

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

Maryland Department of Health Hepatitis B Vaccine Standing Order Children 0-18 years Old

Effective Date: December 5, 2025

Purpose: To reduce morbidity and mortality from hepatitis B infection among infants and children, this Maryland Department of Health statewide Standing Order hereby authorizes health care professionals qualified to administer vaccinations under the Health Occupations Article, to administer hepatitis B vaccine and outlines the policies and procedures necessary for administering the hepatitis B vaccine to infants and children who meet the criteria established by the Maryland Department of Health, as supported by evidence-based guidance from the American Academy of Pediatrics (AAP).

Authority: The Maryland Department of Health is the lead agency responsible for protecting the health interests of the people of Maryland and in accordance with Health-General Articles §§ 2-105(b) and 18-102, the Secretary is authorized to issue this Standing Order to act properly in controlling the spread of an infectious and contagious disease that affects the public health of Marylanders. This standing order authorizes health care providers to administer hepatitis B vaccine to newborns and children, consistent with applicable law and the terms and conditions below. For pharmacists only, this Standing Order authorizes hepatitis B vaccinations for children aged 7 to 18 years old in accordance with Health Occ. Article, § 12-508(a).

Scope of Standing Order: This Standing Order applies only to those providers already licensed and qualified to administer vaccinations by the appropriate health occupation board. In accordance with this Standing Order, Maryland health care providers should adhere to the most current evidence-based guidelines developed by the AAP as standards, and exercise reasonable clinical judgment in vaccinating their patients as set forth below.

Procedure:

- 1. <u>Assess the individual for hepatitis B vaccination</u> consistent with reasonable clinical judgment and using the following evidence-based guidance:
 - Pediatrics (ages birth –18 years): American Academy of Pediatrics (AAP) hepatitis B vaccine guidance at www.AAP.org/ImmunizationSchedule
- 2. Screen the individual for the contraindications and precautions for hepatitis B vaccination:
 - Contraindications for hepatitis B vaccination:
 - Severe allergic reaction (eg, anaphylaxis) after a previous dose or to a vaccine component including yeast

- Precautions for hepatitis B vaccination:
 - Moderate to severe acute illness, with or without fever.

3. Obtain informed consent and provide the appropriate Vaccine Information Statements (VIS):

- Provide the individual qualified to give consent for that patient's vaccination with a copy of the most current federal vaccine information statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired.
 - Current Hepatitis B Vaccine VIS: https://www.cdc.gov/vaccines/hcp/current-vis/downloads/hep-b.pdf

4. Prepare to administer the vaccine:

- Verify that the label on the vaccine states hepatitis B vaccine.
- Choose the needle gauge, needle length, and injection site appropriate for the patient.

5. Administer hepatitis B vaccine products according to guidance below:

Routine hepatitis B vaccination is a <u>3-dose series at age 0 (at birth), 1-2 months</u>, and <u>6-18 months</u>. Administration of 4 doses is permitted when a combination vaccine containing Hep B is used after the birth dose.

For birth dose:

- Birth weight <2000 grams: 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2000 grams)
- For Birth weight ≥2000 grams: 1 dose within 24 hours of birth if medically stable

Infants who did not receive a birth dose should begin the series as soon as possible (with minimal intervals between doses in accordance with <u>AAP guidance</u>.).

Children who did not receive the routine hepatitis B vaccine series should be vaccinated in accordance with the <u>AAP's catch up schedule guidance</u> as per current practice guidelines.

Hepatitis B vaccine products (and dosage) approved for <u>birth dose</u> (use <u>monovalent hepatitis B</u> <u>vaccine only for birth to 6 weeks old):</u>

A	Age (per product package insert)	Hepatitis B Vaccine Product	Dosage	Package Insert
	0-6 weeks old (monovalent)	ENGERIX-B (0.5 mL prefilled syringes)	0.5 mL/10 μg	Engerix-B
	0-6 weeks old (monovalent)	RECOMBIVAX HB (pediatric formulation)	0.5 mL/5 μg	Recombivax HB

Hepatitis B vaccine products (and dosage) approved for children 6 weeks old and older:

Age (per product package insert)	Hepatitis B Vaccine Product	Dosage	Package Insert
0 years old through 19 years (monovalent)	ENGERIX-B (0.5 mL prefilled syringes)	0.5 mL/10 μg	Engerix-B
11 through 19 years old (for booster dose or alternate schedule per package insert)	ENGERIX-B (1 mL single dose vials or prefilled syringes)	1.0 mL/20 μg	Engerix-B
0 years old through 19 years (monovalent)	RECOMBIVAX HB (pediatric formulation)	0.5 mL/5 μg	Recombivax HB
11 through 15 years (for adolescents receiving a 2-dose rather than 3-dose series)	RECOMBIVAX HB (pediatric formulation)	1.0 mL/10 μg	Recombivax HB
6 weeks old through age 6 years (combination)	PEDIARIX (Diphtheria/tetanus/per- tussis/hep B/polio)	0.5 mL	<u>Pediarix</u>
6 weeks old through age 4 years (combination)	VAXELIS (Diphtheria/tetanus/per- tussis/hep B/polio/Hib)	0.5 mL	<u>Vaxelis</u>
18 years old and older	HEPLISAV-B (monovalent)	0.5 mL	<u>Heplisav-B</u>

6. <u>Document the vaccination</u> in the following places:

- Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient.
- ImmuNet (the Maryland immunization immunization system): Ensure that the vaccination is recorded in ImmuNet, in accordance with Health-General §18-109 and COMAR 10.06.03.

7. Be prepared to manage medical emergencies:

 Vaccinators should know how to recognize and respond to vaccine reactions, including anaphylaxis. Have a plan and supplies ready to provide appropriate medical care if an event occurs. At a minimum, plans used under this standing order should include the elements included in Immunize.org's "Medical Management of Vaccine Reactions" plans for adults and children, or teens.

- i. For Immunize.org's "Medical Management of Vaccine Reactions in Children and Teens in a Community Setting," go to www.immunize.org/catg.d/p3082a.pdf.
- ii. For Immunize.org's "Medical Management of Vaccine Reactions in Adults in a Community Setting," go to www.immunize.org/catg.d/p3082.pdf.
- 8. Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).

Expiration: This policy and procedure is effective December 05, 2025 and shall remain in effect until withdrawn by the Maryland Department of Health Secretary, or on December 04, 2026, whichever comes first. The Maryland Department of Health retains the right to modify, rescind or supplement this order as needed.

Signature:

Meg Sullivan, MD, MPH

Deputy Secretary, Public Health Services Administration

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