Maryland
DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Meena Seshamani, M.D., Ph.D., Secretary

December 5, 2025

Dear Colleague:

We are writing to reaffirm our commitment to ensuring widespread access to vaccines in Maryland and to following evidence-based vaccination guidance, including to the extensive evidence that supports the safety and effectiveness of routine administration of hepatitis B vaccine to newborns and completing the full vaccination series in accordance with the American Academy of Pediatrics' Recommended Child and Adolescent Immunization Schedule.

As detailed in a statement by the Northeast Public Health Collaborative, of which Maryland is a member, hepatitis B is a viral infection that attacks the liver and can cause both acute and chronic disease, including cirrhosis, liver failure, liver cancer, and death.[1] Hepatitis B infection is particularly devastating to infants.[2] Of infants infected with the virus in the first year of life, 90% develop chronic hepatitis B.[3] One in four people infected with hepatitis B virus during childhood die from liver cirrhosis or liver cancer in later life.[4] This can be prevented by vaccination.

The hepatitis B vaccine has been tested extensively for safety and efficacy, and when administered within 24 hours of birth (birth dose), is highly effective in preventing newborn infection. Hepatitis B vaccine has a strong safety profile, with adverse effects that are typically mild and transient. According to post-licensure monitoring, the most frequently reported reactions include localized pain, erythema, or swelling at the injection site, as well as low-grade fever and fatigue, all of which generally resolve within 24–48 hours. Large meta-analyses and systematic reviews that include millions of children have consistently found no link between vaccines and autism.[5,6] Severe adverse reactions are estimated to occur at a rate of 1.1 per million doses, consistent with the overall rate of anaphylaxis to vaccines.[7] Among healthy infants, 25%, 63% and 95% achieve anti-HBs levels ≥10 mIU/mL after the first,

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[1] Offit P. Hepatitis B Vaccine. Chop.edu. Published 2020. https://www.chop.edu/vaccine-education-center/vaccine-details/hepatitis-b-vaccine

[2] Kimberlin D, Banarjee R, Barnett E, Lynfield R, Sawyer M,. Hepatitis B. In: Kimberlin D, Banarjee R, Barnett E, Sawyer M, Lynfield R, eds. *Red Book: 2024–2027 Report of the Committee on Infectious Diseases (33rd Edition)*. American Academy of Pediatrics; 2024:437-457.

[3] Dudley MZ, Halsey NA, Omer SB, et al. The state of vaccine safety science: systematic reviews of the evidence. *Lancet Infect Dis*. 2020;20(5):e80-e89. doi:10.1016/S1473-3099(20)30130-4

[4] Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No. RR-1):1–31. DOI: http://dx.doi.org/10.15585/mmwr.rr6701a1

[5] Dudley MZ, Halsey NA, Omer SB, et al. The state of vaccine safety science: systematic reviews of the evidence. *Lancet Infect Dis*. 2020;20(5):e80-e89. doi:10.1016/S1473-3099(20)30130-4

[6] Taylor LE, Swerdfeger AL, Eslick GD. Vaccines are not associated with autism: an evidence-based meta-analysis of case-control and cohort studies. Vaccine. 2014 Jun 17;32(29):3623-9. doi: 10.1016/j.vaccine.2014.04.085.

[7] Centers for Disease Control and Prevention. *The Epidemiology and Prevention of Vaccine-Preventable Diseases (The Pink Book)*. 14th ed. 2021. https://www.cdc.gov/pinkbook/hcp/table-of-contents/index.html

second and third dose, respectively.[4] The persistence of protection when stopping the series after one or two doses has not been established.[8]

Risk-based vaccination strategies (e.g., vaccinating only babies born to parents known to have hepatitis B) have historically been insufficient to prevent perinatal and early childhood transmission.[9] A 2023 study estimated that 12 –16% of pregnant people do not receive the recommended hepatitis B screening, illustrating the potential gaps in a risk-based based approach[10] and other recent studies have suggested up to 18% of pregnant people do not receive the recommended hepatitis B screening.[11] Since 1991, the year the Centers for Disease Control and Prevention and the American Academy of Pediatrics recommended universal hepatitis B vaccination for newborns, hepatitis B infections in children and teens have decreased by 99%.[12]

A universal birth dose of hepatitis B vaccine:

- Prevents mother-to-infant transmission in 70-90% of cases
- Prevents household transmission between family members and other caregivers
- Provides a safety net to prevent perinatal transmission when infection occurs after testing, or errors, such as misinterpreted laboratory test results, errors in documentation, or false-negative test results, occur.

Therefore, MDH continues to make the following recommendations to Maryland health care providers:

- **All newborns should receive a hepatitis B vaccine birth dose.**
- **Newborns born to birth parents who test positive for hepatitis B infection or have an unknown status should be vaccinated and given hepatitis B immunoglobulin within 12 hours of birth.**
- **All children should complete the full vaccination series within 18 months.**
- **Children who are not fully vaccinated by 18 months should follow the AAP's age appropriate catch up schedule.**

These recommendations align with the American Academy of Pediatrics' Recommended Child and Adolescent Immunization Schedule. They also correspond to recently published research that showed that the birth dose functions as a critical safety net to the more than 17,000 infants born each year to women infected with hepatitis B virus, with up to 18% of the pregnant women failing to receive hepatitis B testing, and 35% lacking all recommended follow-up care. Delaying the birth dose of hepatitis B vaccination misses a crucial period of potential exposure, putting infants at risk.[11]

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[8] Conners E, et al.Screening and Testing for Hepatitis B Virus Infection: CDC Recommendations — United States, 2023 https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm?s_cid=rr7201a1_w

[9] Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination, 1991.

[10] Pham TTH, Maria N, Cheng V, et al. Gaps in Prenatal Hepatitis B Screening and Management of HBsAg Positive Pregnant Persons in the U.S., 2015-2020. *Am J Prev Med*. 2023;65(1):52-59. doi:10.1016/j.amepre.2023.01.041

[11] Universal Hepatitis B Vaccination at Birth. Center for Infectious Disease Research and policy, University of Minnesota, published December 2, 2025. Universal Hepatitis B Vaccination at Birth December 2, 2025

[12] Why Hepatitis B Vaccination Begins at Birth | Johns Hopkins Bloomberg School of Public Health. Johns Hopkins Bloomberg School of Public Health. Published September 24, 2025. https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth

In order to help ensure that access to the hepatitis B vaccine for infants and children aligns with this evidence-based guidance, MDH has issued a statewide hepatitis B vaccination standing order today, December 5, 2025, that authorizes qualified health care professionals to administer the hepatitis B vaccine series using the most current evidence-based guidelines endorsed by the American Academy of Pediatrics as standards, and exercising reasonable clinical judgement in vaccinating their patients. **(Standing Order attached.)**

We also want to provide information and resources regarding Shared Clinical Decision Making (SCDM) (also called "Individual Decision Making"), which involves a documented discussion between the health care provider and patient or parent/guardian about the benefits and risks of vaccination. As you know, clinicians already routinely discuss the risks and benefits of vaccines with all patients. A health care provider for SCDM includes physicians, physician assistants, nurse practitioners, registered nurses, and pharmacists. For more information, please refer to the Common Health Coalition vaccine resources webpage and an AAP news article on Shared Clinical Decision Making.

The actions taken by ACIP today should not impact insurance coverage of any hepatitis B vaccine dose in Maryland.

MDH will update you via these clinician letters with any changes or updates to this guidance. For VFC providers, we will be sharing additional information when it is available. We remain committed to widespread access to vaccinations and to evidence-based vaccination guidance, developed by medical associations such as the American Academy of Pediatrics, the American Academy of Family Physicians and the American College of Obstetricians and Gynecologists.

For questions about these recommendations, please contact MDH's Infectious Disease Epidemiology and Outbreak Response Bureau (IDEORB) at 410-767-6700, or your local health department.

Thank you,

Meg Sullivan, MD, MPH
Deputy Secretary, Public Health Service

Lucia Donatelli, MD, FAAP
Chief, Center for Immunizations

Attachments: MDH Standing Order Hepatitis B Vaccines for Children