

October 8, 2020

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

RE: Request for Information: Viral Hepatitis National Strategic Plan 2021-2025

Dear Ms. Hayes,

On behalf of Hep B United, we appreciate the opportunity to comment on the draft Viral Hepatitis
National Strategic Plan: A Roadmap to Elimination (2021-2025) (Hepatitis Plan). Hep B United is a
national coalition of nearly 50 organizations in 23 states dedicated to reducing the health disparities
associated with hepatitis B by increasing awareness, screening, vaccination, and linkage to care for highrisk communities across the United States.

As the ongoing COVID-19 pandemic puts increasing pressure on the nation's public health infrastructure, we commend the Department of Health and Human Services (HHS) for reviewing and updating its Hepatitis Plan during this challenging time, and for upholding its critical role in guiding, implementing, and coordinating national strategies to eliminate hepatitis.

Hep B United compiled the following comments for consideration regarding the draft Hepatitis Plan.

1. Do the draft plan's goals, objectives, and strategies appropriately address the viral hepatitis epidemics?

Overall, the draft Hepatitis Plan for 2021-2025 provides a comprehensive and ambitious roadmap to address and ultimately eliminate viral hepatitis in the U.S. As a coalition of national and community organizations, provider and student organizations, state and local health departments, academic and research institutions, and other groups, we appreciate that the Hepatitis Plan emphasizes the importance of collaboration and partnership with community-based and other relevant stakeholders throughout all five of the plan's goals.

We feel that the Hepatitis Plan should continue to emphasize the goal of viral hepatitis elimination, rather than control. The U.S., as a Member State participating in the World Health Assembly, endorsed the WHO global elimination goals. Following an appropriate, comprehensive plan, the U.S. is in a unique position to serve as a global model for hepatitis B and C elimination.

We applaud Objective 1.2 for encouraging better vaccine uptake and innovation, and strategy 1.2.6 in particular, for addressing the need for increased research and scale up of hepatitis B vaccination best practices. Data show that adult hepatitis B vaccine completion rates remain low among high-risk groups despite current recommendations. We agree that research is needed which may lead to a universal adult hepatitis B vaccination recommendation. Vaccination is the most cost-effective option available to reach public health goals and we encourage the utilization of the best available vaccines for the American public. In better utilizing new resources, such as the new 2-dose hepatitis B vaccine, and expanding vaccination opportunities in non-traditional healthcare settings, we can help achieve the targets listed within this plan.

We also strongly support that Goal 3 is focused specifically on reducing hepatitis-related disparities and health inequities. Significant disparities are associated with hepatitis B, with Asian American, Pacific Islander, and African communities comprising up to 80% of all chronic hepatitis B infections in the U.S. It will be impossible to achieve hepatitis B elimination without targeted strategies to address barriers to awareness, prevention, testing and care, as well as data collection and surveillance, among these priority populations.

2. Are there any critical gaps in the Hepatitis Plan's goals, objectives, and strategies? If so, please specify the gaps.

Overall, hepatitis B has been under-prioritized as an urgent public health threat. This has led to a lack of funding for research, surveillance, and programs and will continue to hinder progress towards hepatitis B elimination if not appropriately addressed.

Hepatitis B Cure Research: Finding a cure for hepatitis B should have priority status at the national level. The current treatment paradigm poses significant challenges for patients and providers, and serves as a barrier for prioritization of hepatitis B elimination. Finding a functional cure for hepatitis B is a critical step that could open the path towards elimination.

Chronic Hepatitis B Among Foreign-Born Populations: More focus is needed for screening and linkage to care for highly impacted foreign-born populations, under a health equity lens. It is important to explicitly prioritize high-risk foreign-born populations for objectives and activities to reduce morbidity and mortality associated with hepatitis B — specifically Asian Americans, Pacific Islanders, and those of African descent. This is especially important, as foreign-born communities face tremendous challenges related to stigma, discrimination, and health care access. For Objective 2.1, to "Increase the proportion of people who are tested and aware of their viral hepatitis status," increasing screening/diagnosis for

these communities should be a separate strategy. Currently, these communities, the most impacted by hepatitis B, are not highlighted in this objective.

Data on African Immigrants: African immigrant communities are disproportionately impacted by hepatitis B and are estimated to comprise 29% of chronic hepatitis B patients in the U.S.¹ As noted on page 41 of the draft Hepatitis Plan, "the prevalence of chronic hepatitis B among sub-Saharan African immigrants in the United States ranged from 9.1 to 11.8%." Because of this high prevalence, we urge HHS to add 'Black, non-Hispanic' as a priority population under chronic hepatitis B prevalence (Table 2, page 40) and to incorporate this population into Disparities Indicator #10 (Table 5, page 51). *Ideally, we would recommend that African immigrants have their own baseline measure and targets for increasing the proportion of people within this population who are aware of their hepatitis B infection.* For example, by splitting indicator #10 into 10a for Asian and Pacific Islanders and 10b for Africans — mirroring how indicators 11a and 11b are currently presented. However, this would first require HHS and CDC to work towards publishing disaggregated data on viral hepatitis. We believe this can be done as part of Goal 4, to improve viral hepatitis surveillance and data usage overall. For hepatitis B, the availability of data on African (as well as Asian and Pacific Islander) ethnicities and/or country of birth for people with chronic hepatitis B infection would be particularly helpful, given the high risk and prevalence among these communities.

Hepatitis Delta Surveillance: Hepatitis delta, which can only be acquired by people already infected with hepatitis B, is the most severe form of viral hepatitis. In the U.S., hepatitis delta is estimated to affect approximately 5% of people already living with chronic hepatitis B. However, there is a severe lack of awareness and data around hepatitis delta. We recommend including hepatitis delta under Objective 4.1.1 to encourage more states to include acute and chronic hepatitis delta as a reportable condition.

Liver Cancer Screening for People with Viral Hepatitis: The CDC reports that viral hepatitis is responsible for 65% of new liver cancer cases.² Studies have also shown that liver cancer-related deaths are highest amongst people living with chronic hepatitis B and C.³ Screening high-risk groups and people with viral hepatitis can prevent liver cancer, lead to early detection, and may help to reduce early deaths from liver cancer, which is the second deadliest cancer and the fastest increasing cause of cancer-related deaths in the U.S.⁴ We therefore recommend adding the following strategy under Objective 2.2: "2.2.9: Improve implementation and uptake of liver cancer screening for people with viral hepatitis, as part of their care and disease management."

¹ Kim WR, Benson JT, Therneau TM, Torgerson HA, Yawn BP, Melton LJ 3d. Changing epidemiology of hepatitis B in a U.S. community. Hepatology 2004;39(3):811–6. https://www.ncbi.nlm.nih.gov/pubmed/22105832

² Centers for Disease Control and Prevention. (2016). CDC Fact Sheet: Viral Hepatitis and Liver Cancer (pp. 1-2). CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

³ American Liver Foundation. (2016). Liver Cancer on the Rise. Retrieved from https://liverfoundation.org/liver-cancer-rise/

⁴ American Association for Cancer Research. (2018). Why Is Liver Cancer on the Rise?. Retrieved from https://blog.aacr.org/liver-cancer-rising/

Universal Hepatitis B Screening: Ultimately, we believe that in order to achieve hepatitis B elimination goals, we must move beyond targeted screening to universal HBV screening in order to close the major gaps in identifying all undiagnosed cases. Targeted or risk-based HBV screening strategies are being implemented primarily through community-based settings by smaller and often under-resourced organizations and clinics. Additionally, targeted screening is difficult to implement in hospitals and health care systems where there is little provider awareness and incentive. We encourage HHS to include an objective/strategy around working with federal and community partners to assess and eliminate cost-related challenges to HBV screening and care.

3. Do any of the Hepatitis Plan's goals, objectives and strategies cause concern? If so, please specify the goal, objective or strategy, and describe the concern regarding it.

References to acute HBV rates throughout the report are not consistent. Page 12 states that "The rate of acute HBV cases has plateaued since 2010," while also noting that "the rate of acute hepatitis B cases increased 11% from 2014 (0.9 per 100,000 to 2018 (1.0 per 100,000)." Page 22 then cites a different number, noting a "19% increase in acute cases" from 2014 to 2018, the same time period that was highlighted on page 12.

In addition, we are concerned that only highlighting the national average increase in acute HBV hides the reality that hepatitis B, like hepatitis A and C, has also risen in several parts of the country as a consequence of the opioid epidemic. We recommend using the following language where relevant to help make the connection between acute hepatitis B and injection drug use:

"From 2006 to 2018, increased rates of acute hepatitis B ranged from 56% to 457% in states heavily affected by the opioid epidemic, including Kentucky, Tennessee, West Virginia, North Carolina, and Maine" [1],[2],[3],[4].

References

[1] Centers for Disease Control and Prevention. https://www.cdc.gov/hai/pdfs/bbp/exp_to_blood.pdf. Updated July 2003. Accessed January 25, 2018.; Centers for Disease Control and Prevention.

https://www.cdc.gov/hepatitis/featuredtopics/youngpwid.htm. Accessed March 25, 2019.

- [2] Harris AM, Iqbal K, Schillie S, et al. Increases in acute hepatitis B virus infections—Kentucky, Tennessee, and West Virginia, 2006-2013. MMWR Morb Mortal Wkly Rep. 2016;65(3):47-50. doi:10.15585/mmwr.mm6503a2.
- [3] Maine Center for Disease Control and Prevention. Maine surveillance report 2018: acute hepatitis B. https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/publications/index.shtml#surveillance.
- [4] Hepatitis B, C on rise in N.C.; health officials encourage precautions, testing [press release]. Raleigh, NC: North Carolina Department of Health and Human Services; May 30, 2017. https://www.ncdhhs.gov/news/press-releases/hepatitis-b-c-rise-nc-health-officials-encourage-precautions-testing.

In alignment with language used by CDC, we also request that the Hepatitis Plan adopts the language "people who use drugs" or "people who inject drugs" as opposed to "people who misuse drugs."

Lastly, we wanted to note that on page 62, Table B.2, there is not a 2030 target specified for Disparities Indicator #10; however, on page 51, Table 5, it lists the 10-year target for this same indicator as 90. We ask that HHS add the 2030 target for this indicator on page 62.

Thank you again for this opportunity to provide feedback on the draft Viral Hepatitis National Strategic Plan for 2021-2025. We look forward to working with federal and community partners to continue the momentum toward eliminating viral hepatitis. Please do not hesitate to contact Chari Cohen, Hep B United co-chair (chari.cohen@hepb.org) or Kate Moraras, Director of Hep B United (kate.moraras@hepb.org), with any questions or to request additional information.

Sincerely,

Hep B United