March 11, 2019

Submitted electronically to HepHIVStrategies@hhs.gov

RE: Request for Information (RFI): Improving Efficiency, Effectiveness, Coordination, and Accountability of HIV and Viral Hepatitis Prevention, Care, and Treatment Programs

Dear colleagues working in HIV prevention and care,

The Fenway Institute is the research, education and training, and policy arm of Fenway Health, a federally qualified health center and Ryan White Part C HIV clinic in Boston, MA. We have been conducting HIV prevention research since the 1980s. We provide care to 2,200 people living with HIV and about 32,000 patients overall. Half of our patients are lesbian, gay, bisexual and transgender (LGBT). We thank you for the opportunity to provide comment regarding the next iteration of the National HIV/AIDS Strategy (NHAS). We make the following recommendations about how to best maintain and expand areas of the current NHAS in order to improve the effectiveness, impact, coordination, and funding of the national response to HIV:

Support and strengthen training, education, and messaging about “Undetectable Equals Untransmittable” (U=U)

On September 27, 2017, the CDC released a memorandum in honor of National Gay Men’s HIV/AIDS Awareness Day stating that “when ART results in viral suppression…it prevents sexual HIV transmission.”¹ This finding is based on years of scientific evidence, including a decade-long international study of over 1600 serodiscordant couples that clearly demonstrated that early and consistent treatment leading to viral suppression was also highly effective in preventing sexual transmission of HIV.² The U=U message has the potential to help enhance the lives and well-being of people living with HIV (PLWH) by reducing HIV stigma, encouraging medication adherence, and bolstering prevention efforts. Providers should have access to educational resources, messaging, and training about U=U so that they are able to pass on this information effectively to their patients living with or affected by HIV. A national U=U social marketing campaign should be launched to educate the American people about U=U in order to tackle stigma, break down barriers to HIV care, and enhance HIV prevention efforts to end the epidemic. The next iteration of the NHAS could expand on the current NHAS with goals related to U=U under “Step 2.B: Take deliberate steps to increase the capacity of systems as well as the number and diversity of available providers of clinical care and related services for people living with HIV,” “Step 1.C: Educate all Americans with easily accessible, scientifically accurate

information about HIV risks, prevention, and transmission,” and “Step 3.C: Reduce stigma and eliminate discrimination associated with HIV status.”

**Maintain and expand programs that increase access to health insurance**

The 2010 Patient Protection and Affordable Care Act (ACA) resulted in at least 20 million Americans gaining access to health insurance.\(^3\) This increase in coverage has significantly benefited groups that experienced lower rates of health insurance coverage, including LGBT people and PLWH. In 2013, before key provisions to expand access to health insurance were implemented, just 17% of the estimated 1.2 million Americans living with HIV had private health insurance.\(^4\) The U.S. Centers for Disease Control and Prevention and the Kaiser Family Foundation estimate that the percentage of people living with HIV who lacked any kind of health insurance coverage was 22% in 2012 and dropped to 15% in 2014, following implementation of key elements of health care reform.\(^5\) The percentage of PLWH on Medicaid increased from 36% in 2012 to 42% in 2014.\(^6\)

The ACA significantly contributed to increases in health insurance coverage among PLWH by prohibiting preexisting conditions discrimination in insurance coverage. Requiring health insurance providers to cover those with preexisting conditions, including PLWH, at comparable rates to the general public is essential for expanding insurance coverage and healthcare access for PLWH and should be maintained. In his first two years in office President Trump has taken a number of steps to undermine the ACA. Most recently he allowed inexpensive, short-term insurance plans to be sold that do not cover pre-existing conditions, such as HIV or cancer, and that do not offer most of the benefits and safeguards that the ACA requires.\(^7\) Such policies only undermine the success of our National HIV/AIDS Strategy, and should be discontinued.

The ACA also expanded eligibility criteria for Medicaid, which increased insurance coverage and healthcare access for low-income PLWH. Medicaid is the largest source of insurance coverage for PLWH in the United States.\(^8\) Prior to 2014—and currently in states where Medicaid eligibility still has not been expanded—an individual must either be extremely poor with dependent children or be disabled to qualify for Medicaid. This severely limits access to Medicaid for low-income PLWH, which in turn limits access to healthcare. This

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\(^3\) United States Department of Health and Human Services. (2016, Mar 3). “20 million people have gained health insurance coverage because of the Affordable Care Act, new estimates show.” Available online at: https://www.hhs.gov/about/news/2016/03/03/20-million-people-have-gained-health-insurance-coveragebecause-affordable-care-act-new-estimates


\(^6\) Ibid.


disproportionately affects Black Americans living with HIV, who are overrepresented in states where Medicaid eligibility has not expanded. This includes nearly all of the Southern states, where stark HIV disparities exist. In order to reduce the HIV disparities that these populations experience, the expansion of Medicaid must be maintained, as well as adopted by the states that have not yet expanded it.

As you know, Black and Latino Americans experience striking disparities in the HIV epidemic. For example, of the 40,324 new HIV diagnoses in the United States in 2016, 25% occurred among Black gay and bisexual men, and 19% occurred among Latino gay and bisexual men. The CDC estimates that MSM of all races are about 2% of the adult population; Black and Latino MSM would represent about 0.5% of the total adult population.

Prior to implementation of the Affordable Care Act (ACA), studies showed that 22% of Black adults and 33% of Latino adults were uninsured, compared with just 14% of White non-Hispanic adults. The Kaiser Family Foundation estimates that uninsurance rates declined among Latino nonelderly individuals from 30% in 2013 to 21% in 2015. Among Black individuals the uninsurance rate declined from 19% in 2013 to 11% in 2015. Among Asian American individuals the uninsurance rate was cut in half, from 14% to 7%, and among White non-Hispanic individuals the uninsurance rate declined from 12% in 2013 to 7% in 2015. Of the 20 million newly insured for whom we have racial ethnic data, 7.4 million were White non-Hispanic, 2.6 million were Black, and 4.0 million were Hispanic. On a per capita basis, Black and Latino people have disproportionately benefited from the increases in insurance coverage under the ACA.

Finally, gay and bisexual men and transgender women represent a small percentage of the adult population (perhaps 2-3%), but represent two thirds of new HIV infections each year in the U.S. Expanding health insurance access for LGBT people is critical to expanding HIV and STI screening, prevention and care. Between June/September 2013 and December 2014/March 2015,

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the percentage of LGB adults without health insurance decreased from 21.7% to 11.1%, which is a larger decrease than in the non-LGB adult population.16

New goals related to maintaining and expanding access to health insurance could be added to the next iteration of the NHAS under “Step 2.A: Establish seamless systems to link people to care immediately after diagnosis, and support retention in care to achieve viral suppression that can maximize the benefits of early treatment and reduce transmission risk,” and “Step 3.B: Adopt structural approaches to reduce HIV infections and improve health outcomes in high-risk communities.” A new indicator about reducing the uninsurance rate among PLWH could also be added to the next iteration of the NHAS.

Increase funding for the Ryan White HIV/AIDS Program

The Ryan White Program is critical for ensuring access to care for PLWH in the United States, a population that increases annually as people are newly diagnosed with HIV each year, and as people with HIV live longer thanks to better antiretroviral medications. The Ryan White Program provides comprehensive services for the most vulnerable and low-income PLWH. Two thirds of PLWH receiving services from the Ryan White HIV/AIDS Program are poor, and three quarters are members of a racial or ethnic minority group.17 While many Ryan White Program participants are covered by other insurance, private and public insurance programs often fail to provide the comprehensive services that some PLWH need, such as case management, mental health and substance use treatment, transportation, nutritional support, and legal support. The AIDS Drug Assistance Program helps offset costs of treatment for low-income PLWH so that they are able to access healthcare.

The Ryan White Program has been essentially flat funded since the early 2000s, even though the number of people accessing Ryan White services has nearly doubled, and the value of the funding has decreased due to inflation.18 Despite this, it has been incredibly effective. HIV patients receiving Ryan White services are more likely to be retained in HIV care and virally suppressed. According to the Health Resources and Services Administration at the Department of Health and Human Services:

85.9 percent of Ryan White HIV/AIDS Program clients were virally suppressed in 2017, which is a 16.4 percentage point increase in viral suppression from 69.5 percent in 2010. This exceeds the national viral suppression average of 59.8 percent.19

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In order for the next iteration of the NHAS to be successful in improving health outcomes for PLWH, especially for those most vulnerable, it is essential that Congress significantly increase funding for the Ryan White HIV/AIDS Program.

*Improve access to pre-exposure prophylaxis (PrEP) for HIV prevention and increase research into new PrEP modalities*

Research has shown that PrEP is an acceptable and effective means of HIV prevention when taken as prescribed. Daily PrEP can reduce the risk of acquiring HIV by more than 90%.

The next iteration of the NHAS should scale up and emphasize goals related to increasing access, ensuring affordability, implementing training, and investing in research related to PrEP.

The wholesale price for the PrEP brand-name medication Truvada has increased by 45% since it was approved for HIV prevention up, with a 30-day supply now costing about $2,000. Even with insurance, the out-of-pocket expenses can quickly become prohibitive, especially for low-income individuals. Affordability and access issues should be addressed in the next iteration of the NHAS. One potential strategy could be to increase funding for the Ryan White Program so that in addition to financial support for HIV treatment, it can provide financial assistance for accessing PrEP to low-income individuals at risk for HIV infection. Funding for research into alternative longer-lasting methodologies, such as antibody-mediated prevention and injectable PrEP, should be increased. These methodologies could be more cost-effective and preferable for individuals who have difficulty adhering to a daily pill.

The Centers for Disease Control and Prevention estimate that 1.1 million people in the United States would benefit from PrEP. As of mid-2017, only 136,000 unique prescriptions had been written since approval of the drug for use as PrEP by the FDA in 2012. According to data presented by PrEP manufacturer Gilead at the International AIDS Conference in 2017, 85% of those on PrEP were men, and 15% were women. The average age of those on PrEP was 38 for men and 35 for women. Only 11% of the men on PrEP, and 24% of the women, were younger than 25. Thirty percent of new HIV diagnoses in 2014 occurred among individuals 13 to 24. For those on PrEP for whom race and ethnicity data were available, 73% were White, 13% Latino, 10% Black, and 4% Asian.

Data on what percentage of PrEP users were gay and bisexual men and transgender women were not available. There are some indications that priority populations such as Black men who have sex with men (MSM) are not accessing PrEP at the rates necessary to address the disproportionate HIV diagnoses occurring among Black MSM. At a Birmingham, Alabama PrEP clinic from 2014-2016, 18% of 120 patients screened for PrEP were Black MSM. In Jefferson

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20 Centers for Disease Control and Prevention. HIV/AIDS: PrEP. Available online at: https://www.cdc.gov/hiv/basics/prep.html
County, which includes Birmingham, 50% of new HIV diagnoses in 2014 were among Black MSM.\textsuperscript{24}

Black Americans are less likely to access PrEP for a number of reasons, including the fact that half of Black Americans live in the South, where, by and large, Medicaid has not been expanded to low-income individuals without dependent children or a disability.\textsuperscript{25} Higher poverty and unemployment rates among Black Americans also play a role. Medical mistrust is another barrier that prevents Black people, including Black gay and bisexual men, from accessing routine, preventive health care.\textsuperscript{26} Compared to other MSM, Black and Latino MSM were more likely to regard having to talk with their doctor about their sex lives as a barrier to PrEP, and were more likely to report concerns related to PrEP efficacy and stigma.\textsuperscript{27} Medical mistrust is also a major issue with Native American and Alaska Native people.\textsuperscript{28} Finally, lack of culturally competent health care for Black LGBT people is a barrier to access.\textsuperscript{29}

If we are to reduce the striking racial and ethnic disparities in PrEP uptake, the next iteration of the NHAS must address these structural barriers that make it difficult for Black and Latino gay and bisexual men, Black and Latina transgender women, and Black cisgender women to access PrEP. This includes expanding Medicaid eligibility in the South, Texas, Florida, and other places where Black and Latino Americans disproportionately reside. It also includes reducing poverty and addressing medical mistrust.

An updated NHAS should expand upon the current NHAS’s “Step 1.A: Intensify HIV prevention efforts in communities where HIV is most heavily concentrated” and “Step 1.B: Expand efforts to prevent HIV infection using a combination of effective, evidence-based approaches” with new goals related to improving PrEP access and affordability, especially among Black and Latino/a MSM, transgender women, and cisgender women.

\textit{Acknowledge and address the social drivers of HIV disparities, including anti-LGBT discrimination}

The next iteration of the NHAS should also expand and enhance its focus on the social drivers of HIV infection, including factors such as stigma, poverty, and homelessness. Under the current NHAS, “Step 3.C: Reduce stigma and eliminate discrimination associated with HIV status” could be expanded with a goal to end HIV criminalization. In the United States, 38 states have

\textsuperscript{26} Cahill S, Taylor SW, Elsesser SA, et al. Stigma, medical mistrust, and perceived racism may affect PrEP awareness and uptake in black compared to white gay and bisexual men in Jackson, Mississippi and Boston, Massachusetts. \textit{AIDS Care}. 2017;29:1351-8.
\textsuperscript{27} Lelutiu-Weinberger C & Golub SA (2016, Dec 15). Enhancing PrEP access for Black and Latino men who have sex with men. \textit{J Acquir Immune Defic Syndr}. 73(5); 547-555.
HIV-specific criminal laws or broader criminal laws related to perceived or potential exposure or transmission of HIV. Additionally, in six states that do not have HIV-specific laws, PLWH have been prosecuted under general criminal laws, such as aggravated assault or reckless endangerment, related to their HIV status and perceived or potential exposure. For example, although Texas does not have an HIV-specific criminal law, PLWH have been prosecuted for general crimes like aggravated assault for potential HIV exposure through spitting. Criminalization of HIV, whether by HIV-specific laws or through use of general criminal laws, perpetuates anti-HIV stigma and worsens health outcomes and disparities for PLWH. For PLWH who are incarcerated, adherence to treatment and continuity of care can become very difficult. HIV criminalization should be addressed in the next iteration of the NHAS.

Discriminatory policies against people living with HIV by the Trump Administration—such as the firing of a bilingual Peace Corps volunteer after he tested positive for HIV in Cambodia, and the discharging of two men from the Air Force after they were diagnosed with HIV—contribute to HIV stigma and undermine efforts to reduce HIV infections and improve treatment outcomes for people living with HIV.

The next iteration of the NHAS should also be expanded to include goals related to addressing anti-LGBT discrimination. Gay and bisexual men and transgender women, especially in communities of color, are disproportionately burdened by HIV infection. Discrimination and stigma against these communities only worsens HIV-related disparities and health outcomes. Anti-LGBT discrimination is common in healthcare settings, with a national study of nearly 5,000 individuals finding that 56% of LGB respondents reported at least one discriminatory experience in healthcare, including being refused care outright, being physically or verbally abused, or being blamed for their own health conditions. The 2015 US Transgender Survey of nearly 28,000 respondents found that 33% of respondents reported anti-transgender treatment in healthcare, and 23% did not see a doctor when they needed to out of fear of mistreatment.

Anti-LGBT discrimination in healthcare acts as a barrier to seeking necessary routine preventative services, including HIV and STI screening and risk reduction counseling, and also acts as a barrier to retention in care. Currently, only 20 states have laws that explicitly prohibit discrimination based on sexual orientation and gender identity in public accommodations,
including healthcare settings.\textsuperscript{37} Furthermore, four states have targeted religious exemption laws that permit medical professionals to refuse to serve LGBT patients.\textsuperscript{38} Most alarmingly, the Trump Administration is promoting religious refusal policies that encourage social conservatives to refuse to provide health care or other services to LGBT people, or to hire LGBT people, based on “religious or moral objection.”\textsuperscript{39,40} These policies, promoted by Christian right organizations and activists, are dangerous and will undermine the success of the President’s plan to end HIV. They also violate the “equal protection of the law” guaranteed by the U.S. Constitution.

We are especially concerned about the newly created the Division of Conscience and Religious Freedom under the Office of Civil Rights (OCR) at the Department of Health and Human Services. Led by anti-LGBT Christian right activist Roger Severino, this division was created following President Trump’s 2017 executive order, which directed federal agencies to expand religious freedom protections in ways that could increase discrimination against LGBT individuals and same-sex couples.\textsuperscript{41} Also in early 2018, OCR collected public comments regarding a new proposed rule titled, “Protecting Statutory Conscience Rights in Health Care; Delegations of Authority.” While this proposed rule did not specifically mention LGBT people, sexual orientation, or gender identity, it could easily be interpreted as codifying anti-LGBT discrimination in health care. The rule states that “freedom from discrimination on the basis of religious belief or moral conviction…does not just mean the right not to be treated differently or adversely; it also means being free not to act contrary to one’s beliefs.” This language is exceptionally broad, and could be interpreted to allow providers to deny general health care services to LGBT people, as well as specific services such as STI screening to a gay man, fertility treatment to a lesbian couple, or gender affirmation treatment to a transgender individual. Rules and regulations that allow health care providers to discriminate based on religious beliefs will only exacerbate anti-LGBT discrimination in health care.

Also of concern to providers of health care to LGBT people and HIV prevention and care providers are the Trump Administration’s attempted rollback of a 2016 nondiscrimination regulation prohibiting some forms of anti-LGBT discrimination in health care that constitute sex stereotyping. In May 2016 the U.S. Department of Health and Human Services Office of Civil Rights (OCR) published a final rule implementing Section 1557, the Affordable Care Act’s


The rule states that discrimination based on gender identity is prohibited in health facilities, programs, and activities receiving federal funding, as it constitutes a form of sex discrimination banned by Title IX of the Education Amendments of 1972. Because of a number of federal court rulings and Equal Employment Opportunity Commission rulings that interpreted sex discrimination as encompassing some forms of anti-LGBT discrimination, the rule also provides some protection against anti-gay discrimination in health care, although this is less robust and not explicit. While this rule has great potential to reduce discrimination in health care experienced by LGBT people, it was enjoined nationwide by a federal district court judge on December 31, 2016. The order prohibited the Department of Health and Human Services from enforcing the nondiscrimination rule’s gender identity component.

In May 2017 the U.S. Department of Justice (DOJ) requested that the federal courts “remand this matter to HHS and stay this litigation [seeking to overturn the December 2016 injunction blocking the rule]…pending the completion of the rulemaking proceedings.” The DOJ, which under then Attorney General Jeff Sessions rescinded a different transgender nondiscrimination regulation, sought “the opportunity to reconsider the regulation at issue,” including “the reasonableness, the necessity, and the efficacy” of the Section 1557 nondiscrimination regulation related to gender identity. Federal LGBT health policy advocates have heard that the Trump Administration is preparing to rescind the ACA nondiscrimination regulation’s explicit protection against anti-transgender discrimination. However, many advocates maintain that this regulation is still in force and remains the law of the land.

In an October 2018 brief to the U.S. Supreme Court, the Department of Justice argued that gender identity is outside of the scope of Title VII of the Civil Rights Act of 1964, which prohibits discrimination on the basis of “race, color, religion, sex and national origin.” This contradicts six federal appellate court rulings as of October 2018 that gender identity discrimination is a form of sex discrimination and therefore prohibited under Title VII. The Equal Employment Opportunity Commission describes this important body of jurisprudence, and states:

While Title VII of the Civil Rights Act of 1964 does not explicitly include sexual orientation or gender identity in its list of protected bases, the Commission, consistent with Supreme Court case law holding that employment actions motivated by gender
stereotyping are unlawful sex discrimination and other court decisions, interprets the statute’s sex discrimination provision as prohibiting discrimination against employees on the basis of sexual orientation and gender identity.\textsuperscript{48}

Discrimination in health care is a major reason why LGBT people don’t access health care, which can include HIV screening or HIV treatment and care. Rather than expanding discrimination against LGBT people, the Trump Administration’s NHAS should include goals related to reducing anti-LGBT discrimination, especially discrimination in healthcare, as a barrier to receiving HIV prevention and treatment services for populations disproportionately burdened by HIV.

The next iteration of the NHAS should also expand upon goals to address other social and structural drivers of HIV disparities, including poverty and housing instability. Housing instability and homelessness is of great concern for many PLWH, and can act as a significant barrier to accessing preventive care and being retained in care to achieve viral suppression. In 2016, about 138,400 PLWH were in need of housing assistance, and an estimated half of all PLWH will need housing assistance in their lifetime.\textsuperscript{49} As treatment options for HIV have improved, a new and growing area of concern is housing for elders living with HIV who may fear accessing senior housing services due to stigma surrounding HIV. This is especially true for LGBT elders living with HIV, as older Americans are more likely to have homophobic beliefs\textsuperscript{50} and misconceptions about HIV.\textsuperscript{51} While Housing Opportunities for Persons with HIV/AIDS (HOPWA) provides some federal housing assistance for PLWH, the funding for HOPWA does not meet the need. One goal of the next iteration of the NHAS should be to more directly address housing instability as a driver of HIV disparities by increasing funding for housing assistance programs for low-income PLWH. This could be included under “Step 2.C.1: Address policies to promote access to housing and other basic needs and other supportive services for people living with HIV.”

\textit{Increase efforts to support harm reduction and substance use disorder treatments}

The recent opioid epidemic has become a major public health concern in the United States and needs to be addressed in the next iteration of the NHAS in order to make progress towards ending the HIV epidemic. From 1990 to 2015, the share of HIV infections attributed to injection drug use (IDU) dropped significantly, from 40\% to 6\%.\textsuperscript{52} In 2015, the number of HIV diagnoses attributed to IDU in the United States rose for the first time in two decades, largely associated

\begin{footnotesize}
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\item \textsuperscript{49} AIDS United, Act Now: End AIDS. \textit{Ending the HIV Epidemic in the United States: A Roadmap for Federal Action}. Available online at: https://www.aidsunited.org/data/files/Site_18/Policy/Ending_the_HIV_Epidemic_U.S._Roadmap_for_Federal__20Action_FINAL.pdf
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with an outbreak of HIV in Indiana among social circles of people who inject drugs (PWID) who were sharing needles. Similar HIV outbreaks among PWID have been occurring across the United States, including in Lawrence, Lowell, and Boston, Massachusetts, and globally in cities like Athens, Bucharest, and Dublin.

Harm reduction strategies, such as syringe exchange programs, are effective in reducing HIV transmission risk associated with IDU, and the CDC states that these programs are “an effective component of a comprehensive, integrated approach to HIV prevention among PWID.” Unfortunately, the availability of syringe exchange programs is limited, and often does not align with the opioid epidemic. Of 220 counties determined by the CDC to be vulnerable to HIV or HCV outbreak among PWID, just 18 had a syringe exchange program. The next iteration of the NHAS should expand on addressing HIV transmission through IDU by increasing federal support for syringe exchange programs. This could be included as a goal under “Step 3.A: Reduce HIV-related disparities in communities at high risk for HIV infection.”

People who suffer from substance use disorders, both with injection and non-injection drugs, are at increased risk of HIV infection. Effective and evidence-based substance use disorder treatments have been shown to decrease HIV transmission through reducing frequency of drug use and risk behaviors. Substance use disorder treatment has also been shown to lead to improved adherence and sustained viral suppression. The next NHAS should expand its focus on PWID and call for increased resources and support for comprehensive substance use disorder treatment programs.

We thank you for the opportunity to provide comment on the next iteration of the NHAS. Should you have any questions or require further information, please contact Sean Cahill, Director of Health Policy Research at the Fenway Institute, at scahill@fenwayhealth.org or 617-927-6016. For other recommendations, we recommend Ending the HIV Epidemic in the United States: A Roadmap for Federal Action, created by our colleagues at AIDS United and Act Now: End AIDS.

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53 Ibid.
61 Link here: https://www.aidsunited.org/data/files/Site_18/Policy/Ending_the_HIV_Epidemic_U.S._Roadmap_for_Federal_%20Action_FINAL.pdf
Sincerely,

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