No change from the previous order.

**Abbreviations:** anti-HBc = antibody to hepatitis B core antigen; anti-HBs = antibody to hepatitis B surface antigen; HBsAg = hepatitis B surface antigen; HBV DNA = hepatitis B virus deoxyribonucleic acid; IgM = immunoglobulin class M.

### I. OREGON IMMUNIZATION MODEL STANDING ORDER:

1. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.
2. Screen clients for contraindications.
3. Provide a current Vaccine Information Statement (VIS) to parent or legal guardian, and answer any questions.
4. Record all required data elements in the client’s permanent health record.
5. Give hepatitis B vaccine. See section II Table 1. for schedules
II. Table 1. VACCINE SCHEDULE:

<table>
<thead>
<tr>
<th>Dose number (0.5 mL, intramuscularly in the vastus lateralis)</th>
<th>Babies Born to HBsAg-POSITIVE or Unknown Moms</th>
<th>Babies Born to HBsAg-NEGATIVE Moms</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum age</td>
<td>HBIG</td>
</tr>
<tr>
<td>1</td>
<td>Birth (0–12 hours)</td>
<td>Birth (0–12 hours)</td>
</tr>
<tr>
<td>2</td>
<td>4 weeks</td>
<td>4 weeks after birth dose #1</td>
</tr>
<tr>
<td>3</td>
<td>8–12 weeks</td>
<td>4 weeks after dose #2</td>
</tr>
<tr>
<td>4</td>
<td>6 months</td>
<td>8 weeks after dose #3 and 16 weeks after dose #1; no earlier than age 24 weeks</td>
</tr>
</tbody>
</table>

**Note:** Babies born to HBsAg-positive mothers need to have post-vaccine serology for HBsAg and Hepatitis B surface antibody (anti-HBs) drawn 1 to 2 months after completing the 3-dose vaccine series, but not before 9 months of age.
III. Table 2. LICENSED VACCINES

<table>
<thead>
<tr>
<th>PRODUCT NAME</th>
<th>VACCINE COMPONENTS</th>
<th>ACCEPTABLE AGE RANGE</th>
<th>LATEX</th>
<th>THIMEROSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recombivax HB&lt;sup&gt;®1&lt;/sup&gt;</td>
<td>Hepatitis B</td>
<td>Birth through Adult</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Engerix-B&lt;sup&gt;®2&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

IV. A. Table 3. RECOMMENDATIONS FOR USE BASED ON MOTHER’S STATUS

<table>
<thead>
<tr>
<th>Infant Birth Weight</th>
<th>Maternal Hepatitis B Status</th>
<th>Recommendation&lt;sup&gt;3&lt;/sup&gt;</th>
</tr>
</thead>
</table>
| <2000 g             | Positive*                  | • Administer HBIG and single-antigen hepatitis B vaccine at separate sites within 12 hours of birth.  
|                     |                            | • Do not count the birth dose as part of the vaccine series.  
|                     |                            | • Administer 3 additional hepatitis B vaccine doses [total of 4] with single-antigen vaccine at ages 1, 2–3, and 6 months, or Pediarix<sup>®</sup> vaccine at ages 2, 4, and 6 months.  
|                     |                            | • Test for HBsAg and anti-HBs 1–2 months after completion of the hepatitis B vaccine series, but not before age 9 months nor within 4 weeks of the most recent vaccine dose (i.e., at age 9–12 months, generally at the next well-child visit). |
| Unknown             |                            | • Test mother for HBsAg.  
<p>|                     |                            | • Administer HBIG + single-antigen hepatitis B vaccine at separate sites within 12 hours of birth. |</p>
<table>
<thead>
<tr>
<th>Status</th>
<th>Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown but suspected</td>
<td>• The infant should receive both HepB vaccine and HBIG within 12 hours of birth.</td>
</tr>
<tr>
<td></td>
<td>• Infants born to women for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of maternal HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should be managed as if born to an HBsAg-positive mother (new recommendation).</td>
</tr>
<tr>
<td>Negative</td>
<td>• Delay first dose of hepatitis B vaccine until chronological age 1 month or hospital discharge, even if the infant weighs less than 2000 g.</td>
</tr>
<tr>
<td></td>
<td>• Complete the hepatitis B vaccine series with single-antigen vaccine at ages 2 and 6–18 months, or Pediarix®) vaccine at ages 2, 4, and 6 months.</td>
</tr>
</tbody>
</table>

*HBsAg-positive, HBe-Ag-positive, or HBV DNA-positive. All HBsAg-positive or HBeAg-positive pregnant women should be tested for HBV DNA to guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission (new recommendation).
IV. B. INDICATIONS FOR POST-VACCINATION SEROLOGIC TESTING

- Post-vaccination serologic testing for anti-HBs and HBsAg should be performed after completion of the vaccine series at age 9–12 months (generally at the next well-child visit following completion of the HepB vaccine series).\(^3\)

- Serologic testing should be performed for HBsAg and anti-HBs using a method that allows detection of the protective concentration of anti-HBs (≥10 mIU/mL). Testing should not be performed before age nine months to avoid detection of passive anti-HBs from HBIG administered at birth and to maximize the likelihood of detecting late HBV infection.

- Anti-HBc testing of infants is not recommended because passively acquired maternal anti-HBc might be detected in infants born to HBsAg-positive mothers up to age 24 months.

- HBsAg-negative infants with anti-HBs levels ≥10 mIU/mL are protected and need no further medical management.

- HBsAg-negative infants with anti-HBs <10 mIU/mL should be revaccinated with a single dose of HepB vaccine and receive post-vaccination serologic testing 1–2 months later (new recommendation). Infants whose anti-HBs remains <10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine to complete the second series, followed by post-vaccination serologic testing 1–2 months after the final dose.\(^+\)

- For infants transferred to a different facility after birth (e.g., a hospital with a higher level of neonatal care), staff at the transferring and receiving facilities should communicate regarding the infant’s HepB vaccination and HBIG receipt status to ensure prophylaxis is administered in a timely manner (new recommendation).

- HBsAg-positive infants should be referred for appropriate follow-up.

\(^+\)Based on clinical circumstances or family preference, the complete 3-dose series may be readministered before repeating anti-HBs testing.
IV. C. VACCINE INTERCHANGEABILITY

ACIP recommends completion of any vaccination regimen with the same product whenever possible. However, if the originally used product is not available or known, vaccination with another monovalent product or with a combined vaccine is acceptable.4

IV. D. POST-VACCINATION SEROLOGIC RESTING AVAILABLE AT THE OREGON STATE PUBLIC HEALTH LABORATORY (OSPHL)

OSPHL offers serologic testing for HBsAg, anti-HBs, hepatitis B core antibody (anti-HBc), and IgM anti-HBc. HBeAg testing is not routinely available, but may be arranged under special circumstances; consult with the Acute and Communicable Disease Prevention section at 971-673-1111. For more information regarding properly specimen submission, refer to the Lab Test Menu at [www.healthoregon.org/labtests](http://www.healthoregon.org/labtests). As of January 2017, OSPHL does not provide PCR testing for hepatitis B virus.

Note: As of January 2017, testing is available to Oregon local public health authorities through the Oregon State Public Health Laboratory at no charge. This will be maintained as long as funding is available to support this testing. There is a charge for testing ordered by private providers.

V. CONTRAINDICATIONS

RecombivaxHB®, Engerix–B®: Hypersensitivity to baker’s yeast

VI. PRECAUTIONS

A. RecombivaxHB®, Engerix–B®: Apnea following IM vaccination has been observed in some infants with birth weights <2000 grams.

B. RecombivaxHB®, Engerix–B®: Dry natural rubber latex is used in the vial stopper, the syringe plunger stopper and tip cap. Dry natural rubber latex in tip caps may cause allergic reactions in latex-sensitive individuals.
VII. OTHER CONSIDERATIONS

1. In populations with currently or previously high rates of childhood HBV infection (e.g., Alaska Natives; Pacific Islanders; and immigrant families from Asia, Africa, and countries with intermediate or high endemic rates of infection), the first dose of HepB vaccine should be administered at birth and the final dose at age 6–12 months.3

2. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.1, 2

3. **DO NOT RESTART A SERIES.** Count the number of doses the recipient has had, and give the next dose due, observing client age and minimum spacing.4

VIII. Table 4. SIDE EFFECTS AND ADVERSE EVENTS1, 2

<table>
<thead>
<tr>
<th>Event</th>
<th>Infants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain at injection site</td>
<td>3%–22%</td>
</tr>
<tr>
<td>Mild systemic complaints (fatigue, headache)</td>
<td>0–20%</td>
</tr>
<tr>
<td>Temperature up to 37.7 °C (≤99.9°F)</td>
<td>0.4%–10%</td>
</tr>
<tr>
<td>Severe systemic reactions</td>
<td>Rare</td>
</tr>
</tbody>
</table>

IX. Table 5. STORAGE AND HANDLING

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).

<table>
<thead>
<tr>
<th>Vaccine1, 2</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Engerix–B®</td>
<td>Store at 2°–8°C</td>
<td>Do not use if vaccine has been frozen</td>
<td>Do not dilute</td>
</tr>
<tr>
<td>Reombivax HB®</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
X. Table 6. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/reportevent.html

Private providers are to report events directly to VAERS and can read about options on how to do so at http://vaers.hhs.gov/index.

VAERS Reporting Table:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

<table>
<thead>
<tr>
<th>Event and interval from vaccination</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Anaphylaxis or anaphylactic shock (7 days)</td>
</tr>
<tr>
<td>B. Shoulder Injury Related to Vaccine Administration (7 days)</td>
</tr>
<tr>
<td>C. Vasovagal syncope (7 days)</td>
</tr>
<tr>
<td>D. Any acute complications or sequelae (including death) of the above event (interval not applicable)</td>
</tr>
<tr>
<td>E. Events described in manufacturer’s package insert as contraindications to additional doses of vaccine (interval—see package insert)</td>
</tr>
</tbody>
</table>

Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: http://1.usa.gov/OregonStandingOrders
REFERENCES


