HIV+HEP

POLICY INSTITUTE

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B. Kaye Hayes, MPA
Acting Director, Office of Infectious Disease and HIV/AIDS Policy (OIDP)
Office of the Assistant Secretary for Health (OASH)
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Room 715-G
Washington, D.C. 20201

Re: Draft *Viral Hepatitis National Strategic Plan for the United States: A Roadmap for Elimination 2021-2025*

Dear Ms. Hayes,

Thank you for the opportunity to provide comments on the draft *Viral Hepatitis National Strategic Plan for the United States: A Roadmap for Elimination 2021-2025* (VH Plan). The **HIV+Hepatitis Policy Institute** is a leading HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. **HIV+Hep** congratulates the U.S Department of Health and Human Services for updating the viral hepatitis strategic plan and taking the bold and necessary step of calling for the elimination of viral hepatitis in the U.S. Ending hepatitis A, B, and C is clearly doable through adequate prevention, including vaccines for hepatitis A and B, along with curative medications for hepatitis C. Incorporating the goal of ending hepatitis fulfills the U.S. commitment to the World Health Organization (WHO) in calling for ending hepatitis worldwide by achieving a 90 percent reduction in new chronic infections and a 65 percent reduction in mortality. Now, we, as a country must turn to implementing the strategy once it is finalized.

We are also pleased that the plan fully recognizes the syndemics of viral hepatitis and HIV, and how addressing both infectious diseases helps achieve the goals of ending both epidemics in the U.S.

In response to OIDP's questions in the *Federal Register*, we agree that the draft plan's goals, objectives, and strategies appropriately address the VH epidemic. We fully support the plan's vision and contents. However, as discussed below, financial resources and leadership will be critical to ensure that the bold goals are achieved in the five- and ten-year periods outlined in the strategy.

Please find below specifics comments on the plan, along with suggestions on ways we believe it can be strengthened.

Executive Summary and Introduction

HIV+Hep is pleased there is a significant focus on the important goal of integrating the response to VH across the federal, state, and local governments; public and private providers of health care; community-based organizations; and researchers. We are particularly pleased of the emphasis on integrating VH prevention, screening, diagnosis and treatment amongst HIV, sexually transmitted infections (STIs), substance use disorders, and other public health efforts. Addressing these conditions requires a robust and well-funded public health infrastructure.

Creating a robust system able to appropriately scale-up public health interventions will require leadership and an investment of resources from the federal government as well as state and private funding. The VH Plan acknowledges that "[a]ppropriate public health interventions and sufficient resources can slow and eventually eliminate viral hepatitis, thereby preventing needless disease and loss of life and saving billions of dollars that could be redirected toward other public health needs" (page 12). Unfortunately, our nation has not prioritized funding for viral hepatitis programs. The viral hepatitis programs at the Centers for Disease Control and Prevention (CDC) are severely underfunded, receiving only $39 million annually to be distributed throughout the country. This is far short of what is needed to build and strengthen our public health response to hepatitis. While other agencies have a role in addressing viral hepatitis across our healthcare system, CDC's viral hepatitis program is the *only* division in the federal government with the main goal of addressing hepatitis A, B and C.

In the list of Challenges and Opportunities, **HIV+Hep** believes a discussion of the nation's current healthcare landscape is warranted. Over the past ten years, our nation has witnessed an expansion of health coverage opportunities through the Affordable Care Act in the form of expanding Medicaid and increased access and affordability of private health insurance. Health coverage has been key to identifying, linking, and treating people with viral hepatitis. However, not all people have been able to take advantage of these expanded opportunities and millions have lost coverage in recent years. As has been highlighted by COVID-19, we know access to and health-related outcomes due to this expanded health care landscape have not been equitable across regions and populations in the U.S.

As part of the health care landscape, we also believe that the work of the Veterans Administration (VA) should be recognized. The VA has been a key partner in developing best practices and methods to eliminating hepatitis C within their population.

Goal 1: Preventing New Viral Hepatitis Infections

HIV+Hep appreciates the emphasis on increasing public awareness of hepatitis and vaccination as a critical intervention requiring scale-up to address hepatitis A and B. It should be noted in the Viral Hepatitis plan that CDC and the Advisory Committee on Immunization Practices (ACIP) recommend hepatitis A and hepatitis B vaccinations for gay and bisexual men. Despite the

availability of a vaccine, hepatitis A outbreaks among gay and bisexual men have been frequently reported and vaccination rates among this population is estimated to be between 25 percent and 44 percent.[1] We believe gay and bisexual men should be added as a priority population.

The plan also notes on page 26 that "[t]o address low vaccination rates among adults, the Hepatitis Plan recommends opportunities for vaccination in high-risk settings." While these settings can be inferred from subsequent paragraphs in the document, it would be best to define what you mean by "high-risk settings".

Syringe service programs (SSPs) are a critical place to prevent hepatitis transmission and to co-locate services such as screening, vaccination, and testing for hepatitis and HIV. Unfortunately, SSPs are still not legal in every state despite overwhelming evidence of their benefits to individuals and communities. HHS notes that "[n]early 30 years of research shows that comprehensive SSPs are safe, effective, and cost-saving; do not increase illegal drug use or crime; and play an important role in reducing the transmission of viral hepatitis, HIV, and other infections."[2] The strategy should include plans to reduce barriers to SSPs.

Goal 2: Improve Viral Hepatitis-Related Health Outcomes of People with Viral Hepatitis

HIV+Hep agrees that testing and treatment is an incredible opportunity to address hepatitis B and hepatitis C and to prevent further new infections. We fully support this section as proposed. We are pleased there is a mention of the need to develop a cure for hepatitis B and suggest that the strategy be modified to include efforts to ensure that eventual treatment reaches those who are in need of it. Curative treatments are worthless if people cannot access or afford them.

The U.S. Preventive Services Task Force issued a recommendation in March of this year that all adults aged 18 to 79 should be screened for hepatitis C. Thanks to the ACA, this significant step forward means that public and private health insurers will cover screening and testing for hepatitis C.[3] It will be critical that agencies across the federal government identify actions in their implementation plans to ensure widespread uptake of these recommendations and coverage to ensure uptake occurs at the ground level. This also applies to vaccination for A and B, along with screening for hepatitis B. All these activities are covered by insurers and people with coverage should be able to take advantage of them with no cost-sharing.

HIV+Hep applauds the inclusion of Strategy 2.2.3: "Remove insurance coverage and payment barriers to viral hepatitis care and treatment, including prior authorization requirements."

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[1] Centers for Disease Control and Prevention, *Men who Have Sex with Men and Viral Hepatitis*, https://www.cdc.gov/hepatitis/populations/msm.htm, updated August 24, 2020.

[2] Department of Health and Human Services, *Syringe Service Programs, https://www.hiv.gov/federal-response/policies-issues/syringe-services-programs,* updated January 31, 2020.

[3] U.S. Preventive Services Task Force, *Recommendation: Hepatitis C Virus Infection in Adolescents and Adults: Screening,* https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-c-screening, March 2, 2020.

Despite the declining costs of hepatitis curative drugs, there are still many access challenges including formulary restrictions, prior authorization and prescriber requirements by state Medicaid programs, and high levels of cost-sharing for the patient in the private insurance market.

Goal 4: Improve Viral Hepatitis Surveillance and Data Usage

As noted in the VH Plan, the poor quality of hepatitis data limits federal, state, and local governments' ability to respond and direct the limited resources available. Currently, the CDC is not able to fund all jurisdictions to conduct enhanced hepatitis surveillance, which harms our nation's ability to respond to the infectious disease consequences of the opioid epidemic and to understand the true disease burden of hepatitis A, B, and C. Funding must be invested to increase the nation's ability to measure disease burden and the effects of hepatitis. We are pleased that this strategic plan includes this new goal on surveillance and data usage.

Goal 5: Achieve Integrated, Coordinated Efforts that Address the Viral Hepatitis Epidemics among All Partners and Stakeholders

HIV+Hep applauds the inclusion of Objective 5.1: "Integrate programs to address the syndemics of viral hepatitis, HIV, STIs, and substance use disorders." Public health programs have made strides in the past several years to integrate funding, services, and capacity; but more can be done to ensure increases in services for viral hepatitis and to ensure individuals receive a one-stop experience when receiving prevention and care messages. This is being accomplished at the CDC, through their funding announcements for HIV, hepatitis, and STD prevention programs, and also should be through HRSA's Ryan White HIV Program. Everyone with HIV should be tested, vaccinated, and treated, if appropriate, for hepatitis.

We support the inclusion of the recommendation to create viral hepatitis strategic planning groups at the state, local, and national levels that include people with lived viral hepatitis experience. Additionally, we recommend that the federal government create a formal advisory panel similar to the Presidential Advisory Council on HIV/AIDS (PACHA) for viral hepatitis. This will elevate the work of the federal government related to viral hepatitis, bring in new public and private partners, monitor the implementation of the VH Plan, and ensure increased coordination.

Priority Populations

Throughout the document and particularly in the paragraph discussing high-impact settings, we propose adding Ryan White Program clinics and Federal Qualified Health Centers/Community Health Centers (FQHCs/CHCs) to the list of settings. Ryan White funded programs provide a key entry point to increase vaccination rates of priority populations. The program has also been focused on curing hepatitis C. Health Centers serve nearly 30 million patients, which presents an incredible opportunity to provide hepatitis A and B vaccination and screening, as well as testing, treatment and care services for hepatitis A, B, and C. According to the Bureau of Primary Health Care (BPHC), health centers tested 887,787 patients for hepatitis B and

1,070,417 patients for hepatitis C. They provided services to 53,676 patients diagnosed with hepatitis B and 195,946 patients diagnosed with hepatitis C.

Indicators

HIV+Hep believes the core and disparity indicators chosen for the VH Plan are comprehensive, measurable, and will allow HHS to track progress over the next ten years. We also support the inclusion of the developmental indicators; however, we believe data is available through public and private sources to begin estimations of many of these critical data points. For example, it is public knowledge of what state Medicaid programs are restricting access to hepatitis C curative drugs. We urge the federal government to prioritize releasing available information even if there is not a full, nationally representative picture.

Implementation and Accountability

HIV+Hep looks forward to the implementation process and the agency implementation plans. We believe that to reach the goals of hepatitis elimination set out in the VH Plan, resources need to be invested throughout our health system, including dedicated funding for the Office of Infectious Diseases and HIV/AIDS Policy to coordinate the government's response, develop and disseminate best practices, and bring together stakeholders to further the conversations and solutions in addressing viral hepatitis.

Again, the **HIV+Hepatitis Policy Institute** applauds and is grateful for all the hard work across the federal government on this draft plan. We know that federal agencies are already hard at work addressing viral hepatitis using the limited resources that they already have. We hope the calls for elimination contained in this plan will reenergize and further the work. We look forward to its finalization and implementation.

Should you have any questions or comments, please feel free to contact me at cschmid@hivhep.org or (202) 462-3042. Thank you.

Sincerely,

Carl E. Schmid II
Executive Director