

November 20, 2025

Submitted electronically via regulations.gov

ACIP Secretariat, Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention
1600 Clifton Road NE, Mailstop H21-12
Atlanta, Georgia 30329-4027

RE: APHA and Public Health Deans and Scholars' Comments on the Centers for Disease Control and Prevention Notice announcing the meeting of the Advisory Committee on Immunization Practices (Docket ID: CDC-2025-0783-0001)

Dear Gentlepersons:

We appreciate the opportunity to submit these comments pursuant to FR Notice CDC-2025-0783-0001 (90 Fed. Reg. 50944, November 13, 2025), which announces a meeting of the Advisory Committee on Immunization Practices (ACIP), to be held on December 4, 2025.

Our comments focus on ACIP's potential vote to revise its recommendation regarding administration of vaccine to protect infants and children against the hepatitis B virus (HBV). In considering this question, ACIP is carrying out its duties under law, and as such, must necessarily rely on its long-established scientific review process. This process has been designed to ensure that all recommendations rest on sound scientific evidence, with full consideration of risks and benefits.

ACIP's recommendations play a seminal role in public health and health care policy and practice, spanning virtually the entire health care system. The recommendations inform the general schedule that guides "dosing interval, dosage, and contraindications" in preventive health care practice. Their recommendations define the reach and scope of the Vaccines for Children program, which covers over half of all U.S. children;¹ the coverage standards that guide Medicare, Medicaid, the Children's Health Insurance Program (CHIP); Section 2713 of the Public Health Service Act, which established coverage of immunizations without patient cost-sharing under nearly all private insurance plans including both state-regulated plans and employer plans governed by the Employee Retirement Income Security Act (ERISA); and other health plans of high importance including plans covering federal employees and plans used in military health system.

No population group is more affected by ACIP's recommendations than infants and children.

These comments are submitted on behalf of 73 public health and health policy Deans and scholars and the American Public Health Association (APHA). The individual commenters

¹ Valier MR, Yankey D, Elam-Evans LD, et al. *Vital Signs: Trends and Disparities in Childhood Vaccination Coverage by Vaccines for Children Program Eligibility* — National Immunization Survey-Child, United States, 2012–2022. *MMWR Morb Mortal Wkly Rep* 2024;73:722-730. DOI: <http://dx.doi.org/10.15585/mmwr.mm7333e1>

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possess extensive expertise in public health and health care policy and practice, including adherence to health care strategies that promote child health and reduce the risk of preventable illness, disability and death. These individuals write solely in their individual capacities and not as representatives of their institutions.

APHA is a non-partisan, non-profit organization that champions the health of all people and all communities; strengthens the profession of public health; shares the latest research and information; promotes best practices; and advocates for public health issues and policies grounded in scientific research. APHA represents more than 23,000 individual members and has 52 state and regional affiliates. APHA's membership also includes organizational members, including groups interested in health, state and local health departments, and health-related businesses. APHA is the only organization that combines a 150-year perspective, a broad-based member community, and the ability to influence federal policy to improve the public's health.

Based on extensive evidence, commenters believe that ACIP should maintain the current recommended HBV vaccination schedule, which begins with a routine dose at the time of birth, because of the high level of protection it confers, the absence of evidence suggesting efficacy or safety concerns, and the risks of delaying infant immunization. Our conclusion rests on the scientific record following one of the most important child health policy achievements in recent decades: the near elimination of HBV in infants and children through the introduction of universal immunization at birth. This achievement is the direct consequence of the ACIP's watershed 1991 decision to recommend ² universal newborn administration of the initial dose of HBV vaccine. This recommendation, and the results that followed, have become a core element of U.S. childhood immunization policy.³

Extensive research underscores the success of the current HBV immunization protocol, which begins with a universal birth dose, in eliminating chronic infection among children.⁴ The existing evidence of vaccine safety and efficacy continues uninterrupted as a standard element of the childhood immunization schedule.⁵ Given the absence of new information raising efficacy or

² Bixler D, Roberts H, Panagiotakopoulos L, Nelson NP, Spradling PR, Teshale EH. Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019. *Public Health Reports*®. 2023;0(0). doi:[10.1177/00333549231175548](https://doi.org/10.1177/00333549231175548); U.S. Centers for Disease Control and Prevention, Hepatitis B Birth Dose Vaccination, CDC Advisory Committee for Immunization Practices Meeting, September 18, 2025, <https://www.cdc.gov/acip/downloads/slides-2025-09-18-19/02-langer-hep-b-508.pdf>

³ Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). CDC. *MMWR Morb Mortal Wkly Rep*. 1991;40(RR-13);1-19. Accessed November 17, 2025. <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

⁴ Universal Infant Vaccine Birth Dose Saves Thousands of Lives: A response from the Hepatitis B Foundation. Hepatitis B Foundation. Published June 25, 2025. Accessed November 17, 2025. <https://www.hepb.org/news-and-events/news-2/universal-infant-vaccine-birth-dose-saves-thousands-of-lives-a-response-from-the-hepatitis-b-foundation/>

⁵ Rosen A. Hepatitis B Vaccination is an Essential Safety Net for Newborns. Johns Hopkins University Bloomberg School of Public Health. Published September 24, 2025. Accessed November 17, 2025.

safety concerns⁶ and the serious health risks that would likely flow from such a delay, the current universal birth dose policy should be maintained.

Hepatitis B Virus (HBV)

CDC's June 2025 communication to the public⁷ explains that HBV infection can lead to chronic disease culminating in liver failure, liver cancer, and death. CDC further reports that most cases of chronic disease arising from HBV infection stem from infections acquired in infancy or early childhood. According to CDC, prevention requires administration of "at least three" doses of the HBV vaccine, beginning with "the first dose (known as a "birth dose") [that] should be given to babies within 24 hours of birth."

The 1991 establishment of a universal "birth dose" HBV vaccination policy

The birth dose policy, coming within a decade of the commercial availability of the HBV vaccine in the U.S.,⁸ was a centerpiece of ACIP's landmark 1991 recommendation, "Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)".⁹ The Committee specifically adopted this recommendation in response to evidence of a major increase in the incidence of acute HBV throughout the 1970s and 1980s. Between 1979 and 1989, the reported incidence of acute infection increased by 37%, with approximately 200,000-300,000 reported annual infections from 1980 to 1991.¹⁰

Furthermore, the Committee determined that HBV infection carried especially severe risks in infants and young children. The Committee found that, despite the advent of testing during pregnancy, identification of infection in advance of delivery was unreliable; furthermore, newborn infants returning home could be infected by other household members living with undiagnosed disease. The Committee explicitly recognized the life-threatening consequences of perinatal transmission. Infants and young children under age five living with HBV-infection are typically

<https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth#:~:text=An%20infant%20infected%20with%20hepatitis,lasts%20at%20least%2030%20years%20>

⁶ Su J. A Review of the Safety of Hepatitis B Birth Dose Vaccination. CDC. September 18, 2025.

Accessed November 17, 2025. <https://www.cdc.gov/acip/downloads/slides-2025-09-18-19/02-su-hep-b-508.pdf>

⁷ About Global Hepatitis B Vaccination in Children. CDC. Published June 30, 2025. Accessed November 17, 2025.

⁸ Hepatitis B Foundation. Accessed November 17, 2025. <https://www.hepb.org/>

⁹ Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). CDC. *MMWR Morb Mortal Wkly Rep*. 1991;40(RR-13);1-19. Accessed November 17, 2025.

<https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

¹⁰ *Id.*

asymptomatic,¹¹ but those infected during the perinatal period have a 90 percent risk of developing chronic hepatitis B (CHB), which substantially increases the risk of cirrhosis and liver cancer; within this group, twenty-five percent will die of chronic liver disease as adults.

In 1982, following the commercial availability of the HBV vaccine,¹² ACIP recommended pre-exposure immunization for high-risk groups. By 1989, however, it had become evident that this policy had failed, since vaccination rates remained low.¹³ The risk of perinatal HBV infection among infants born to infected mothers was great, ranging from 10 percent to 85 percent, depending on the mother's hepatitis B antigen (HBsAg) status.¹⁴ However, selective screening for HBsAg during pregnancy missed a significant proportion of hepatitis B-positive cases.¹⁵ Improper and insufficient maternal screening continued to be a problem, as did non-perinatal, environmental exposures to HBV following birth.¹⁶

In the face of this evidence, the Committee elected to move away from its previous recommendation of "selective vaccination of persons with identified risk factors." It did so based on its conclusion that:

[T]his strategy has not lowered the incidence of hepatitis B, primarily because vaccinating persons engaged in high-risk behaviors, life-styles, or occupations before they become infected generally has not been feasible. In addition, many infected persons have no identifiable source for their infections and thus cannot be targeted for vaccination.¹⁷

The core of its 1991 recommendation for children thus became routine HBV vaccination beginning with a universal birth dose. This recommendation was bolstered, in the Committee's view, by the proven safety and efficacy of the vaccine and the serious consequences of infection in infants.

Over the decades, ACIP has clarified and strengthened its policy. In 2005, ACIP recommended all medically stable newborns weighing more than 4.4 pounds receive their first dose of HBV

¹¹ Clinical Overview of Perinatal Hepatitis B. CDC. Published September 18, 2025. Accessed November 17, 2025. <https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/index.html>

¹² Hepatitis B Foundation. Accessed November 17, 2025. <https://www.hepb.org/>

¹³ Achievements in Public Health: Hepatitis B Vaccination --- United States, 1982—2002. CDC. *MMWR Morb Mortal Wkly Rep*. 2002;51(25):549-552,563. Accessed November 17, 2025. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5125a3.htm>

¹⁴ Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP). CDC. *MMWR Morb Mortal Wkly Rep*. 1991;40(RR-13):1-19. Accessed November 17, 2025. <https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>

¹⁵ *Id.*

¹⁶ 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>

¹⁷ *Id.*

vaccine before hospital discharge¹⁸ In 2018, ACIP reiterated its recommendation of universal infant HBV vaccination within 24 hours of birth¹⁹

The universal birth dose recommendation has had a significant, positive impact on health

The impact of this policy shift can be seen in both immunization rates and health outcomes. Between 1993 and 2000, HBV immunization rates among children aged 19 to 35 months rose from 16 percent to 90 percent; dramatic gains also were seen among children aged 13 to 15 years, rising from near zero to 67 percent as HBV immunization became a standard part of the CDC pediatric schedule.²⁰

The health impact has been profound; scientific estimates show that since the 1991 recommendation took effect, the universal HBV birth dose has prevented over 500,000 childhood infections and prevented an estimated 90,100 childhood deaths.²¹ Furthermore, vaccination at birth, regardless of risk/perinatal exposure, protects infants from contracting hepatitis B later in life if they fail to achieve full vaccination status.²² Between 1991 and 2019, HBV infection among children and adolescents dropped 99%, preventing cases of cirrhosis, liver cancer, and death.²³ The evidence shows that now the annual rate of infection is extremely low: fewer than 1,000 US children and adolescents become infected,²⁴ and fewer than 20 infants are infected at birth.²⁵ Between 2021 and 2022, the U.S. reported only 17 and 13 cases of perinatal hepatitis B, respectively.²⁶

¹⁸ Newborn Hepatitis B Vaccination Coverage Among Children Born January 2003--June 2005 --- United States. CDC. *MMWR Morb Mortal Wkly Rep.* 2008;57(30):825-828. Accessed November 17, 2025. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5730a3.htm#:~:text=Hepatitis%20B%20vaccine%20was%20first,the%20first%20days%20of%20life>

¹⁹ Bixler D, Roberts H, Panagiotakopoulos L, Nelson NP, Spradling PR, Teshale EH. Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019. *Public Health Reports®.* 2023;0(0). doi:10.1177/00333549231175548, <https://pubmed.ncbi.nlm.nih.gov/37300309/>

²⁰ Achievements in Public Health: Hepatitis B Vaccination --- United States, 1982—2002. CDC. *MMWR Morb Mortal Wkly Rep.* 2002;51(25):549-552,563. Accessed November 17, 2025. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5125a3.htm>

²¹ Why We Give Hepatitis B Vaccines to Infants. National Foundation for Infectious Diseases. Published October 20, 2025. Accessed November 17, 2025. <https://www.nfid.org/why-we-give-hepatitis-b-vaccines-to-infants/>

²² *Id.*

²³ Bixler D, Roberts H, Panagiotakopoulos L, Nelson NP, Spradling PR, Teshale EH. Progress and Unfinished Business: Hepatitis B in the United States, 1980-2019. *Public Health Reports®.* 2023;0(0). doi:10.1177/00333549231175548

²⁴ Hepatitis B Surveillance. CDC. Published April 4, 2024. Accessed November 17, 2025. <https://www.cdc.gov/hepatitis-surveillance-2022/hepatitis-b/index.html#toc>.

²⁵ National Profile of Viral Hepatitis. CDC. Published September 30, 2024. Accessed November 17, 2025. <https://www.cdc.gov/hepatitis-surveillance-2022/about/national-profile.html#>

²⁶ Fact Checked: Hepatitis B Vaccine Given to Newborns Reduces Risk of Chronic Infection. American Academy of Pediatrics. Updated June 25, 2025. Accessed November 17, 2025.

Following completion of the dose series, 98 percent of healthy infants achieve full immunity lasting at least 30 years.²⁷ The birth dose reduces the risk of liver cancer by 84 percent and liver disease-caused death by 70 percent.²⁸ Between the 1988-1994 period and the 1999-2006 period, HBV infection prevalence decreased significantly (from 1.9 percent to 0.6 percent) among children ages 6 to 19 years, as vaccination became widespread.²⁹ Special population studies showed dramatic effects: In 1994, hepatitis B infection in Alaska Native children under age 10 was zero, compared to 16 percent among Alaska Natives ages 11 to 30 years.³⁰

The vaccine has proven to be not only highly effective but safe; the HBV vaccine birth dose has had no statistically significant adverse impact on infant and child health. Extensive surveillance monitoring over decades has shown that HBV does not increase the risk of infant death³¹, fever or sepsis,³² multiple sclerosis,³³ autoimmune thyroid disease,³⁴ allergic reactions, all-cause mortality, deaths resulting from sudden infant death syndrome, or seizures/neurologic disease.³⁵

<https://www.aap.org/en/news-room/fact-checked/fact-checked-hepatitis-b-vaccine-given-to-newborns-reduces-risk-of-chronic-infection/?srltid=AfmBOorncwMD63JIKSZ-14gS8zNQTBa0BTih4HVsakk34Ly94O4juUx2>

²⁷ Rosen A. Hepatitis B Vaccination is an Essential Safety Net for Newborns. Johns Hopkins Bloomberg School of Public Health. Published September 24, 2025. Accessed November 17, 2025.

<https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth#:~:text=In%201991%2C%20the%20Advisory%20Committee,%E2%80%93%20dropped%20by%2068%25%20>

²⁸ Qu C, Chen T, Fan C, et al. Efficacy of neonatal HBV vaccination on liver cancer and other liver diseases over 30-year follow-up of the Qidong hepatitis B intervention study: a cluster randomized controlled trial. *PLoS Med*. 2014;11(12):e1001774. Published 2014 Dec 30. doi:10.1371/journal.pmed.1001774

²⁹ Wasley A, Kruszon-Moran D, Kuhnert W, et al. The prevalence of hepatitis B virus infection in the United States in the era of vaccination. *J Infect Dis*. 2010;202(2):192-201. doi:10.1086/653622

³⁰ Achievements in Public Health: Hepatitis B Vaccination --- United States, 1982—2002. CDC. *MMWR Morb Mortal Wkly Rep*. 2002;51(25):549-552,563. Accessed November 17, 2025.

<https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5125a3.htm>

³¹ Eriksen EM, Perlman JA, Miller A, et al. Lack of Association Between Hepatitis B Birth Immunization and Neonatal Death: A Population-Based Study From the Vaccine Safety Datalink Project. *The Pediatric Infectious Disease Journal*. 2004;23(7).

https://journals.lww.com/pidj/fulltext/2004/07000/lack_of_association_between_hepatitis_b_birth.12.aspx

³² Lewis E, Shinefield HR, Woodruff BA, et al. Safety of neonatal hepatitis B vaccine administration. *The Pediatric Infectious Disease Journal*. 2001;20(11).

https://journals.lww.com/pidj/fulltext/2001/11000/safety_of_neonatal_hepatitis_b_vaccine.9.aspx

³³ Mikaeloff Y, Caridade G, Rossier M, Suissa S, Tardieu M. Hepatitis B Vaccination and the Risk of Childhood-Onset Multiple Sclerosis. *Archives of Pediatrics & Adolescent Medicine*. 2007;161(12):1176-1182. doi:10.1001/archpedi.161.12.1176

³⁴ Yu O, Bohlke K, Hanson CA, et al. Hepatitis B vaccine and risk of autoimmune thyroid disease: a Vaccine Safety Datalink study. *Pharmacoepidemiol Drug Saf*. 2007;16(7):736-745. doi:10.1002/pds.1354.

³⁵ Su J. A Review of the Safety of Hepatitis B Birth Dose Vaccination. CDC. September 18, 2025. Accessed November 17, 2025. <https://www.cdc.gov/acip/downloads/slides-2025-09-18-19/02-su-hep-b-508.pdf>

Withdrawing the recommendation of a universal HBV birth dose vaccination carries significant adverse child health risks

In September 2025, the Committee considered, but then tabled, a change in HBV immunization policy that would eliminate the birth dose for infants born to mothers who tested negative for the virus and delay initial vaccination by at least one month. This proposal may again be considered during the December 4th meeting.

The record appears devoid of evidence suggesting a change in the safety and efficacy record in connection with a birth dose of HBV vaccine. Therefore, the issue becomes what risks are associated with moving away from this longstanding policy, one embraced by health care professionals.³⁶ Indeed, there appears to be no indication that health care providers have reported difficulties or complications in administering the birth dose, nor does there appear to be evidence that administering the birth dose has complicated the birth delivery process itself. In other words, the practice of HBV birth dose is routine.

Of course, parents have the option to refuse the vaccine at birth and to delay vaccination until a later point in infancy. But there is evidence to suggest that parental rejection of the HBV birth dose is substantially lower than the refusal rate for other childhood vaccines, suggesting widespread acceptance of optimizing protection against a deadly disease.³⁷

The risks of ending the birth dose and delaying the initial dose would be significant for children given HBV's highly infectious nature. For example, in Florida, where population HBV infection rates are surging, with a reported ten-fold increase in cases,³⁸ eliminating the universal birth dose carries significant risks.

Substantial evidence shows the ease with which doctors and pregnant women can miss diagnosing infections. For example, the CDC recommends that pregnant women be tested for hepatitis B at the first prenatal visit.³⁹ An early testing regimen is important to detect the presence of the virus. But it also means that mothers infected later in pregnancy -- for example, as a result

³⁶ Hubbard K. Sen. Cassidy says he's "very concerned" about possible hepatitis B vaccine schedule change. CBS News. Updated November 16, 2025. Accessed November 17, 2025.

<https://www.cbsnews.com/news/bill-cassidy-hepatitis-b-vaccine-schedule-change/>

³⁷ Yang YT, Leslie TF, Delamater PL. Hepatitis B Vaccine Refusal Trends in Washington, DC, Newborns, 2017-2022. *JAMA Network Open*. 2024;7(7):e2421202-e2421202. doi:10.1001/jamanetworkopen.2024.21202

³⁸ Schmidt L. As Hepatitis B Cases Soar in Florida, Childhood Vaccination Will Soon Be Optional. Hep. Published September 15, 2025. Accessed November 17, 2025. <https://www.hepmag.com/article/hepatitis-b-cases-soar-florida-childhood-vaccination-will-soon-optional>.

³⁹ Clinical Overview of Perinatal Hepatitis B. CDC. Published September 18, 2025. Accessed November 17, 2025. <https://www.cdc.gov/hepatitis-b/hcp/perinatal-provider-overview/index.html>

of exposure to infected persons at home or through work (especially in the case of health care and public health professionals) -- may go undetected.

Furthermore, delaying the first dose until a mother and infant return home unnecessarily exposes the infant to risks in the home and community environment from infection among household members that remains undetected. With evidence such as that emerging in Florida, where infection rates have increased exponentially, infants at home would face a high level of community risk. Growing HBV infection rates underscore the high value of the birth dose, which begins to build a shield against infection immediately at birth.

An additional risk arises from the fact that the U.S. health care system is notoriously fragmented and lacks a universal, uniform system for making essential health information available. Of the 3.5 million births that occur annually, about 1.5% take place in emergency departments as unplanned births. This is not a small number of births – it exceeds 50,000 annually. The urgency and confusion inherent in an emergency department birth should be a matter of high concern. Emergency personnel are likely to lack complete information on maternal health risks, including their hepatitis B status. Universal birth vaccination becomes an essential protection under such circumstances.

Eliminating the HBV birth dose would affect infants and children across the economic landscape. But the poorest infants and families who depend on Medicaid and the VFC program likely would face the greatest risks. Government reports show that the quality of maternity care for low-income mothers insured through Medicaid remains elusive.⁴⁰ Compared to their higher income, privately-insured counterparts, women who rely on Medicaid experience higher rates of preterm births (necessitating emergency hospital deliveries in many cases) and a lower rate of access to early prenatal care. The quality of care that women do receive has been shown to be significantly less comprehensive than care available to women with higher family incomes, because the providers available to them, no matter how capable, are simply overwhelmed by a demand for care that exceeds the capacity of a health care system struggling to operate in health care deserts. Under these circumstances, it is essential to maximize the preventive steps that can be taken when facing health risks this substantial.

For these reasons, we urge no change in the current approach to HBV vaccination in children, beginning with a universal birth dose. Thank you for your consideration of our comments. If you need any additional information, please contact MaryBeth Musumeci at marybethm@gwu.edu.

⁴⁰ Access in Brief: Pregnant Women and Medicaid. MACPAC. Published November 2018. Accessed November 17, 2025. <https://www.macpac.gov/wp-content/uploads/2018/11/Pregnant-Women-and-Medicaid.pdf>

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B. Public Health Deans

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RE: APHA and Public Health Deans and Scholars' Comments on the Centers for Disease Control and Prevention Notice announcing the meeting of the Advisory Committee on Immunization Practices

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