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 Update of the National Viral Hepatitis Action Plan (NVHAP)

Dear Dr. Beckham,

The AIDS Institute, a nonpartisan, nonprofit organization focused on ensuring access to treatment for individuals living with chronic conditions such as hepatitis and HIV, appreciates the opportunity to provide comments for your consideration as you update the National Viral Hepatitis Action Plan. We congratulate you and the entire administration for your focus on combating and eliminating infectious diseases in the United States. The update to the Action Plan comes at an opportune time as the nation is in the midst of an opioid crisis that is driving the number of new cases of hepatitis C (HCV) to skyrocketing levels nationwide. We hope you continue to rely on input from patients and advocates, and the strategies laid out in the Action Plan, as you move forward with efforts to combat the viral hepatitis epidemics.

As you begin to draft the new Action Plan, we hope you will continue to promote the overall goals that were developed in previous versions of the NVHAP. We believe that concentrating on: 1) preventing new infections, 2) increasing access to curative HCV treatments, 3) increasing resources and coordination, and 4) increasing government leadership, will result in an effective document that puts the United States on the path to eliminating viral hepatitis.

Achieving the goals of the Action Plan will continue to take concerted effort, leadership, and resources by all stakeholders, including the federal government. We urge the administration to prioritize viral hepatitis programs in future budgets and in discussions with Congress as annual appropriation measures are considered. We also urge the government to use the updated Action Plan as the basis for a larger comprehensive plan and effort to eliminate viral hepatitis nationwide.

The comments below include some specific recommendations that we would like to highlight for inclusion in the updated Action Plan:

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1. **Promote Elimination**: The ultimate goal of the Action Plan should continue to be to end viral hepatitis in the United States. We are supportive of the vision set forth in the current Action Plan that “[t]he United States will be a place where new viral hepatitis infections have been eliminated, where all people with chronic hepatitis B and C know their status, and everyone with chronic hepatitis B and C has access to high quality health care and curative treatments, free from stigma and discrimination.” This vision is more achievable than ever due to a highly effective, curative treatment for HCV that is well-tolerated and can be administered in just eight weeks, and an effective vaccine for hepatitis B (HBV) that prevents individuals from acquiring the disease. Proper leverage of these two medical advancements along with robust testing, education, prevention, and surveillance efforts can lead to the successful elimination of viral hepatitis in the country.

The ability of the United States to eliminate viral hepatitis is well documented. The National Viral Hepatitis Action Plan 2017-2020 laid out the key goals, strategies, and indicators that are needed to successfully eliminate viral hepatitis in the country. The National Academies of Science, Engineering, and Medicine released a comprehensive report in early 2017 with recommendations on how the United States could eliminate HBV and HCV as a public health threat in the country by 2030. The World Health Organization drafted an ambitious strategy to eliminate HBV and HCV globally by 2030. All of these strategies have several items in common: an investment in resources, strong leadership, and the expanded use of the HCV curative treatment and HBV vaccine.

2. **Expand Federal Leadership**: The current viral hepatitis epidemics are a threat to the public health of the United States. Despite our ability to easily cure people of their HCV, which prevents further infections, we are still experiencing drastic increases in the number of new cases. Currently there are at least 2.4 million people living with HCV in the country, with 41,000 new cases occurring in 2016. Overall there has been a 350 percent increase in the number of new cases since 2010.

With no sign of these increases abating, there is a clear need for strong federal leadership and coordination of the federal agencies working on hepatitis. The Action Plan should include a focus on the leadership needed to coordinate federal agencies’ response to these epidemics. This effort could be housed at the White House or at the upper levels of the Department of Health and Human Services (HHS) such as in the Office for the Assistant Secretary for Health (OASH). There are currently viral hepatitis efforts being conducted at the Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration, Substance Abuse and Mental Health Services Administration, Indian Health Services, and the Veterans’ Administration. Improved coordination between the federal entities overseeing viral hepatitis activities would help prevent duplication of efforts and ensure key populations are being properly targeted for testing and treatment.

The administration has successfully shown its ability to create a comprehensive plan and provide the federal leadership necessary for the elimination of an infectious disease with its initiative “Ending the HIV Epidemic: A Plan for America.” This initiative will work to reduce new HIV infections by 75 percent in the next five years and by 90 percent in the next ten years, averting more than 250,000 infections in that timespan. A strategy requesting the creation and implementation of a similarly aggressive and comprehensive federal plan for the elimination of
viral hepatitis should be included in the Action Plan. Many of the lessons learned in the planning of the Ending the HIV Epidemic Plan can be used in the planning of a viral hepatitis elimination plan, and much of the public health infrastructure that will be relied on to implement the Ending the HIV Epidemic Plan can be used to implement a viral hepatitis elimination initiative.

3. **Increase Resources:** The current and recent drastic increases in the number of new HCV cases makes it clear that the resources dedicated to viral hepatitis activities by the federal government are insufficient. Currently the CDC, together with its grantees, oversees viral hepatitis prevention, education, testing, surveillance, and linkage to care efforts across the country, is funded at only $39 million a year. This level of funding results in states only being able to hire one less-than-full-time person to oversee viral hepatitis activities across the entire state. Some states have resorted to holding testing events only using test kits donated from industry partners since the state does not have the resources necessary to purchase the needed supplies.

We request that the Action Plan include the importance of increased resources directed to CDC and other agencies engaged in viral hepatitis activities so they may be successful in their work to eliminate viral hepatitis in the United States. We also request that the Action Plan include the importance of states and local communities increasing the resources they need for viral hepatitis programs. Increasing viral hepatitis support and infrastructure for prevention, education, testing, vaccination, surveillance, and linkage to care will allow for better prevention, detection, and response to new infections. It will also enhance the ability to conduct cluster identification and investigations, which is critical to addressing identified vulnerabilities and improving linkage to care so people living with viral hepatitis can be treated.

There is also inadequate funding for the hepatitis activities being implemented by the OASH, of which the Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) is a part. OHAIDP and OASH are essential parts of the federal plan to eliminate viral hepatitis, although neither receives dedicated funding for those activities. We request that the Action Plan include the need for increased funding directed for OASH and OHAIDP so they may carry out viral hepatitis elimination activities, including updating and implementing the NVHAP and coordinating the federal government’s response.

4. **Increase Testing:** Testing is the gateway to treatment and for HCV, a cure. The vast majority of those living with HBV and HCV are asymptomatic, often going years without becoming aware they are living with the disease and with no reason to seek out a consultation with a provider or to request testing. This can lead to new cases of viral hepatitis as individuals unknowingly pass the disease onto others. In an effort to combat this, the CDC and the United States Preventive Services Task Force (USPSTF) recommends all persons at high risk for infection be periodically tested for HBV and HCV, and all Baby Boomers, those born between 1945-1965, have a one-time test for HCV. The USPSTF gave this recommendation a B grade, meaning there is a moderate to high level of certainty that the net benefit of this recommendation is moderate to substantial, and that private and public payers reimburse providers for these tests without patient cost-sharing. The CDC estimates that one-time HCV testing for Baby Boomers could identify 800,000 infections and, with linkage to care and treatment, avert more than 120,000 HCV-related deaths. Left untreated, viral hepatitis can lead to liver disease, liver cancer, and death. In fact, HBV and HCV remain the leading causes of liver cancer, one of the most lethal, most expensive to battle, and fastest growing cancers in the country, with 5-year survival rates...
of only 15 percent.

While the current recommendations are robust, have helped increase the number of HCV tests conducted nationally, and resulted in more people being linked to treatment, they were drafted before the impact of the current opioid crisis was fully known. The majority of new cases of HCV are among a population younger than Baby Boomers, who may not know they are at risk, or who may not openly discuss their risk factors with their provider. As a result, their providers do not know to request a test and new cases may go undiagnosed. To combat these cases from going undiagnosed and untreated, the Action Plan must urge the CDC and USPSTF to adopt a recommendation for universal testing of HCV, instead of the current population-based testing recommendation. There are real world examples of universal screening being successful. The Cherokee Nation HCV Elimination Program implemented universal HCV testing in its program, testing nearly 29,000 individuals, and found that 57 percent of population it screened that tested positive for HCV were born after 1965, and may not have been tested under the current CDC and USPSTF recommendations.

5. **Eliminate Payer Access Restrictions to Hepatitis C Cures:** As has already been noted, the existence of a highly effective, well-tolerated HCV curative treatment with a short treatment time presents an opportunity to eliminate HCV. However, access to this treatment has continually been restricted by public and private health payers in the United States, preventing individuals from receiving life-saving treatments and exacerbating their HCV.

Often, states cite the high cost of the HCV curative treatment as the reason for restricting access within their Medicaid programs. However, competition has been steadily increasing since the first HCV curative treatment entered the market in 2013, and prices have significantly dropped since that time. In fact, all three of the major manufacturers of the HCV curative treatments have taken steps to bring the list price of some of those drugs down to the low-to-mid $20,000 range. These reductions, in addition to the automatic rebates state Medicaid programs receive on FDA-approved drugs and the state’s ability to negotiate additional discounts, means the state can cure Medicaid recipients at a much lower cost than many states are publicly acknowledging. Treatment cost should no longer be an excuse to restrict access to treatment.

Numerous state Medicaid programs restrict access to curative HCV treatment to only those Medicaid recipients who have severe liver damage, and/or who have abstained from substance use, and/or have been seen by a specialist. Before allowing treatment, there are currently 13 states plus the District of Columbia that require Medicaid beneficiaries to have some amount of liver fibrosis, and 27 states that require sobriety from drugs and/or alcohol for some period of time. These restrictions are in place despite the Centers for Medicare and Medicaid Services warning states that they cannot restrict access to FDA-approved drugs for non-medical reasons. Multiple states have had litigation filed against their Medicaid programs for failing to treat people living with HCV in a timely manner. In almost every instance, those cases have either resulted in rulings that require the state to cover treatment, or the states have voluntarily agreed to increase access to treatment prior to a final ruling. A large proportion of the populations at-risk for HCV are eligible for Medicaid services, causing these restrictions to have an outsized negative impact on the ability to treat those individuals living with HCV. We request that the Action Plan call for the removal of access barriers in Medicaid and that the administration enforce its previously stated policy that requires Medicaid recipients have access
to medically-necessary treatments, including HCV curative treatments.

State Medicaid programs are not the only payers implementing access restrictions to HCV curative treatments. A review of Qualified Health Plans on the Federal Marketplace in a select state found that nearly every plan placed the HCV curative treatments on the highest drug formulary tier, which range between 30 and 50 percent co-insurance after having to meet a very high deductible, making access to these curative medications prohibitively expensive. Every plan reviewed also included prior authorization requirements for the HCV curative treatments, further restricting access. While insurers are allowed implement these utilization tools, there is a concern that they can be used to discriminate against those living with HCV. Additionally, access restrictions are a barrier to eliminating HCV in the United States. We request that the Action Plan urge insurers to remove access restrictions to HCV curative treatments, and that the administration ensure Qualified Health Plans on the Federal Marketplace are not using utilization management tools to discriminate against people living with HCV.

6. Leverage Existing Health Infrastructure: The existing public health infrastructure provides an unique opportunity in the effort to eliminate viral hepatitis in the United States. The Action Plan should include a focus on incorporating or increasing hepatitis services such as prevention, education, testing, vaccination, and linkage to care efforts at community health centers, Ryan White HIV/AIDS Program providers -- for those who are co-infected with HIV -- and other public health entities. While many of these entities already contribute to elimination efforts, additional coordination and resources could improve the quality and/or amount of services being provided and ensure that Ryan White grantees and community health centers are following federal guidelines on testing for HBV and HCV, vaccination against HBV, and offering appropriate care and treatment for those clients who test positive for these viruses, including access to HCV curative treatment.

7. Incorporate Infectious Disease Activities Within Opioid Crisis Response: The newest barrier to eliminating viral hepatitis in the United States is the ongoing opioid crisis, which has devastated communities across the country and resulted in 47,600 opioid overdose deaths in 2017. The crisis has caused a significant increase in injection drug use, which is responsible for at least 70 percent of new HCV cases in recent years. The CDC has identified 220 counties that are most vulnerable to outbreaks of HCV and HIV related to injection drug use. These counties are spread across 26 states and represent five percent of total counties in the country.

If the country is to fully tackle the consequences of the opioid crisis, a comprehensive response is needed that marries infectious disease and substance use prevention and treatment efforts. This means drug treatment centers and harm reduction entities must include infectious disease prevention, education, testing, vaccination, and linkage to infectious disease and substance use care when interacting with people who inject drugs (PWID). We ask that the Action Plan include a call to incorporate infectious disease education, prevention, testing, vaccination, and linkage to care efforts into opioid crisis response grant programs, and that states, localities, and community-based organizations conducting harm reduction and substance use treatment include infectious disease education, prevention, testing, vaccination, and linkage to care efforts in their activities with PWID.

While incorporating infectious disease activities into the work of existing harm reduction and substance use treatment entities will help increase the number of identified new cases of HCV
and link additional individuals into treatment, there will still be a shortage of entities doing the work. Currently, 90 percent of the 220 vulnerable counties do not have comprehensive syringe service programs (SSPs). 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. These programs are an effective component of an integrated approach to addressing the harms associated with drug use. Most SSPs offer additional services, such as overdose prevention with naloxone, referral to substance use disorder treatment programs, and counseling and testing for viral hepatitis and HIV. We urge the Action Plan to call for an increase in the number of SSPs, removal of barriers that prevent or restrict SSPs from existing in those states and localities where barriers exist, and continued technical assistance from the CDC for states pursuing a Determination of Need.

8. **Ensure Comprehensive Access to Healthcare:** Included in the current NVHAP vision statement is ensuring “everyone with chronic hepatitis B and C has access to high quality health care and curative treatments, free from stigma and discrimination”. We believe this goal must continue to be a central tenant of the updated Action Plan. Less than half the people living with HCV in the country know they have the disease, and those who are aware of their status face multiple barriers to accessing curative treatment. Much more must be done to inform more people of their status and to link them to curative treatment.

To achieve any of the goals established in the Action Plan, the avenues by which healthcare is accessed 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 viral hepatitis. 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. We urge the administration to strengthen the ACA as a means to increase access to care and improve health outcomes for people living with viral hepatitis. Furthermore, it can be expected that as access to healthcare is broadened, lower rates of transmission will be achieved as those who are cured of their HCV will not transmit the disease.

An equally important health reform for people living with viral hepatitis, made possible by the ACA, has been Medicaid expansion. In order to increase hepatitis treatment and cures, states should expand Medicaid for their low-income population, which are disproportionately impacted by viral hepatitis.

We are 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 HCV-related deaths while ensuring vulnerable populations who access their healthcare through this source will be able to continue to effectively manage their health.

Access to viral hepatitis care and treatment through insurance coverage and benefits is important in order to achieve the goals of the Action Plan, and nothing is more critical to that end than broad, unhindered access to innovative medications to treat viral hepatitis. As the
update to the Action Plan is developed, we urge the administration to take into consideration ways to mitigate the 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. 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.

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. The Action Plan should incorporate and encourage policies that remove barriers that impede patient access to health care and prescription drugs.

Medicare also plays a strong role in achieving the Action Plan’s goals, in particular through the program’s prescription drug benefit, Medicare Part D. As noted in the current Action Plan, Baby Boomers have a low rate of new HCV infections but comprise approximately 75 percent of all people who are chronically infected with HCV in the United States. This age group also experiences one of the highest mortality rates from HCV. As these individuals live with HCV that continues to go undiagnosed, they are increasingly likely to develop severe liver disease and liver cancer. Many Baby Boomers are already enrolled in Medicare, or soon will be eligible. They will need to be able to access prescriptions – including HCV curative treatments – that they can afford, and without prior authorization and other utilization management.

We encourage the authors of the Action Plan 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 the Action Plan.

9. Increase Testing and Treatment in Corrections: Approximately 1 percent of the general population of the United States is currently living with HCV. Among the incarcerated population however, that number increases dramatically to the 17.4-23.1 percent range. Successfully eliminating viral hepatitis in the United States requires a special focus on the corrections population. As many as 1 million individuals with undiagnosed HCV infection might come into contact with the correctional system each year, although few are tested and even fewer treated. Since incarcerated individuals are considered “at-risk” by the USPSTF, it is recommended they undergo HCV testing upon entry into the system. However, many jails and prisons provide no testing, or only offer opt-in testing, requiring the individual request the test in order to receive it. In order to better utilize corrections facilities as a way to identify undiagnosed cases of viral hepatitis, we request that the Action Plan recommend corrections systems implement opt-out viral hepatitis testing upon an individual’s entry into the corrections system. This would result in every person entering the corrections system receiving a test for HCV unless they request otherwise.

In addition to failing to provide adequate testing for viral hepatitis, the corrections system has
been reluctant to provide life-saving curative treatment to those incarcerated individuals living with HCV. A recent study found that 97 percent of incarcerated individuals living with HCV have not been treated. Corrections systems use cost as a reason to deny access to curative treatment, despite having a constitutional requirement to provide treatment, recent reductions in the cost of the treatment, and manufacturers’ willingness to enter into agreements with corrections systems that lower treatment costs even more. Recently, some incarcerated individuals have successfully sued for access to treatment, but access remains out of reach for many living with the disease. We request that the Action Plan recommend corrections systems provide HCV curative treatments to all those advised to be treated under current treatment guidelines. We also request that the Action Plan urge the administration to enforce requirements that corrections systems provide medically necessary treatment to incarcerated individuals in their care. Treating those incarcerated individuals living with HCV will help greatly reduce the prevalence of HCV within corrections systems, and positively impact the community’s health when those individuals reintegrate from incarceration into the community.

10. Continue to Focus on Priority Populations: HCV disproportionately impacts certain populations within the country. Any comprehensive plan focusing on the elimination of viral hepatitis needs to include a focus on these priority populations, as efforts within these populations are likely to have an outsized impact. The need to focus on PWID, individuals in the corrections system, and Baby Boomers has already been noted, but another priority population requiring attention are individuals co-infected with HIV and HCV. The Action Plan should prioritize efforts focused on improving testing and diagnoses, and linkage and access to care and treatment among these populations.

Among the 1.1 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 treatment because liver-related complications 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.

The AIDS Institute thanks you for your continued leadership and work on eliminating viral hepatitis in the United States. We look forward to working with you in implementing the new Action Plan so the goals and strategies can be achieved in a timely and successful manner. Should you have any questions or comments, please feel free to contact Franklin Hood at (202) 835-8373 or fhood@theaidsinstitute.org.

Sincerely,

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