieving the goals of NHAS.

2. **Set Data-Driven Goals for Priority Populations:** The HIV epidemic does not impact all people in the United States equitably. Unfortunately, HIV tends to have a disproportionate impact on already vulnerable populations - almost three quarters of new HIV infections occur among racial and ethnic minorities; half of all new HIV infections occur in the Southern United States; young gay and bisexual men continue to have higher rates of HIV; and the rate of HIV diagnosis is almost 15 times higher for black women than white women. Additionally, while overall HIV infections have plateaued since 2013, the CDC reported that some populations are experiencing increased HIV infections, proving that our nation is not ensuring that the effective tools to prevent HIV are being accessed by those who need them the most.

The previous update of NHAS recognized that HIV does not impact everyone equitably, and specifically noted that populations that are most impacted. The Strategy noted that funding for HIV prevention programs must focus on these populations. In the next NHAS, we encourage you to again set aggressive data-based goals to reduce the number of new infections, especially in the following groups: gay and bisexual men in general with a focus on black gay and bisexual men and Latinx gay and bisexual men, black women, people aged 13-25, transgender women, people living in the South, and people who inject drugs.

Because of the comprehensive surveillance system we have in place, we know where HIV is and who is being impacted. We recommend that the next NHAS uses this collective data to target resources and reduce the disproportionate impact of HIV on these communities.

3. **Expand and Promote Effective Prevention Tools:** Since the last iteration of NHAS, our nation has a better understanding about the importance of PrEP. We know that if taken as directed, PrEP is one of the most effective methods of prevention, and it is an important tool in the HIV prevention toolbox. We also have begun to understand the challenges of ensuring that PrEP is utilized by people who can benefit from it the most. Recent data shows that while 1.1 million
people in the U.S. could benefit from a PrEP prescription, only an estimated 78,360 filled a prescription for PrEP in 2016. This data also showed that only 11.2% and 13.3% of those prescriptions were filled by black and Hispanic users, respectively.

The next NHAS must prioritize the expansion of PrEP and set goals to expand PrEP to all 1.1 million people who could benefit from this important prevention tool. We encourage NHAS to focus on priority populations, and promote research to better understand and combat barriers for accessing PrEP care. Those barriers include lack of provider knowledge, lack of patient knowledge, stigma within the healthcare system, insurance coverage and financial issues, and overall gaps in PrEP knowledge.

Recently, the US Preventive Services Task Force (USPSTF) recommended that PrEP receive an “A” grade, proving that PrEP is an effective preventive medication and paving the way for PrEP to be covered by most insurances with no cost-sharing. We encourage NHAS to call for the complete implementation of this recommendation and ensure that all costs associated with maintaining a PrEP prescription, such as quarterly HIV and STD tests and labs, are covered without patient cost-sharing. We also would like NHAS to call for a Medicare coverage determination of PrEP so that Medicare patients can access PrEP at no cost, as well.

While we know about the effectiveness of PrEP, we must also continue to promote all effective tools in the HIV prevention toolbox. NHAS must recognize that all forms of effective prevention should be available to those at risk for HIV. This includes condoms, general HIV prevention and sexual education, syringe services, and treatment as prevention. No single prevention technique works for everyone, so all forms of prevention must be expanded.

4. **Expand HIV Testing:** In order to truly end the epidemic, we must ensure that all people living with HIV are aware of their status so that they can be connected to high-quality and effective care. One in seven people living with HIV is still unaware of their status, and CDC data shows that in 2015, half of all people diagnosed with HIV that year had been living with HIV for more than three years, and one quarter of people diagnosed that year had been living with HIV for more than seven years. Evidenced by these statistics, NHAS must continue to set goals for the expansion of HIV testing, which is the gateway to treatment.

NHAS must ensure that medical professionals provide CDC recommended routine HIV testing. This includes everyone being tested for HIV in their lifetime, and those at higher risk for HIV being tested more frequently. Also, because of USPSTF’s “A” grade for HIV testing, all tests for those with health coverage must be available at no cost. State and local health departments, CDC grantees, health clinics and other providers of HIV testing must take advantage of this coverage and seek reimbursement for HIV testing.

While we support routine HIV testing, where there are limited resources for testing, including among CDC grantees, we must ensure that these limited dollars are used wisely and focused on priority populations. We also hope that NHAS promotes all forms of HIV testing, including rapid and at-home tests. Finally, HIV testing must be coupled with rapid connection to HIV treatment in order to prevent a gap in care.

5. **Increase Federal Funding:** To implement the recommendations that will be put forth in NHAS and scale up the President’s Ending the Epidemic Plan, sustained and increased federal funding
for domestic HIV and related programs must be a priority. As CDC has reported, the rates of new HIV infections have plateaued since 2013, and The AIDS Institute believes this is partly because federal funding has remained relatively flat. Because of the growing number of people living with HIV and inflation, flat funding for programs is, in fact, a decrease in funding. We believe that NHAS must describe the need for increased investments in prevention, treatment, and research in order to reach the goals of NHAS. In the long run, it will result in cost savings to the U.S. Government. The Administration should be commended for seeking a substantial amount of new funding for the End the HIV Epidemic initiative.

The changing face of HIV in the United States requires funding that is robust, flexible and targeted so that resources are wisely spent on projects that have the most impact on our HIV prevention and treatment efforts. This includes funding targeted to at-risk populations and regions. We urge NHAS to specify where increased funding will be most valuable.

6. **Recognize the Continued Importance of the Ryan White HIV/AIDS Program:** In order to achieve the goals of the Strategy, all parts of the Ryan White HIV/AIDS Program must continue and be adequately funded. The Ryan White HIV/AIDS Program plays a critical role in providing a comprehensive system of primary care, essential support services, and medications for low-income people living with HIV who are uninsured and underserved. The Ryan White HIV/AIDS Program has consistently shown improvements in viral suppression rates, largely attributable to the comprehensive approach to providing care and treatment, proving that it is one of our most effective tools in ending the HIV epidemic. As the payer of last resort, the program supports the existing systems of care in each state and is especially important in states that have not expanded Medicaid.

As a safety net for patients that may not have coverage through other means, the Ryan White HIV/AIDS Program does not have the resources or capacity to be the sole provider of services for all individuals and families affected HIV. As previously mentioned, when policy changes threaten health insurance and healthcare access, resources within the Ryan White Program will undoubtedly be strained, jeopardizing the progress made thus far. To meet the healthcare needs of people living with HIV through the Ryan White HIV/AIDS Program and strive for improved national health outcomes, The AIDS Institute urges NHAS to prioritize funding for the program.

7. **Ensure Resources Follow the Epidemic:** The Ryan White HIV/AIDS Program has been a model of success in care and treatment for people living with HIV since it was signed into law in 1990. Serving more than half a million people living with HIV, the Ryan White Program is a vital element in achieving the goals of NHAS and the fight to end HIV, however, the funding must continue to be prioritized and the distribution of funding should be carefully considered to determine to how to best address areas most in need to achieve greater viral suppression nationwide.

The AIDS Institute conducted an analysis of 2017 Ryan White HIV/AIDS Program Funding to determine if funds are reaching the regions with a high HIV burden. Examining the funding by each program part, across the states, and by HIV case count, helps to foster a discussion with community advocates and federal leaders about ways in which the funding methodology could be adapted to reach the NHAS goals more effectively.
The analysis demonstrated that funding is not being distributed equitably, or distributed to those areas with the greatest need. Breaking the funding down by state and by Ryan White HIV/AIDS Program Parts A – D, as well as by HIV case count in the states, shows the influence each award has on the state’s overall funding, and highlights the differences between the formulary awards and those based on need. When the base formula awards were analyzed, some states with lower HIV case counts receive more funding per case. The distribution of supplemental awards presents an opportunity to direct resources to jurisdictions and states that experience a high disease burden, truly allowing the funding to follow the epidemic. Through the update to NHAS we encourage the officials and the Health Resources and Services Administration (HRSA) to explore the current distribution of Ryan White Funding, particularly supplemental funding so that it can be distributed more equitably to align more with changing landscape of the HIV epidemic.

We also believe that NHAS should ensure that funding to grantees is spent in a timely and efficient manner so that funds allocated each year to the program are made available to patients without delay.

This NHAS must recognize the importance of high-impact, targeted prevention done through the CDC and their partners, which ensures that funding for prevention programs flows to populations and regions that are impacted the most. High-impact prevention has been successful in efficiently using federal dollars, and NHAS must ensure that communities in most need of funding can benefit from these efficiencies. To do this, we must leverage surveillance data to ensure that money follows the epidemic.

8. **Address the Intersections of Opioids and Infectious Diseases:** The opioid and injection drug epidemic in the United States continues to have a major impact on the public health and public safety infrastructures, with skyrocketing overdose rates and strained resources on already underfunded public health programs. Additionally, the infectious disease consequences of the opioid epidemic are currently being felt and will have long lasting implications in the decades to come. While great progress was made in reducing HIV infections associated with injection drug use in the 1990s and 2000s, the changing demographics of people who inject drugs (PWID) is challenging that progress, with increased rates of new injection drug associated HIV infections among younger, populations located outside of urban centers.

This epidemic has taken hold since the last iteration of NHAS, and we urge that the new Strategy lay out bold and aggressive goals to prevent new infections in populations affected by the opioid epidemic. We urge the Strategy to include prevention goals for PWID and to call for the development of prevention techniques that target rural PWID. We also believe that substance use treatment centers are an important touch point for connecting people to healthcare and believe that HIV and viral hepatitis testing and counseling should be available for people within these treatment centers. We urge the Substance Abuse and Mental Health Administration to ensure that the infectious disease consequences of the opioid epidemic are consistently addressed as they continue to combat the opioid epidemic.

One key tool in preventing HIV infections among PWID is Syringe Service Programs (SSPs). Research has shown that these programs are effective in reducing infectious diseases associated with injection drug use and are an important way to connect PWID to HIV and viral hepatitis prevention and treatment services, as well as substance abuse treatment. The AIDS Institute is
pleased that in recent years there has been a partial lift in the ban on using federal funds for SSPs. We believe that a total lift on the funding ban to allow for federal funds to purchase syringes is important in order to allow for the expansion and financial sustainability of SSPs. We believe this Strategy must call for the expansion of SSPs, the removal of legal barriers within states that prevent the establishment of SSPs, continued technical assistance from the CDC for states pursuing a Determination of Need, and the co-location of HIV and hepatitis prevention services within SSPs.

9. **Expand and Promote HIV/AIDS Research:** The ultimate goal to completely eliminate HIV cannot be achieved without an effective vaccine and durable cure for HIV. Continued resources and leadership by the NIH and private partners should be directed to these two goals to make sure they are achieved.

Additionally, NIH and its partners should continue research into new modalities for PrEP, both in new formulations beyond the currently FDA approved drug, and new delivery methods for PrEP. Research is being done on injectables, long-lasting implantable PrEP, vaginal rings, and topical applications. More options for PrEP delivery will allow users to choose which mode of PrEP is best suited for their prevention needs, and research must ensure these options are available. In order to do this, trials into new PrEP and HIV treatment must be representative and include participants who reflect the HIV epidemic. NHAS should call for clinical trials to include more people of color, women, transgender people, and other populations disproportionately impacted by the epidemic. NHAS also must recognize and promote implementation science so that we understand how to bring medical breakthroughs and new science up to scale.

10. **Expand Comprehensive Sexuality Education:** Since HIV is predominantly transmitted sexually, it is important that young people receive age-appropriate, non-stigmatizing, and comprehensive sexuality education that includes positive discussion of homosexuality and gender identity. NHAS must ensure that comprehensive sexuality education includes information on HIV prevention methods, including PrEP, as well as STD prevention. The intersections of STDs and HIV are well established and ending the HIV epidemic must also include combatting the skyrocketing rates of new STD infections. The federal government should not fund abstinence-only until marriage programs that have been proven to be ineffective and discriminatory.

11. **Address Social Determinants of Health:** The AIDS Institute believes that the NHAS must continue many of the previous Strategy’s goals of reducing the impact of social determinants of health. While the medical interventions to treat and prevent HIV are effective, social determinants of health impact the ability of a patient to access these life-saving tools. The Strategy must include goals to address homelessness, hunger, access to transportation, mental health, poverty, racism, homophobia, transphobia, and disparities in education. The AIDS Institute also urges HHS and the administration to not pursue ideological policies that would contrast with these goals.

12. **Address HIV/Viral Hepatitis Co-Infection Rates:** The AIDS Institute is pleased that a new NHAS is being drafted at the same time HHS is drafting a new National Viral Hepatitis Action Plan (NVHAP). Among the 1.2 million people in the United States living with HIV, nearly one in four is coinfected with HCV. People who are coinfected with HIV and HCV are a priority population for HCV prevention, diagnosis, and cure because liver-related death is a common cause of death among this population. In comparison with HCV-monoinfected patients, persons coinfected with
HIV have higher liver-related mortality as well as overall mortality. In order to end the HIV epidemic, we must also address the viral hepatitis syndemic, and ensure cooperation between federal, state and local organizations that are combating these two epidemics. Because the risk factors and priority populations for HIV and viral hepatitis are similar, we can ensure that limited resources are well spent if we address both epidemics concurrently.

13. **Enhanced Federal Interagency Cooperation:** The Federal response to HIV/AIDS prevention and care/treatment rests with numerous federal agencies, each acting within their respective independent authorities. Previous versions of NHAS focused on breaking down these silos, and there have been great examples of cooperation, such as projects funded through the HHS Secretary’s Minority AIDS Initiative. We would particularly recognize the increased cooperation between the CDC and HRSA and trust it will continue in the future. The President’s Ending the Epidemic Plan will require even further cooperation between CDC, HRSA and the NIH. As this plan is implemented, we hope NHAS be a guiding document for interagency cooperation. Since state and local governments receive most federal HIV/AIDS dedicated funding, coordination between the federal government and state/local governments should be increased and flexibility be given to state/local grantees to address the needs within their jurisdictions.

NHAS must also coordinate the federal response with departments outside of HHS. The Housing Opportunities for Persons With AIDS (HOPWA) Program at the Department of Housing and Urban Development is a great example of non-HHS programs serving people living with HIV. As HOPWA continues to phase in their formula modernization, we trust that NHAS will coordinate across federal departments to ensure that no HOPWA clients lose their housing benefits.

Many of the goals we have laid out in this document can be accomplished in conjunction with the President’s Ending the Epidemic Plan. The AIDS Institute strongly supports the aggressive and achievable goal of reducing new infections by 90% in the next ten years laid out by the President and his administration. We believe it is possible with sustained increases in federal funding, increased cooperation between all levels of government, and meaningful community involvement in crafting the plan. The AIDS Institute will support this plan and work with Congress to ensure that new funding is appropriated to begin this 10-year project and intensified in the coming years. We hope that the goals of NHAS can incorporate and expand on the goals of the Plan so that one day, we can end the HIV epidemic and the need for a National HIV/AIDS Strategy will be obsolete.

The AIDS Institute thanks you for your continued leadership. We look forward to working with you and the entire administration in helping in the new Strategy’s implementation so that the goals will be achieved in a timely and successful manner. Should you have any questions or comments, please feel free to contact Michael Ruppal at (813) 258-5929 or Carl Schmid at (202) 462-3042.

Sincerely,

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