

October 24, 2019

Tammy R. Beckham, DVM, PhD
Director, Office of Infectious Disease and HIV/AIDS Policy
Department of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

RE: Request for Information (RFI) from Non-Federal Stakeholders: Developing the 2020 National Vaccine Plan

Dear Dr. Beckham,

On behalf of Hep B United, we appreciate the opportunity to comment on OIDP's Request for Information (RFI) regarding the development of the 2020 National Vaccine Plan.

Hep B United is a national coalition of over 40 organizations in 21 states dedicated to reducing the health disparities associated with hepatitis B by increasing awareness, screening, vaccination, and linkage to care for high-risk communities across the United States. An estimated 2.2 million Americans are infected with chronic hepatitis B virus (HBV). Yet, only 25% of people are aware of their infection and less than 10 percent of infected individuals are able to access care and receive treatment. Living with chronic hepatitis B can lead to serious health complications; 1 in 4 people with unmanaged chronic hepatitis B will develop cirrhosis, liver cancer, or liver failure. Significant disparities are associated with hepatitis B. Asian American, Pacific Islander, and African communities are disproportionately affected by the epidemic, with these communities comprising up to 80% of all chronic hepatitis B infections in the U.S.

We appreciate HHS' inclusion of non-federal stakeholders in the process to update and strengthen our Nation's immunization infrastructure. We support a comprehensive national vaccine plan that implements vaccine strategies across the lifespan – strategies that are essential to the elimination of hepatitis B in the United States. We offer the following comments in response to the RFI areas 1, 3, 4, and 5.

1. Priorities for the 2020 National Vaccine Plan during 2020-2025. What do you recommend as the top priorities for vaccines and immunizations in the United States? Why are these priorities most important to you?

We recommend that the 2020 National Vaccine Plan prioritizes goals, objectives, and strategies that will result in increased coverage and utilization of adult immunizations. We feel there is an urgent need to focus on vaccine-preventable diseases with very low coverage rates among adults, such as hepatitis B. This is particularly important given the significant increases in acute hepatitis B infections tied to the opioid crisis and injection drug use in several states.

Increasing coverage and utilization of adult immunization is an essential strategy for preventing hepatitis B transmission in the U.S. The hepatitis B vaccine is safe and effective, providing lifelong protection from hepatitis B. It was the first anti-cancer vaccine to be developed and is projected to have prevented 310 million cases of hepatitis B worldwide by 2020. Significant progress has been made with childhood vaccination against hepatitis B in the U.S. since clinical guidelines recommended universal childhood vaccination starting in the 1990s. However, adult hepatitis B vaccination rates have remained low. Only 25% of adults age 19 and older are fully immunized against hepatitis B. Among health care personnel age 19 and older, only 65% are vaccinated for hepatitis B. Hepatitis B vaccine coverage is also low among people with diabetes, HIV-infected individuals, hepatitis C-infected individuals, and individuals with chronic liver disease and chronic kidney disease, who are all at significantly increased risk of hepatitis B infection without immunization. Hepatitis B vaccination is recommended for adults with diabetes, who make up approximately 12% of the U.S. population. For people already compromised by a chronic condition, an infection with hepatitis B can lead to more serious consequences.

Many barriers stand in the way of efforts to increase the low rate of adult hepatitis B vaccination rate in the U.S., including:

- Lack of awareness among the general public about hepatitis B (risk factors, modes of transmission, the link to cirrhosis, liver failure and/or liver cancer)
- Lack of awareness among providers; insufficient guidance from CDC to providers about hepatitis
 B screening and vaccination for adults

Additionally, although significant progress has been made towards achieving national infant and childhood immunization goals for hepatitis B, gaps and challenges still remain in ensuring that all newborns in the U.S. receive the birth dose and complete the vaccine series.

3. What are the goals, objectives, and strategies for each of your top priority areas? Are there any goals in the current strategy that should be discarded or revised? Which ones and why?

The top priority area we would like to see addressed in the 2020 National Vaccine Plan is increasing coverage and utilization of adult hepatitis B vaccination. To achieve this goal, we recommend focusing on the following objectives and strategies.

- 1) Increase education, demand and access to adult hepatitis B vaccination.
 - a. Provide resources to develop and implement national public information/awareness campaigns about the availability of adult hepatitis B vaccination and the importance of getting vaccinated to prevent hepatitis B infection and liver cancer.
 - b. Promote greater investment, coordination, and collaboration of resources and efforts related to hepatitis B vaccination across HHS for example, by including guidance in CDC funding opportunity announcements that encourages collaboration among state immunization and infectious disease prevention programs.
 - c. Partner with state, local, and tribal health departments, criminal justice programs, along with relevant patient and community stakeholder organizations to develop a plan that takes into account best practices and model strategies to increase hepatitis B immunization coverage among adults and reduce the number of hepatitis B cases.

- 2) Reduce provider barriers to offering immunizations and ensure that providers are actually administering ACIP-recommended vaccines for adults.
 - Update/clarify existing guidelines and recommendations for adult hepatitis B vaccination, taking into account the current challenges providers face in implementing complex, risk-based guidelines.
 - b. Improve provider reimbursement for administering adult hepatitis B vaccination.
- 3) Strengthen and support the dissemination and adoption of federal measures to encourage improved monitoring and reporting on immunization activities.
 - a. Utilize existing data sources/health surveys to measure and track hepatitis B immunization rates across the lifespan.
 - b. Incorporate hepatitis B vaccination goals across the lifespan within Healthy People 2030.
- 4. What indicators can be used to measure your top priorities and goals? Are there any indicators in the 2010 National Vaccine Plan or the National Adult Immunization Plan that should continue to be used? If so, which ones, and why?

The National Adult Immunization Plan currently includes an indicator to measure the percentage of health care personnel age 19 years and older who are vaccinated against hepatitis B. The baseline from 2008 was 64% and the 2020 milestone from the NAIP is 90%. We support maintaining this indicator.

However, in order to effectively and comprehensively measure progress of lifespan hepatitis B vaccine coverage and address the low rates of adult hepatitis B vaccination, we recommend adding the following indicators:

- Hepatitis B vaccination for *all adults* age 19 years and older. Data is available from the National Health Interview Survey. The baseline measure from 2016 is 24.8% coverage (≥3 doses).
- Hepatitis B birth dose coverage among infants. Data is available from the National Immunization Survey-Child. The baseline measure from 2017 is 73.6% birth dose coverage among infants.
- Hepatitis B vaccination among children age 19-35 months. Data is available from the National Immunization Survey-Child. The baseline measure from 2017 is 91.4% coverage (≥3 doses).

Elements of the 2020 National Vaccine Plan should also be in alignment with goals and objectives of other federal plans, including the National Viral Hepatitis Action Plan and the CDC National Viral Hepatitis Progress Report.

5. Identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the 2020 National Vaccine Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles that you or your organization might have in the 2020 National Vaccine Plan.

We believe federal and non-federal stakeholders all share responsibility in ensuring access to and increasing coverage of vaccines. Federal agencies, state and local governments, and non-federal/community partners (including health care provider organizations) have responsibility for enacting the objectives and strategies in the 2020 NVP. We would also emphasize that pharmacists and insurance payors are additional stakeholders who are important to engage in implementation of the

2020 NVP strategies. Pharmacists and payors play major roles in direct engagement with the public and reducing vaccine access barriers, particularly in relation to any efforts to increase reimbursement in the pharmacy setting.

As a community stakeholder, Hep B United can play a role in supporting goals and objectives related to increasing awareness and knowledge of routine vaccines, including the hepatitis B vaccine. As a community of organizations working with hard-to-reach, under-immunized populations, our coalition looks forward to providing feedback on cultural and linguistic approaches to health education, outreach, and development and dissemination of communications strategies (including around vaccine hesitancy).

Again, thank you for the opportunity to offer our comments and recommendations regarding the 2020 National Vaccine Plan. We look forward to working with OIDP and other federal and non-federal stakeholders to strengthen and enhance access to and utilization of immunizations across the lifespan. For additional information, please contact Kate Moraras, Director of Hep B United, at kate.moraras@hepb.org.

Sincerely,

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