



**TEXAS**  
Health and Human  
Services

Texas Department of State  
Health Services

# **TEXAS PERINATAL HEPATITIS B PREVENTION PROGRAM (PHBPP) MANUAL**

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## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

### Perinatal Hepatitis B Prevention Quick Reference Guide

<b>Maternal hepatitis B surface antigen (HBsAg) testing</b>
<ul style="list-style-type: none"><li>According to state law, all pregnant women must be screened for hepatitis B infection at the first prenatal visit and again upon admittance for delivery for each pregnancy.</li></ul>
<b>Reporting</b>
<ul style="list-style-type: none"><li>All HBsAg-positive pregnant women must be reported within one (1) week to the DSHS PHR or LHD or the DSHS Immunization Section PHBPP.</li><li>Infants born to HBsAg-positive pregnant women and household contacts <math>\leq 24</math> months of age should be identified, reported to the DSHS PHR or LHD within one (1) workday, and case managed by program staff.</li></ul>
<b>Vaccination of infants at birth, born to...</b>
<b><u>A woman who is HBsAg-positive</u></b> <ul style="list-style-type: none"><li>Hepatitis B Immune Globulin (HBIG) and Hepatitis B vaccine within 12 hours of birth (regardless of birthweight).</li><li>For pre-term or low birthweight infants <math>&lt; 2,000</math> grams (<math>&lt; 4.4</math> pounds), the hepatitis B vaccine series should be re-initiated at 1 month of age.</li></ul>
<b><u>A woman whose HBsAg status is unknown</u></b> <ul style="list-style-type: none"><li>Hepatitis B vaccine within 12 hours of birth.</li><li>Mother should be tested immediately to determine HBsAg status.</li><li>If mother is determined to be HBsAg-positive or refuses to be tested, immediately administer HBIG to the infant before hospital discharge. <b>NOTE:</b> <i>HBIG should not be administered more than seven (7) days after birth.</i></li><li><b>Infants weighing <math>&lt; 2,000</math> grams (<math>&lt; 4.4</math> pounds) and born to HBsAg-positive women should receive HBIG and vaccine within 12 hours of birth.</b> The hepatitis B vaccine series should be re-initiated at 1 month of age.</li></ul>

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### Vaccination of infants at birth, born to... (Continued)

#### **A woman who is HBsAg-negative**

- All medically stable infants  $\geq 2,000$  grams ( $\geq 4.4$  pounds) should receive hepatitis B vaccine within 24 hours of birth.
- Pre-term or low birthweight infants of  $< 2,000$  grams ( $< 4.4$  pounds) born to HBsAg-negative mothers can defer vaccination until 1 month of age or hospital discharge.

### Hepatitis B Vaccine Series

- All infants should complete the Hepatitis B vaccine series with either a single-antigen or combination vaccine, according to the ACIP-recommended hepatitis B vaccination schedule.

### Hepatitis B Post-Vaccination Serologic Testing (PVST)

- All infants born to HBsAg-positive pregnant women or infants born to women whose HBsAg status remains unknown indefinitely (e.g., safe surrender infants) should be tested for HBsAg and anti-HBs after completion of the vaccine series.
- PVST testing should be done one to two months after completion of the vaccine series, but no earlier than 9 months of age. For infants who complete the vaccine series on time at 6 months of age, PVST testing should be done at 9 months of age.

# Chapter 1

## Program Background and Introduction

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## **Background**

Screening of all pregnant women for hepatitis B has been recommended since 1991 by the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP). On June 18, 1999, Governor George W. Bush signed legislation requiring pregnant women in Texas to be screened for HBV infection at their first prenatal examination and at delivery for each pregnancy. This law became effective September 1, 1999; and applies to the provider who attends to a pregnant woman during gestation and/or at delivery of her infant\*. In July 2019, the U.S. Preventive Services Task Force (USPSTF) reiterated the importance of screening for hepatitis B virus (HBV) infection in pregnant women at their first prenatal visit by giving it an "A" recommendation. This means there is significant evidence to prove that this screening is beneficial.

The Texas Department of State Health Services (DSHS) Perinatal Hepatitis B Prevention Program (PHBPP) was first implemented in 1991 in Harris, Tarrant, and Dallas counties, as well as the cities of Houston and San Antonio. In 2001, the program was expanded to provide services to the entire state.

The program was tasked with six key responsibilities:

- Identify ALL HBsAg-positive pregnant women and their infants in Texas,
- Assure administration of Post-Exposure Prophylaxis (PEP) is given within 12 hours of birth to exposed infants,
- Identify and vaccinate susceptible household contacts  $\leq 24$  months of age and ensure adult household and sexual contacts are referred out,
- Ensure hepatitis B vaccine birth doses are universally administered,
- Assure completion of hepatitis B vaccine series and Post-Vaccination Serologic Testing (PVST) of exposed infants, and
- Conduct active surveillance, quality assurance, outreach, and education to improve PHBPP program outcomes.

Although vaccine prevention and awareness has steadily increased since the start of the program, it was estimated in 2016 by the Centers for Disease

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Control and Prevention (CDC) that 921-1,231\*\* infants were born to Hepatitis B Surface Antigen (HBsAg) positive women in Texas. However, the Perinatal Hepatitis B Prevention Program (PHBPP) identified 660\* infants as being born to HBsAg-positive women in 2017.

In 2018, a total of 3,322 cases of acute hepatitis B were reported nationwide to the CDC, with the highest rate amongst 40-49-year-olds. From 2011-2016, rates of acute hepatitis B were repeatedly highest among persons aged 30-39 years old, however, 2017 and 2018 saw the highest rate in 40-49-year-olds. The CDC reported in 2018 that over half of all acute hepatitis B cases were in individuals 30-49 years old.

Perinatal transmission of the hepatitis B virus (HBV) is highly efficient and usually occurs from blood exposures during labor and delivery. Although in utero transmission is rare, it does account for nearly 2% of perinatal infections in most studies. Every year, it is estimated that 25,000 infants are born to women chronically infected with hepatitis B in the U.S. Without timely Post-Exposure Prophylaxis (PEP) at birth, approximately 90% of these infants would become chronically infected and approximately 25% of the infected would die prematurely of liver failure or liver cancer.

Transmission of hepatitis B to these high-risk babies could be prevented 85-95% of the time by providing appropriate PEP within 12 hours of birth, as described in this manual. Although perinatal hepatitis B has been nationally notifiable since 1995, the reporting of cases has not been reliable for monitoring purposes.

Less than 5% of the HBV infections that occur among children are reported as cases of acute hepatitis B to the CDC because these infections in infants and children rarely produce signs or symptoms of disease until other complications arise. Infants infected during their first year of life have a 90% chance of developing a chronic HBV infection compared to only 25-50% of children infected between ages 1 and 5 years old. In contrast, less than 5% of otherwise healthy people who become infected during adulthood will develop a chronic infection. Prior to routine PEP of infants and children, cases occurring in children accounted for a disproportionate amount of the disease burden due to chronic infection.

According to the 2018 National Immunization Survey (NIS), 89.2% of Texas children aged 19-35 months, have received three (3) or more doses of hepatitis B vaccine. The 2018 NIS results also show that 79.4% of children

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in Texas received the first dose of hepatitis B vaccine between birth and three (3) days of age.

\* Under Texas law, both acute and chronic infection of hepatitis B in a pregnant woman are conditions that **must** be reported to the DSHS. The Texas Health & Safety Code Title 2, Chapter 81 authorizes LHDs to conduct disease investigations and gather all pertinent medical information.

\*\* Numbers are not inclusive of City of Houston and City of San Antonio.

### **The 10 Key Elements of the Perinatal Hepatitis B Prevention Program**

The DSHS Immunization Section PHBPP has several important features including, but not limited to surveillance; case management; promotion of the universal birth dose; and collaboration between DSHS Public Health Region (PHR) offices, Local Health Department (LHD) offices, medical providers, and laboratories. The 10 objectives of the program are listed below. All case management and reporting forms can be found online at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

#### **1) Ensure that all pregnant women are tested for hepatitis B surface antigen (HBsAg). (Refer to Chapter 5)**

- According to Texas law, providers must screen pregnant women for hepatitis B infection at the first prenatal examination (regardless of trimester) and upon delivery, or as soon as feasibly possible thereafter.
- The CDC recommends the HBsAg as the preferred test for screening for HBV infection during pregnancy. ACIP also recommends HBV DNA viral load testing for HBsAg-positive pregnant women to guide antiviral therapy as needed.
- HBsAg testing should be incorporated into standard prenatal testing panels used by all providers caring for pregnant women. It is recommended that the hepatitis B serologic marker (HBsAg CPT code 87341) and reason for testing (pregnancy) be specified when submitting these specimens to the laboratory.

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- Providers should notify all HBsAg-positive pregnant women of their positive status as soon as possible and give them a copy of the original laboratory result.
- Providers should provide education to all HBsAg-positive pregnant women regarding the potential risks to their infant and what measures (e.g., HBIG, hepatitis B vaccine series, Post-Vaccination Serologic Testing [PVST]) can be taken in an effort to protect the child from Hepatitis B transmission. The patient should also be informed that the DSHS PHR or LHD will be contacting them for case management.
- Delivery facilities/hospitals should determine if a pregnant woman presenting to their facility was screened for HBsAg prenatally and document those results in both the mother's and infant's medical records.
- Delivery facilities/hospitals must draw blood to screen for HBV infection at delivery, regardless of the result obtained at the prenatal examination.
- Delivery facilities/hospitals should safeguard against errors in maternal HBsAg testing and failures in test reporting. This can be done by:
  - Maintaining standing orders for immediate HBsAg testing of all pregnant women upon admission for delivery.
  - Ordering admission lab tests that specify to draw "HBsAg", to avoid confusion with other hepatitis serologic markers.
  - Including a copy of the original HBsAg laboratory report in the delivery record.

### **2) Ensure reporting and case management of all HBsAg-positive women. (Refer to Chapter 7)**

- All HBsAg-positive pregnant women must be reported to the DSHS Immunization Section PHBPP for case management of the mother and infant(s).
- Reporting can be accomplished by providing information directly to the appropriate DSHS PHR or LHD.



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### **3) Ensure that delivery facilities/hospitals receive all prenatal HBsAg lab reports prior to delivery. (Refer to Chapter 5)**

- HBsAg test results should be included on all forms (hard copy and electronic) used by providers to record and transmit information about care during pregnancy.
- For all pregnant women, a copy of the original HBsAg laboratory result should be transferred from the prenatal care provider to the delivery hospital with the mother's medical records.
- Providers caring for HBsAg-positive pregnant women should remind delivery staff (doctors, midwives, nurses) of HBsAg-positive status during a client's pregnancy to ensure the baby receives all necessary care upon delivery.

### **4) Ensure identification and management of infants born to HBsAg-positive women. (Refer to Chapter 4)**

- Delivery facilities/hospitals should implement policies and procedures to ensure proper identification of HBsAg-positive pregnant women and their infants. (Refer to Appendix E for examples.)
- All infants born to HBsAg-positive women require the administration of PEP within 12 hours of birth. Delivery facilities/hospitals must document all required information. (Refer to number 5 under Key Elements for reporting information.)
- Document proper health information on the medical data worksheet for the infant's birth certificate (hepatitis B infection during pregnancy).
- If an HBsAg-positive woman refuses PEP for her newborn, providers must ensure that the mother is informed and educated about her status and the potential consequences to her newborn(s) and the option to receive PEP up to seven days after delivery.
- Document in the infant's medical record the mother's signed declination against medical advice (AMA) form (facility specific) against the medically recommended treatment for her infant(s) and all education provided regarding hepatitis B and the potential consequences to her newborn(s).

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### **5) Ensure reporting of HBsAg-positive women and infants to the health department. (Refer to Chapter 5)**

- HBsAg-positive mothers must be reported within one (1) week by completing the [Mother Case Management Report form](#) and sending it to either their DSHS PHR or LHD.
- HBsAg-positive infants must be reported within one (1) day by completing the [Infant Case Management Report form](#) and sending it to either their DSHS PHR or LHD.
- Delivery facilities/hospitals must document and report the following information on the [Hospital/Provider Report form](#):
  - Maternal HBsAg status (and other serology) at time of delivery,
  - Prenatal Provider & Infant Provider,
  - Date and Time of Birth,
  - Birth Weight, and
  - HBIG and Hepatitis B vaccine administration
    - date and time
    - lot number
    - manufacturer\*
    - formulation/brand name (i.e., Engerix-B, Recombivax HB, HepaGam HB, HyperHEP B, Nabi-HB, etc.) \*

\* Refer to Chapter 4, Post-Exposure Prophylaxis (PEP), for chart of manufacturers and formulations of HBIG.

### **6) Ensure identification and management of infants born to women of unknown HBsAg status. (Refer to Chapter 4)**

- Delivery facilities/hospitals should implement policies and procedures to ensure prompt identification and appropriate PEP administration to infants born to women of unknown HBsAg status.
- An infant whose mother's HBsAg test result comes back positive should immediately receive HBIG.
- Document Hepatitis B infection present during pregnancy on the medical data worksheet for the infant's birth certificate (i.e., Hepatitis B during pregnancy).

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- Complete the "Provider/Hospital Report of a HBsAg-Positive Mother" form and send to the local health department. Document the positive HBsAg result in the mother's and infant's charts.
- 7) Ensure timely completion of the hepatitis B vaccine series for all infants born to HBsAg-positive women. (Refer to Chapter 4)**
- Dose one should ideally be given within 12 hours of birth, and preferably no later than by hospital discharge.
  - Dose two should be given at 1 month of age, but no later than 2 months of age.
  - Dose three should be given at 6 months of age:
    - Must be given at least eight (8) weeks after dose two AND
    - At least 16 weeks after dose one.
  - Combination vaccines may be used to complete the series, giving the infant a total of four doses of hepatitis B vaccine.
  - Providers should document the date, lot number, and name/manufacture for each dose of the hepatitis B vaccine administered to the infant.
  - If the child was not already registered for the Texas Immunization Registry (ImmTrac2) at birth, parental consent should be obtained. The vaccination history of the infant should then be entered into ImmTrac2 as soon as possible after each visit.
- 8) Ensure timely completion of PVST for all infants born to HBsAg-positive women. (Refer to Chapter 4)**
- To determine infant outcomes after appropriate PEP, PVST should be performed on all infants born to HBsAg-positive women or infants born to women whose HBsAg status remains unknown indefinitely (e.g., safe surrender infants) once:
    - the infant has completed a full hepatitis B vaccine series
    - the infant is at least nine months of age
    - at least one month has passed since the infant received the final dose of a hepatitis B containing vaccine
  - Providers should order:
    - HBsAg (CPT: 87340) **and**
    - Quantitative Anti-HBs (CPT: 86137)

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- Providers should document the infant's PVST results and report all results (positive or negative) to their regional or local health department.

### **9) Ensure vaccination of household contacts ≤24 months of age. (Refer to Chapter 7 for case management of household contacts)**

- Household contacts 24 months of age and younger must be identified and a case management record initiated within 15 days of notification.
- These contacts must be offered serologic testing (HBsAg and anti-HBs) and, if susceptible to HBV infection, initiate the hepatitis B vaccine series. If needed, both the testing and vaccine are provided free of charge through the PHBPP for all contacts ≤24 months of age. Refer to Chapter 7 for additional information.
- Records for contacts ≤24 months of age are closed upon hepatitis B vaccine series completion and PVST results. Revaccination may be needed before the case can be closed.
- All contacts >24 months of age, as well as all sexual partners to the HBsAg-positive mother, should be referred to a healthcare provider for Hepatitis B serology testing and vaccination as needed for health care evaluation.

### **10) Ensure program quality, monitoring, and evaluation.**

- Central office provides the following monthly quality assurance reports to PHR and LHD case managers:
  - Infants past due for vaccines and/or serology,
  - Women past due, based on their Estimated Due Dates (EDD),
  - Infants missing Post-Exposure Prophylaxis, and
  - Dashboard of PHBPP outcomes.
- Central office also provides the following reports to help increase identification of HBsAg-positive pregnant women:
  - Report from the Texas National Electronic Disease Surveillance System (NEDSS) of women of childbearing age with a positive HBsAg; and

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- Report from the Vital Statistics Unit of women who indicated Hepatitis B was present during pregnancy on the birth certificate medical questionnaire.
- The PHR/LHD case manager is responsible for reviewing these lists monthly and reporting outcomes of these cases back to Central Office as indicated in the report instructions. Central Office may also create and send out additional reports not listed above to help improve the program.
- The LHD/PHR case managers are also responsible for providing training and education to birthing hospitals, prenatal providers, and pediatric providers. The trainings should cover the entire PHBPP program, Texas laws related to screening and reporting, and the importance of the universal Hepatitis B birth dose.
- If any of the below occur, an Investigational Report form should be completed to determine the cause:
  - Missed maternal screening during pregnancy and/or at delivery.
  - Infant does not receive the appropriate PEP within 12 hours of birth.
  - Child misses any of the hepatitis B vaccine doses.
  - PVST is not done as required.
- Once the case manager has identified problems on the Investigational Report form, training will be provided by the DSHS PHR or LHD in an attempt to correct any identified error(s).

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## Chapter 2

# Hepatitis B Overview

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### **HEPATITIS B OVERVIEW**

#### **Hepatitis B Virus**

The Hepatitis B Virus (HBV) belongs to the Hepadnaviridae family and is known to cause both acute and chronic infections in humans. The virus is found in the blood and certain body fluids (serum, semen, saliva, and vaginal secretions) of people infected. It is relatively stable and has been shown to remain infectious on environmental surfaces for more than seven (7) days at room temperature. It is a small, round, enveloped virus with partially double-stranded circular Deoxyribonucleic Acid (DNA) and is highly infectious; the Centers for Disease Control and Prevention (CDC) has stated that percutaneous or mucosal exposure to Hepatitis B is 50 to 100 times more infectious than the Human Immunodeficiency Virus (HIV). There are nine serotypes and eight genotypes of HBV recognized worldwide.

#### **HBV Infection**

HBV infection is a major cause of acute and chronic hepatitis, cirrhosis of the liver, and liver cancer. It is the most prevalent chronic infectious disease in the world, a common cause of morbidity and mortality worldwide, and a major health problem in the U.S. The World Health Organization (WHO) estimates that two billion people have been infected worldwide with the hepatitis B virus. The CDC estimates 257 million remain chronically infected globally while more than 887,000 people die every year due to the consequences of the virus.

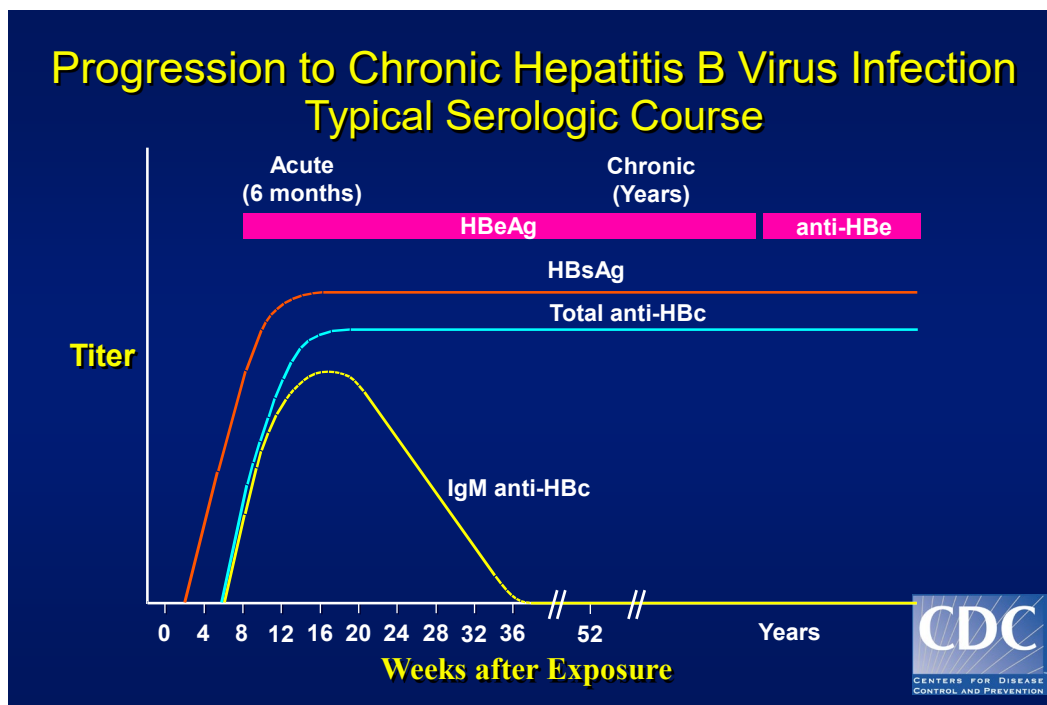
The highest hepatitis B infection rates are found in sub-Saharan Africa and East Asia. Five to ten percent of the adult population in these areas are chronically infected and most became infected during childhood. Liver cancer caused by hepatitis B is among the top three causes of cancer-related death in men, and a major cause of cancer in women in these regions. In the U.S., the CDC estimates 862,000 are living with chronic hepatitis B infection. Also, it is estimated that between 3,000-4,000 people in the U.S. die of hepatitis B-related cirrhosis each year.

After exposure, HBV is transported by the bloodstream to the liver, which is the primary site of viral replication. Infection in adults is generally self-limited, meaning the immune system can eliminate the virus from the blood and provide lasting immunity against reinfection in about 95% of cases. The remainder of adults whose immune systems do not eliminate the virus will

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develop a chronic, lifelong infection. A person with chronic hepatitis B is defined by the CDC as someone with HBsAg present in their bloodstream for greater than six months with continuing viral replication and persistent viremia. (See Figure 2.1.) These “chronic carriers” can transmit the virus to other individuals who are unprotected.

**Figure 2.1. Progression to Chronic Hepatitis B Virus Infection, Typical Serologic Course**



### Communicability

Persons with either acute or chronic HBV infection should be considered potentially infectious.

### Clinical Manifestations

The clinical manifestations of acute HBV infection are age dependent. Infants, children younger than 10 years of age, and immunosuppressed adults with newly acquired HBV infection are usually asymptomatic (no symptoms). Meanwhile, approximately 30-50% of adults will show symptoms of infection. Because many infected persons are asymptomatic, they are often unaware they are infected, resulting in inadvertent transmission to others. Additionally, infected individuals can transmit the

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virus before symptom onset. When symptoms occur, they are not specific to hepatitis B; therefore, laboratory testing is required to distinguish HBV from other diseases.

### **Signs and Symptoms**

The incubation period for HBV infection ranges from 60 to 150 days (average of 90 days). The preicteric (before jaundice), or prodromal, phase usually lasts from three to ten days, from initial onset of symptoms to jaundice.

Symptoms of this phase may include, but are not limited to:

- malaise
- anorexia
- nausea
- vomiting
- fever
- right upper quadrant abdominal pain
- headache
- myalgia
- skin rashes
- arthralgia
- arthritis
- dark urine starting one to two days before the onset of jaundice

The icteric (jaundice) phase is variable but usually lasts one to three weeks. It is characterized by yellowing of the skin, mucous membranes, and conjunctiva; light or gray stools; hepatic tenderness, and hepatomegaly (liver enlargement). During convalescence, malaise and fatigue may persist for weeks or months as the other signs and symptoms disappear.

### **Treatment**

No specific treatment exists for acute hepatitis B; supportive care is the mainstay of therapy.

Persons who have chronic HBV infection require medical evaluation and regular monitoring. Therapeutic agents approved by the Food and Drug Administration (FDA) for treatment of chronic hepatitis B can achieve sustained suppression of HBV replication and remission of liver disease in some persons. Patients interested in treatment should seek a referral from their physician to a gastroenterologist, hepatologist, or an infectious disease specialist.

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For more information on acute and chronic HBV infections, please consult The Red Book: Report of the Committee on Infectious Diseases (31<sup>st</sup> Edition) or visit <http://www.cdc.gov/hepatitis/HBV/>.

### **Complications**

The complications of chronic infection include chronic hepatitis, cirrhosis, liver failure, and hepatocellular carcinoma. Persons with chronic HBV infection are at a much higher risk of hepatocellular carcinoma than non-carriers. Approximately 25% of persons who become chronically infected die prematurely from cirrhosis or hepatocellular carcinoma. This means that approximately, 3,000 to 4,000 people die each year of HBV-related cirrhosis and approximately 1,000 to 1,500 people die each year from HBV-related liver cancer in the U.S. HBV infection is estimated to be the cause of 80% of hepatocellular carcinoma worldwide.

The complications that arise are typically associated with chronic HBV infections. However, in a small number of cases, acute infections can result in fulminate hepatic failure and death. Fulminant hepatitis occurs in about 1-2% of acutely infected persons and has a mortality rate of 0.5–1%, although mortality is suspected to be higher in acutely infected infants. About 200 to 300 Americans die each year of fulminant disease.

## **Epidemiology of the Hepatitis B Virus**

### **Reservoir**

The natural host for the hepatitis B virus is humans. The virus is not known to naturally infect animals, although some non-human primates have been infected under laboratory conditions.

### **Transmission**

The hepatitis B virus is transmitted by parenteral or mucosal exposure to HBsAg-positive body fluids or tissues from persons who have acute or chronic HBV infection. Parenteral exposure routes include, but are not limited to:

- intravenous (IV) drug use,
- shared razor,
- accidental needle sticks or sharps injuries,

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- contaminated multi-dose vials or medical equipment, and
- other breaches of blood-borne pathogen infection control practices.

Mucosal exposure can occur from:

- birth
- sexual contact
- accidental blood exposure to the eyes or mouth
- shared household products (i.e., toothbrush)
- other routes if appropriate barrier precautions are not taken.

The highest concentrations of virus are in blood, serous fluids, and wound exudates; lower titers are found in other fluids, such as saliva and semen. Saliva can be a vehicle of transmission through bites, however, other types of exposure to saliva, including kissing, are unlikely modes of transmission. There appears to be no transmission of HBV via tears, sweat, urine, stool, or droplet nuclei. See Table 2.1.

As previously mentioned, HBV infection can also be transmitted through sexual contact, either heterosexual or homosexual, with an infected person. It is thought that transmission occurs among men who have sex with men (MSM), possibly via contamination from asymptomatic rectal mucosal lesions. Fecal-oral transmission does not appear to occur. Transmission in healthcare settings, long-term care facilities, and in-home health settings are well described due to breaches in infection control practices.

**Table 2.1. Concentration of Hepatitis B Virus in Various Body Fluids**

High	Moderate	Low/Non-detectable
Blood Serum Wound exudates	Semen Vaginal fluid Saliva	Urine Feces Sweat Tears Breast milk

Because HBV can survive for more than seven (7) days on environmental surfaces at room temperature, indirect inoculation of HBV can occur via inanimate objects. A 10% bleach and water solution is recommended to decontaminate a surface after a blood spill.

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## **Perinatal Transmission**

Transmission of HBV from mother to infant during the perinatal period represents one of the most efficient modes of HBV infection. The risk of perinatal transmission is directly related to the viral load of the mother. The hepatitis B "little e" antigen (HBeAg) marker is a commonly used indicator of active viral replication and, thus, high viral load. The absence of HBeAg is generally associated with a low viral load and a lower likelihood of transmission to the infant. However, approximately 20-30% of the chronic infections in the U.S. are due to a variant of HBV called a "pre-core mutant." This variant of the virus does not produce e-antigen while replicating. This pre-core mutant variant may have a viral load somewhere in between the e-antigen positive and e-antigen negative cases. HBV viral load can be directly measured and quantified using molecular technology.

For a newborn whose mother is positive for both HBsAg and HBeAg, the risk for chronic HBV infection is 70-90% by six (6) months of age in the absence of PEP (HBIG and hepatitis B vaccine). However, if the mother is HBsAg-positive but HBeAg-negative, the risk for chronic infection to the infant becomes less than 10% in the absence of PEP.

The exact mechanism of transmission remains unclear, although the mode of delivery (vaginal versus C-section) does not appear to have an impact on the risk of perinatal HBV infection. Infection during pregnancy can occur during the intrauterine, or intrapartum (delivery) periods, however, HBV transmission mainly occurs during delivery. Intrauterine (in utero) transmission is relatively rare, accounting for less than 2% of perinatal infections in most studies. Hepatitis B viral DNA and HBsAg have been detected in amniotic fluid, placental cells, and vaginal secretions of HBsAg-positive women during pregnancy, as well as in the cord blood of their neonates. Postpartum transmission through exposure to infectious maternal saliva, stool, or urine is quite rare.

It has previously been believed that breastfeeding serves as an additional mechanism by which infants may acquire HBV infection. Although trace amounts of HBsAg have been found in breast milk, research strongly suggests that any risk of transmission associated with breast milk is negligible compared to the high risk of exposure to maternal blood and fluids at birth. Because there is no evidence that breastfeeding from an HBV-infected mother poses an additional risk to the infant, even without immunization, both the CDC and WHO support mothers breastfeeding in these cases. They state it is safe for an infected woman to breastfeed her

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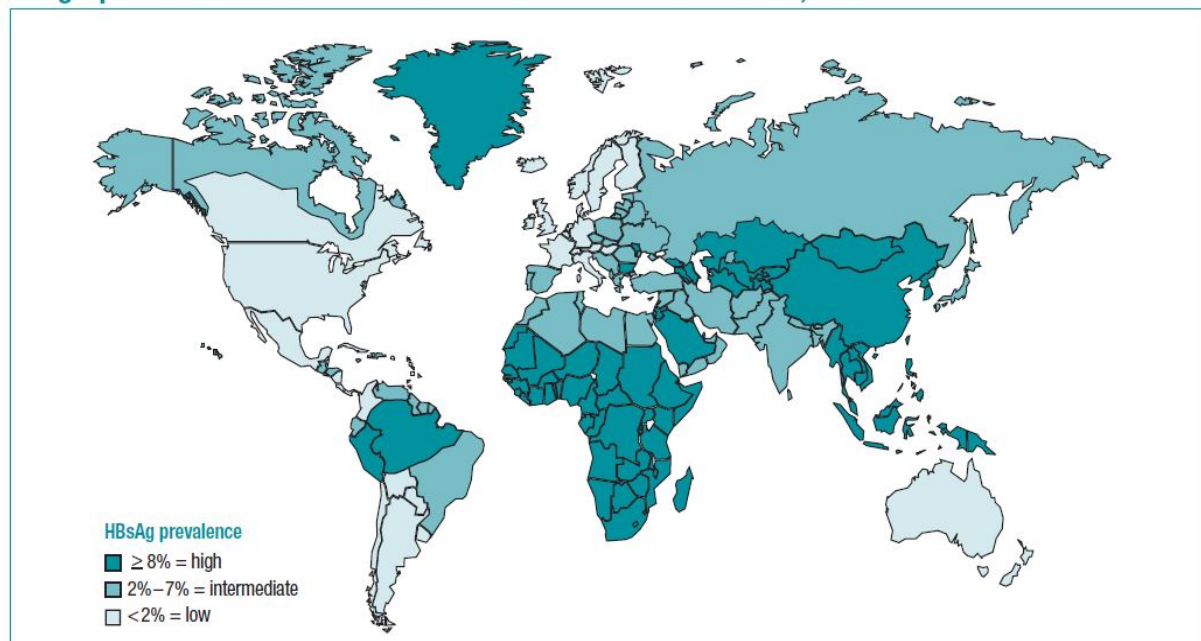
child, as the benefits outweigh the risks. All mothers who breastfeed should pay particular attention to the care of their nipples to avoid any cracking and bleeding.

### Other Risk Factors Associated with Hepatitis B

- People born in Asia, Africa, and other regions with moderate or high rates of hepatitis B (See Figure 2.2.)
- Unvaccinated people whose parents are from regions with high rates of hepatitis B
- Anyone having sex with a person infected with hepatitis B
- People who live with someone with hepatitis B
- Men who have sexual encounters with other men (MSM)
- People who inject drugs
- People with HIV infection
- People on hemodialysis
- Healthcare workers

**Figure 2.2. Geographic Distribution of Chronic HBV Infection**

Geographic Distribution of Chronic HBV Infection — Worldwide, 2006\*



\* For multiple countries, estimates of prevalence of hepatitis B surface antigen (HBsAg), a marker of chronic HBV infection, are based on limited data and might not reflect current prevalence in countries that have implemented childhood hepatitis B vaccination. In addition, HBsAg prevalence might vary within countries by subpopulation and locality.

Source: CDC. Travellers' Health; Yellow Book. <http://wwwn.cdc.gov/travel/yellowbookch4-HepB.aspx>.

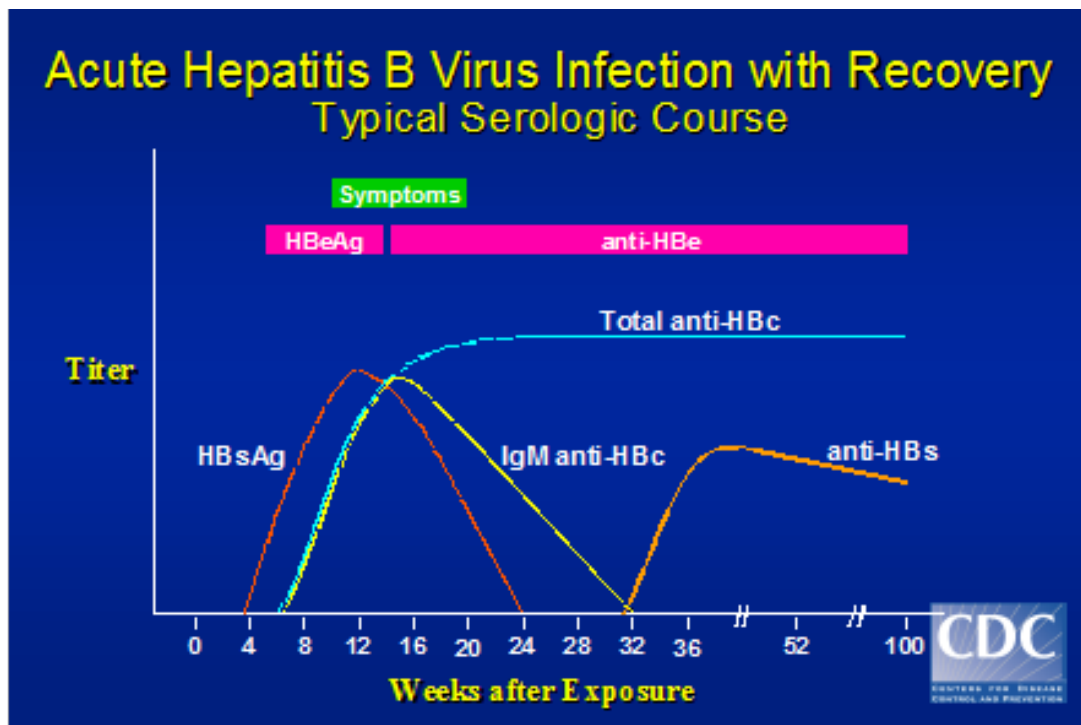
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### HBV Laboratory Testing

There are several antigenic components of the virus that can result in a variety of positive laboratory tests at different points in an infection.

The HBsAg is found on the surface of the virus and can be identified in serum samples 30-60 days after exposure to the virus. This component of the virus is not infectious itself, but its presence in the blood indicates that the complete virus is present, and that the person can transmit the virus to others. Once the immune system detects the HBsAg component of the virus, whether through acute infection or after vaccination, it begins to develop antibodies (anti-HBs). The presence of anti-HBs in the serum indicates immunity to the virus. Anti-HBs may also be referred to as hepatitis B surface antibody (HBsAb), which can easily be confused with HBsAg. Available laboratory testing attempts to detect these various components and antibodies as they become active. (See Figure 2.3)

**Figure 2.3. Acute HBV Infection with Recovery, Typical Serologic Course**



The most common uses for testing are to determine whether a patient's signs and symptoms are due to HBV infection, to diagnose and monitor



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chronic infection, and to detect previous exposure to the virus. Testing may also be done to:

- screen for infection in at-risk populations or blood donors
- to determine carrier status
- screen for immunity due to vaccination or prior infection (See Table 2.2)

**Table 2.2. Diagnostic Tests for HBV Antigens and Antibodies, Quick Reference**

<b>Factor to Be Tested</b>	<b>HBV Antigen or Antibody</b>	<b>Purpose</b>
<b>HBsAg</b>	Hepatitis B surface antigen	Detection of acutely or chronically infected persons.
<b>Anti-HBs</b>	Antibody to HBsAg	Identification of persons who have resolved infections with HBV; determination of immunity after immunization
<b>Anti-HBc</b>	Total Hepatitis B antibody	To determine a current or past Hepatitis B infection
<b>HBeAg</b>	Hepatitis B e antigen	Identification of infected persons at increased risk for transmitting HBV
<b>HBV DNA</b>	Hepatitis B DNA	HBV DNA measures the amount of HBV present. HBV DNA levels guide anti-viral therapy.

### Diagnostic Tests for HBV

Diagnosis of HBV infection (acute vs. chronic) is based on clinical, laboratory, and epidemiologic findings. HBV infection cannot be differentiated from other liver disease based on clinical symptoms alone, and definitive diagnosis depends on the results of laboratory testing. Serologic markers of HBV infection vary depending on whether the infection is acute,

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chronic, or resolved. Commercial tests for Hepatitis B, as summarized in Table 2.2, are widely available and used for various clinical purposes.

Refer to Chapter 5 for more detail on the diagnostic tests for HBV antigens and antibodies. Refer to Appendix D for comprehensive CDC resources on the interpretation of hepatitis B serology and information on assays not routinely required for the PHBPP.

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## Chapter 2: Learning Check

1. True or False: Chronic hepatitis B can lead to cirrhosis and liver cancer.

**Answer:** True! Chronic Hepatitis B can lead to chronic hepatitis, cirrhosis, liver failure, and liver cancer. Worldwide, the most common risk factor for liver cancer is a chronic infection with Hepatitis B or Hepatitis C. The Hepatitis B vaccine was the first cancer preventing vaccine.

2. Hepatitis B virus is spread in the following ways:

- A. Breastfeeding
- B. Needle sticks
- C. During childbirth
- D. Both B & C

**Answer:** D: Hepatitis B is spread through parenteral or mucosal exposure to HBsAg positive body fluids or tissues from those who have acute or chronic hepatitis B. Breast milk is thought to contain negligible amounts of hepatitis B and CDC & WHO state that it is safe for an infected mother to breastfeed their infant.

3. Which of the following clients should be screened, based on their risk factors?

- A. A recent immigrant from Nigeria
- B. A client who recently started dialysis
- C. A recent immigrant from Mexico
- D. Someone who reports a history of injection drug use
- E. A, B, & D

**Answer:** E: Some risk factors for hepatitis B include people born in Asia, Africa, and other regions with moderate or high rates of hepatitis B; people on hemodialysis; and people who inject drugs. Mexico is not an area with high Hepatitis B infections per the CDC's yellow book.

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## **Chapter 3**

# **Texas Statutes and Rules**

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### **Reporting, Screening, and Vaccinating for Hepatitis B in Texas**

The State of Texas provides legislative directives for hepatitis B screening and reporting to protect the residents of Texas from infectious disease. This chapter addresses statutes and rules that require providers to screen pregnant women for hepatitis B, administer vaccines to newborns and children, and report infected mothers and infants to the health department. The test currently recommended by the Centers for Disease Control and Prevention (CDC) for evaluation of hepatitis B infection during pregnancy is the Hepatitis B Surface Antigen (HBsAg). The Texas Department of State Health Services (DSHS) Immunization Section, Perinatal Hepatitis B Prevention Program (PHBPP) website, [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org), provides links to access statutes and rules pertaining to screening, reporting, and vaccinating newborns. Statutory requirements and rules must be shared with health care providers and labor and delivery facilities to reduce the incidence of transmission of perinatal hepatitis B.

#### **Statutory Requirements - Texas Health and Safety Code**

##### **Chapter 81 Section §81.041 – Reportable Diseases**

The Commissioner identifies each communicable disease or health condition that shall be reported. Each reportable disease is classified according to its nature and severity.

##### **Chapter 81 Section §81.042 – Persons Required to Report**

When a reportable disease is suspected, health professionals, and laboratories should report all known information of the case to the local health authority or DSHS.

##### **Chapter 81 Section §81.044 – Reporting Procedures**

The Commissioner shall prescribe the form and method of reporting which may be in writing, by telephone, by electronic data transmission, or by other means. The Commissioner may require reports to contain any information pertaining to a case that is necessary including, but not limited to:

- Patient's name, address, age, sex, race, and occupation
- Date of onset of disease or condition

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- Probable source of infection
- Name of the attending physician.

Please see Texas Administrative Code (TAC) Title 25, Chapter 97, Subchapter F Rule §97.3 (TAC Rule §97.3) referenced later in this chapter for additional reporting requirements.

### **Chapter 81 Section §81.090 – Diagnostic Testing During Pregnancy and After Birth**

Providers that are permitted by law to care for a pregnant woman during gestation are required to perform hepatitis B serologic testing during pregnancy at the first prenatal visit. This report shall be retained for at least nine (9) months and be reported to any successor in the case.

Providers that are permitted by law to care for pregnant women at delivery of an infant are required to perform hepatitis B serologic testing of the mother upon admission for delivery. Before testing a pregnant woman for hepatitis B, providers shall distribute to the patient printed materials about hepatitis B and subsequently document that the distribution of printed materials was made. The materials should inform the patient about the incidence and mode of transmission of hepatitis B and how being infected could affect the health of their child. Information shall also be provided or made available to the pregnant woman relating to the treatment of hepatitis B, which must be in another language if needed, and must be presented in a manner and in terms understandable to a person who may be illiterate, if resources permit. Physicians are complying when referring these individuals to an entity that provides treatment for individuals infected with hepatitis B.

### **Chapter 161 Section §161.004 – Statewide Immunization of Children**

Every child in the state shall be immunized against vaccine-preventable diseases caused by infectious agents, in accordance with the immunization schedule adopted by DSHS.

Hospitals shall be responsible for:

- referring newborns for immunization at the time the newborn screening test is performed,
- reviewing the immunization history of every child admitted to the hospital or examined in the hospital's emergency room or outpatient clinic, and



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- administering needed vaccinations or referring the child for immunization.

Physicians shall be responsible for reviewing the immunization history of every child examined and administering any needed vaccinations or referring the child for immunization.

A child is exempt from an immunization required by this section if either of the following apply:

- a parent, managing conservator, or guardian states that the immunization is being declined for reasons of conscience, including a religious belief, or
- the immunization is medically contraindicated based on the opinion of a physician licensed by any state in the US who has examined the child.

A parent, managing conservator, or guardian may choose the healthcare provider who administers the vaccine or immunizing agent under this chapter.

### **Rules - Texas Administrative Code**

The TAC is a compilation of all state agency rules in Texas with specific rulemaking authority from the Legislature.

#### **Title 25, Chapter 97, Subchapter A, Rule §97.2 – Who Shall Report**

A physician, advanced practice nurse, physician assistant, or person permitted by law to attend to a pregnant woman during gestation or at the delivery of an infant shall report, as required, each patient who has or is suspected of having any notifiable condition. An employee from the clinical or office staff may be designated as the reporter and the provider must ensure that person regularly reports every occurrence.

Any person who is in charge of a clinic laboratory in which a laboratory examination of any human specimen yields serologic evidence of a notifiable condition shall report as required.

Failure to report a notifiable condition is a Class B misdemeanor under the Texas Health and Safety Code §81.049.

The Health Insurance Portability and Accountability Act (HIPAA) allows reporting without authorization for public health purposes and where

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required by law. See Title 45 Code of Federal Regulations §164.512 at the end of this chapter.

### **Title 25, Chapter 97, Subchapter F Rule §97.3 – What Conditions to Report or Submit**

Hepatitis B (acute and chronic) identified prenatally or at delivery (mother) and hepatitis B acquired perinatally (child) are listed as notifiable conditions and must be reported.

The following information is listed as “minimal reportable information requirements” that shall be reported for hepatitis B (chronic and acute) identified prenatally or at delivery:

- Mother’s name, address, telephone number, age, date of birth, sex, race, ethnicity, and preferred language
- Hepatitis B laboratory results
- Estimated delivery date, or date and time of birth
- Name and phone number of delivery hospital or planned delivery hospital
- Name of infant
- Name, phone number, and address of medical provider for infant
- Date, time, formulation, dose, manufacturer, and lot number of Hepatitis B vaccine and Hepatitis B immune globulin (HBIG) administered to infant

The following information is listed as “minimal reportable information requirements” that shall be reported for perinatal hepatitis B infection:

- Name of infant, date of birth, sex, race, and ethnicity
- Name, phone number, and address of medical provider for infant
- Date, time, formulation, dose, manufacturer, and lot number of Hepatitis B vaccine and HBIG administered to infant, and any hepatitis B laboratory results\*

\*Refer to Chapter 4, Post-Exposure Prophylaxis (PEP), for chart of manufacturers and formulations of HBIG.

### **Title 25, Chapter 97, Subchapter A, Rule §97.4 – When to Report a Condition**

Perinatal hepatitis B shall be reported within one (1) working day of identification as a suspected case.

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Hepatitis B (acute and chronic) identified prenatally or at delivery shall be made no later than one (1) week after a case or suspected case is identified.

### **Title 25, Chapter 97, Subchapter A, Rule §97.5 – Where to Report/Submit a Condition**

Physicians, hospitals, labs, and/or any person permitted by law to attend to a pregnant woman during gestation or delivery shall report to the Local Health Department (LHD) where the office, clinic, or hospital is located. If there is no LHD appointed for their jurisdiction, the report shall be made to the DSHS PHRPHR. Under 97.6, local health departments are required to report to DSHS any notifiable conditions report to them.

### **Title 25, Chapter 97, Subchapter A, Rule §97.8 – General Control Measures for Notifiable Conditions**

Control techniques including immunization, chemoprophylaxis, and other accepted measures shall be instituted as necessary to reduce morbidity and mortality by the Commissioner, a health authority, or a duly authorized representative of the commissioner or a health authority. Information concerning [perinatal hepatitis B] and its prevention shall be given to the patient to prevent further spread of the disease. Investigation shall be made, as needed, for verifying the diagnosis, disclosing unreported cases, and finding contacts. On request, a person shall provide DSHS or health authority with records, data, and other information, which DSHS or the health authority will keep confidential.

### **Title 25, Chapter 97, Subchapter A, Rule §97.10 – Confidential Nature of Case Reporting and Records**

All individual morbidity case reports received by the health authority or DSHS are considered confidential records.

To implement disease control measures authorized in the TAC, it may be necessary for the health authority or the department to investigate public or private health records, including patient medical records pertinent to the notifiable condition. On request, a person shall provide the department with records, data, and other information according to the written instruction of the department. The health authority and the department shall keep this information confidential.

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### **Title 25, Chapter 97, Subchapter D, Rule §97.101 – Statewide Immunization of Children by Hospitals, Physicians, and Other Health Care Providers**

All private and public hospitals in Texas that provide health care to children shall administer age-appropriate vaccines or refer newborns for immunization to other healthcare providers at the time of the newborn screening test.

All physicians and other health providers who provide care to children shall review the immunization history of every child examined and administer vaccines or refer every child who needs immunizations to another provider.

Hospitals, physicians, and other health providers, who provide health care to children in Texas, must document in a newborn's or other child's hospital or medical record that the newborn or child has been age-appropriately immunized or that the newborn or child has been referred to another healthcare provider for immunizations. (Refer to Chapter 4 for Immunization Guidelines)

### **Federal Regulations - The Code of Federal Regulations (CFR)**

#### **Title 45, §164.512(b) – Uses and Disclosures for Public Health Activities**

A covered entity may disclose protected health information to a public health authority authorized by law for activities to prevent or control disease such as surveillance, investigations, and interventions.

### **Sources**

The Texas Health and Safety Code is available at:  
<http://www.statutes.legis.state.tx.us/?link=HS>

The Texas Administrative Code is available at:  
<http://www.sos.state.tx.us/tac/index.shtml>

The Code of Federal Regulations is available at:  
<https://www.govinfo.gov/app/collection/cfr/2019/>

## Chapter 4

# Post-Exposure Prophylaxis (PEP)

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## **Prevention**

The Centers for Disease Control and Prevention (CDC) has released a comprehensive document pertaining to the elimination of Hepatitis B Virus (HBV) infection in the U.S. This document provides recommendations of the Advisory Committee on Immunization Practices (ACIP) and strategies to implement these recommendations in both children and adults. The primary focus of the ACIP childhood recommendations is the universal vaccination of infants as a “safety net” to prevent early childhood HBV infection.

The strategies to prevent hepatitis B infection in children include, but are not limited to:

- Universal vaccination of infants beginning at birth
- Routine screening of all pregnant women for Hepatitis B Surface Antigen (HBsAg)
- Post-Exposure Prophylaxis (PEP) of infants born to HBsAg-positive women or to women with unknown HBsAg status
- Routine vaccination of previously unvaccinated children and adolescents

In this document, the CDC also provides strategies to enhance implementation of the ACIP recommendations, such as:

- Establishing standing orders for administration of hepatitis B vaccination at birth; and
- Implementing policies and procedures to improve identification of, and administration of PEP to, infants born to:
  - mothers who are HBsAg positive, and
  - mothers with unknown HBsAg status at the time of delivery.

The CDC and ACIP recommend that providers who practice in primary care and at-risk specialty settings should implement standing orders to identify their at-risk patients and subsequently vaccinate them.

The document can be accessed electronically at:

<https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>.

The Institute of Medicine (IOM) (now called National Academy of Medicine [NAM]) also released a report on preventing and controlling viral hepatitis infections in the U.S. After reviewing evidence on the prevention and control of hepatitis B and hepatitis C, the committee identified the underlying factors

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that impeded current efforts to prevent and control these diseases. In this report, *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*, the committee offers recommendations in four categories: surveillance, knowledge and awareness, immunization, and services for viral hepatitis. This document, along with recommendations from ACIP can be found at the following web site:

<http://www.cdc.gov/hepatitis/pdfs/iom-hepatitisandlivercancerreport.pdf>.

### **Post-Exposure Prophylaxis (PEP)**

#### **Hepatitis B Immune Globulin (HBIG)**

Hepatitis B immune globulin (HBIG) is derived from human plasma. The plasma, which is processed from select human donors with high Hepatitis B Surface Antibody (anti-HBs) titers, contains antibodies that are specific to the hepatitis B virus. Although HBIG is derived from humans, it is purified to prevent passing along disease to the person who receives it. HBIG is used to give temporary protection for individuals who might have been exposed to the virus. It is important to keep in mind that immune globulin does not provide long-term protection in the same way that vaccinations do. The protection is only short term, usually only lasting a few weeks to a few months. In the case of perinatal hepatitis B, HBIG is intended to give infants born to mothers with hepatitis B short-term protection against the hepatitis B virus, which they may have been exposed to during birth.

Infants born to HBsAg-positive women should receive HBIG and the birth dose of hepatitis B vaccine within 12 hours of birth. See Table 4.1 for HBIG products and basic administration information. By the time effectiveness of the HBIG dose has waned, the infant's immune system should be producing its own anti-HBs antibodies to the hepatitis B virus in response to the vaccine. It is important that the infant complete the vaccine series on time to give them the best chance of developing immunity against the virus. See Table 4.2 for indications for HBIG use, based on the infant's birth weight and mother's testing results.



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**Table 4.1 HBIG Product Dosing Information for Perinatal Exposure**

<b>Product Name</b>	<b>Manufacturer</b>	<b>Perinatal Dosing</b>	<b>Presentation*</b>
HepaGamB	Cangene Corporation	0.5 mL	1.0 mL single use <i>vial</i>
HyperHEPB	Grifols	0.5 mL	0.5 mL single dose <i>syringe</i>
Nabi-HB	Biotest Pharmaceuticals	0.5 mL	1 mL single dose <i>vial</i>

\*As relevant only to perinatal administration

### Hepatitis B Vaccine

The hepatitis B vaccine is the best protection against HBV infection. In 1986, research led to a recombinant hepatitis B vaccine that was synthetically modified and did not contain any blood products. It was later licensed for use in the U.S. in 1989. This was the first vaccine licensed in the country that was produced by recombinant DNA technology. HBV infection cannot result from use of the recombinant vaccine, since no potentially infectious viral DNA or complete viral particles are produced in the recombinant system.

The hepatitis B vaccine is available as both a single-antigen formulation (monovalent vaccine) and in a fixed combination with other vaccines (combination vaccine). As of March 2000, all hepatitis B vaccines produced for distribution in the U.S. are thimerosal-free. See Table 4.2 for administration recommendations, based on the infant's birth weight and mother's testing results.

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**Table 4.2 Post-Exposure Prophylaxis (PEP) for Infants at Birth**

Infants weighing <u>at least</u> 2,000 g ( $\geq 4.4$ lbs.) born to...	
HBsAg-positive mother	
HBIG	Administer within 12 hours
Hepatitis B birth dose	Administer within 12 hours
HBsAg-unknown mother	
HBIG	If positive results are received, administer HBIG <b>immediately</b> .
	Administer HBIG prior to discharge or within 7 days, whichever is sooner. HBIG must be administered within 7 days of birth.
	If negative results are received before discharge, no HBIG needed.
Hepatitis B birth dose	Administer within 12 hours
HBsAg-negative mother	
HBIG	No HBIG needed
Hepatitis B birth dose	Administer within 24 hours
Infants weighing <u>less than</u> 2,000 grams ( $< 4.4$ pounds) born to...	
HBsAg-positive mother	
HBIG	Administer within 12 hours
Hepatitis B birth dose	Administer within 12 hours
HBsAg-unknown mother	
HBIG	Administer within 12 hours
Hepatitis B birth dose	Administer within 12 hours
HBsAg-negative mothers	
HBIG	No HBIG needed
Hepatitis B birth dose	Provider may defer to be given at 1 month of age, or at discharge if infant is released before 1 month

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### Importance of the Hepatitis B Vaccine Birth Dose

Hepatitis B vaccine was first recommended for administration to all infants in 1991 by the ACIP as the primary focus of a strategy to eliminate HBV transmission in the United States. The recommended timing of administration of the first dose of hepatitis B vaccine to infants has evolved since then to optimize prevention of perinatal and early childhood HBV infections. In 1991, the first dose was recommended to be administered at birth before hospital discharge or at age 1-2 months. This recommendation helped dramatically decrease the number of new hepatitis B infections among children in the U.S. One study found a 68% decrease in perinatal hepatitis B infections within 10 years of initiation of the universal birth dose. In January 2018, ACIP published recommendations to give the first dose of hepatitis B vaccine within 24 hours of birth for all stable newborns who weigh  $\geq 2,000$  grams ( $\geq 4.4$  pounds).

The CDC recommends that all infants born to HBsAg positive mothers, or mothers whose status is unknown, should receive the birth dose of hepatitis B vaccine at birth, regardless of birth weight. **All infants weighing less than 2,000 grams (4.4 pounds) at birth and who received the birth dose of hepatitis B vaccine should have the series reinitiated at  $\geq 1$  month of age. The birth dose should not be considered a valid dose as part of the series in these infants.** These infants will receive between four (4) and five (5) doses of hepatitis B vaccine, depending on the formulation of vaccine used after the birth dose.

Exceptions to the universal birth dose should be rare and considered on a case-by-case basis. Any healthcare provider who decides to delay the birth dose must document the order to do so and ensure that a copy of the mother's laboratory report, indicating she was HBsAg-negative during *this* pregnancy and at delivery, is present in the infant's medical record. **The birth dose should not be delayed in infants whose mother tested HBsAg-positive prenatally and/or at delivery.**

The hepatitis B vaccine birth dose serves as a "safety net" in the event that a mother was misdiagnosed as HBsAg-negative prenatally and/or at delivery. Children born to HBsAg-positive mothers who do not become infected during the perinatal period remain at high-risk of infection during early childhood. In one study, 40% of infants who were not infected perinatally became infected by the age of 5 years. Guidelines for standing orders in labor and delivery and nursery units to prevent hepatitis B virus

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transmission to newborns can be found in Appendix E of this manual and on the DSHS Immunization Section PHBPP website at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

### **Immunization Action Coalition (IAC) Birth Dose Honor Roll**

The universal birth dose policy is imperative as a safety net for infants who could be at risk for HBV. The Immunization Action Coalition (IAC) recognizes birthing facilities/hospitals that have reached high coverage rates of the Hepatitis B Birth Dose. These facilities are awarded and enrolled in the Hepatitis B Birth Dose Honor Roll. This impressive designation demonstrates the hospital's commitment to preventing HBV transmission.

To qualify for the Hepatitis B Birth Dose Honor Roll, a birthing facility/hospital needs to demonstrate that they achieved a rate of 90% or higher for administering the hepatitis B vaccine dose before hospital discharge to all newborns during a 12-month period. In addition, the facility/hospital needs to have written policies and procedures to ensure that all newborns are protected from HBV infection before hospital discharge. Examples of policies include, but are not limited to:

- Ensuring all parents are informed about the importance of the hepatitis B vaccine birth dose
- Ensuring all newborns routinely receive the hepatitis B vaccine after birth and before discharge
- Reviews of charts to ensure the correct screening test, HBsAg, was ordered for mothers during their current pregnancy
- Results of all mothers' HBsAg testing are reviewed
- Ensuring all infants born to HBsAg-positive mothers receive HBIG and hepatitis B vaccine within 12 hours of birth
- Implementing routine newborn admission orders that include a standing delegation order (SDO) to administer hepatitis B vaccine to all newborns
- Ensuring all mothers with a positive HBsAg are reported to the Local Health Department (LHD) prior to discharge

Texas has the highest number of birth dose honor roll enrollees in the nation! Many of these facilities/hospitals have also qualified for more than a one-time period. This notable achievement demonstrates the outstanding

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efforts of the state's birthing facilities/hospitals and perinatal hepatitis B case managers as they strive to improve health for all Texans.

For more information about the *Hepatitis B Birth Dose Honor Roll* and how to apply, visit: [www.immunize.org/honor-roll/birthdose/](http://www.immunize.org/honor-roll/birthdose/).

For the most current list of all the hospitals enrolled, visit: [www.immunize.org/honor-roll/birthdose/honorees.asp](http://www.immunize.org/honor-roll/birthdose/honorees.asp).

### **Vaccination Schedule and Use**

#### **Infants and Children**

Hepatitis B vaccination is recommended for nearly all infants within 12-24 hours of birth. Common formulations of the vaccine and their administration are:

- Engerix B® (GlaxoSmithKline)
  - 0.5 mL (10 mcg)/dose
  - Approved: 0–19 years of age
  - Three (3) doses – administered Intramuscularly (IM)
  - Schedule: Birth, 1-2 months, 6 months
- Recombivax HB® (Merck)
  - 0.5 mL (5 mcg) / dose
  - Approved: 0-19 years of age
  - Three (3) doses – administered IM
  - Schedule: Birth, 1-2 months, 6 months
- Pediarix® (GlaxoSmithKline): DTaP+Hep B+IPV
  - 0.5 mL (10mcg)/dose
  - Approved: 6 weeks – 6 years of age
  - Three (3) doses\* – administered IM
  - Schedule: 2, 4, 6 months
  - Should not be used for the birth dose

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\* It is important to note that although Pediarix® is approved as a three-dose series, children who receive Pediarix® on the appropriate schedule will receive four doses of the Hepatitis B vaccine, including the birth dose. This is safe and will not harm the child.

It is preferred that the same vaccine/manufacture be used for completion of a series. The FDA licenses combination vaccines based on their efficacy and safety when compared to monovalent vaccines. If the vaccine the child previously received is not immediately available, or is unknown, vaccination should not be delayed; the child should receive the available age-appropriate vaccine.

**Infants should not receive the final dose of hepatitis B vaccine prior to six (6) months of age.** If the third dose is inadvertently given before six months (24 weeks) of age, the dose should be repeated and administered once the child is at least 24 weeks of age.

Because the highest anti-HBs are achieved when the last two (2) doses of vaccine are spaced at least four (4) months apart, schedules that achieve this spacing are preferable. However, schedules with two-month intervals between doses (i.e., Pediarix®), which conform to schedules for other childhood vaccines, have been shown to produce good antibody responses and may be appropriate in populations where it is difficult to ensure that infants will be brought back for all their vaccinations. The minimum intervals for the hepatitis B vaccine schedule to produce a good antibody response in infants are as follows:

- The second dose should be administered at least four (4) weeks after the first dose.
- The third dose should be administered at least eight (8) weeks after the second dose.
- The third dose should be administered at least 16 weeks after the first dose.
- The third dose should not be administered any earlier than 24 weeks of age (6 months).

It is not necessary to add doses or restart the series if the interval between doses is longer than recommended. Doses administered too soon (before the minimum intervals noted above), should be re-administered using the correct interval. The minimum interval that should be used when a dose is

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administered too soon should be calculated from the incorrectly administered dose. For example, children who incorrectly received their third dose of the hepatitis B vaccine at age 5 months, should not receive the correct final dose until eight weeks after the wrong dose was given, meaning the child should not receive the correct/final dose until age 7 months.

Three (3) doses of the hepatitis B vaccine are required for students in Kindergarten-12<sup>th</sup> grade. Hepatitis B vaccine is also required for children to attend licensed childcare facilities. One dose for children 3-4 months, two (2) doses for children 5-15 months, and three (3) doses for all children 16 months of age or older.

### Pre-term and Low Birth Weight Infants

Pre-term infants born to HBsAg-positive women and women with unknown HBsAg status must receive PEP with the hepatitis B vaccine and HBIG within 12 hours of birth.

Pre-term infants and those with low birth weight (<2,000 grams or <4.4 pounds) have a decreased response to the hepatitis B vaccine when administered before 1 month of age. However, by 1 month of age, pre-term infants, regardless of initial birth weight or gestational age, are likely to respond as adequately as full-term infants. Therefore, pre-term infants or those born weighing <2,000 grams (<4.4 pounds) should restart the hepatitis B vaccine series at 1 month of age. Since the birth dose does not count toward completion of the hepatitis B series for these infants, they need to receive a total of at least four (4) doses of the hepatitis B vaccine. Although the birth dose is not considered a valid dose in the series for these infants, it is **imperative** that any infants born to mothers with either HBsAg-positive or HBsAg-unknown status receive the birth dose, in addition to HBIG, for the best protection.

If ordered by the physician, pre-term or low birth weight infants whose mothers tested as HBsAg-negative during this pregnancy and at delivery can defer the first dose of the hepatitis B vaccine series to 1 month of age. In this case, both of the mother's negative lab reports must be documented in the infant's chart by the ordering physician. These infants, if discharged from the hospital before 1 month of age, can also receive the hepatitis B vaccine at discharge if they are medically stable and have gained weight consistently. The full recommended dose should be used. Divided or reduced doses are not recommended.

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### **Vaccine Administration and Contraindications**

The hepatitis B vaccine can be given concurrently with other vaccines. Pregnancy and lactation are not contraindications to receiving a hepatitis B vaccination. The vaccine is to be administered intramuscularly (IM) in the anterolateral thigh or deltoid area, depending on age of the recipient. The choice of site is based on the volume of the injected material and the size of the muscle. In children younger than 3 years of age, the anterolateral aspect of the thigh provides the largest muscle and is the preferred site; the deltoid muscle can be used in children older than 12 months of age if the muscle mass is adequate. In children 3 years and older, the deltoid muscle is usually large enough for IM injection. The upper, outer aspect of the buttocks should never be used for vaccine administration because of diminished immunogenicity and the possibility of damaging the sciatic nerve.

### **Adverse Reactions**

The most common adverse reaction associated with the hepatitis B vaccine administration is pain at the injection site. Less frequent adverse reactions include fatigue, headache, irritability, and a fever greater than 99.9°F. There is no scientific data or evidence to show an association between the hepatitis B vaccine and sudden infant death syndrome (SIDS), multiple sclerosis (MS), autoimmune diseases, chronic fatigue syndrome, or autism.

### **Post-vaccination Serologic Testing (PVST)**

Post-vaccination seroprotection is achieved in 98% of healthy full-term infants who received a three- or four-dose HBV series; infants of low birthweight (<2,000 grams/<4.4 pounds) will generally have a lower seroprotection. Because not all infants will adequately respond to the hepatitis B vaccine series, it is important that all infants born to HBsAg-positive mothers, or mothers whose HBsAg status cannot be determined (e.g., safe surrender), be tested for vaccine response after completion of the series. This will ensure that an adequate immune response is reached.

Testing for immunity following hepatitis B vaccination is routinely recommended by the CDC for at-risk infants who are born to HBsAg-positive women or women whose hepatitis B status remains unknown. The guidance on timing of post-vaccination serologic testing (PVST) provided by the CDC indicates that the optimal time to collect PVST in infants who completed the vaccine series on time is at 9-12 months of age. For infants whose series



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was delayed, the PVST should be collected one to two months after completion of the series.

Please note, testing is not recommended before 9 months of age to avoid possible detection of anti-HBs passively transferred from the mother or from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection. **It is important to test for HBsAg and anti-HBs to determine the success or failure of vaccination.** It is important to keep in mind that testing delays after series completion can lead to false negative anti-HBs results.

Infants who completed the vaccine series on time at 6 months of age, should have PVST performed three (3) months after the final dose of the hepatitis B vaccine series has been administered to determine the success of PEP. This would ideally occur at the next well-child visit at 9 months of age.

Infants who were delayed or delinquent in completing the vaccine series should receive the PVST one to two months after completion, as long as the infant is at least 9 months of age. For example, an infant who did not receive their final dose of the hepatitis B vaccine until 8 months of age can still complete the PVST on time at 9 months of age, so long as at least 28 days has passed since the last vaccination. *Important note: Testing delays after series completion can lead to false-negative anti-HBs results.*

**Providers should not order a hepatitis panel when performing PVST, as it typically does not include testing for immunity, but rather only screens for acute hepatitis infection. Providers should order the individual serology markers, HBsAg and anti-HBs.** Refer to Chapter 5 for additional information on specific serology markers and their interpretation.

### Procedures for Ordering HBIG and Hepatitis B Vaccine

The HBIG and hepatitis B vaccine are costly and delicate biological products. Keeping a large inventory increases the risk for expiration. Review the expiration dates on the vaccines received and use the shortest-dated vaccines first.

Hospitals, pediatricians, and other medical providers may order HBIG and the hepatitis B vaccine directly from the manufacturer. Providers should contact the manufacturer for ordering instructions.

The Texas Department of State Health Services (DSHS) Public Health Regions (PHRs) and Local Health Departments (LHDs) must ensure in

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advance that the hospital has HBIG on hand when a positive HBsAg woman is planning to deliver at the facility to ensure administration of HBIG and hepatitis B vaccine birth dose to the infant within 12 hours of delivery. HBIG can be ordered by PHRs or LHDs from the DSHS Immunization Section on an emergency basis. See below for Ordering Instructions. The LHDs must order HBIG and hepatitis B vaccine through their DSHS PHR. Both biologics must be shipped to a DSHS PHR or LHD location.

### HBIG and Hepatitis B Vaccine Ordering Instructions from DSHS:

To order HBIG and hepatitis B vaccine for newborns, DSHS PHRs and LHDs must email the Texas Perinatal Hepatitis B Prevention Program (PHBPP) at [TxPeriHepB@dshs.texas.gov](mailto:TxPeriHepB@dshs.texas.gov) with the following information:

- **The Provider Identification Number (PIN)**
- **Clinic Days and Hours:** List the hours the clinic will be open to accept vaccine shipments for each day of the work week and note lunch period when no one is available to receive the vaccine. Be sure to note any holidays or clinic closings.
- **Contact Person:** Name of person that is physically present at the clinic to accept the shipment.
- **Phone:** Phone number of the contact person.
- **Clinic Address:** Provide complete name and address of clinic.
- **Pick from List:** Provide the vaccine needed and the vaccine formulation requested and the request for HBIG.
- **Order Amount:** Indicate number of doses needed.
- **Date of Order:** Date the order was completed.

Upon receiving a vaccine request, the DSHS PHBPP will forward the request to the Vaccine Management Group to submit the order in the Inventory Tracking Electronic Assets Management System (ITEAMS).

The order will be shipped via the DSHS Pharmacy Unit. The DSHS Pharmacy Unit ships orders on Monday, Tuesday, and Wednesday of each week. To meet shipping deadlines, orders must be received before 2:00 p.m. on these days. In the event of an emergency, please call the DSHS Immunization Section at (512) 776-7284 extension 0. For after-hours emergencies, call the DSHS emergency telephone number (512) 776-4911, ask for the

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physician on call, then give the physician the information concerning your emergency.

### Handling and Storage

Careful handling of hepatitis B vaccine and HBIG is extremely important. These procedures should be strictly followed:

- Transport only in insulated boxes with coolant to maintain proper temperature.
- Store biologics at 2-8°C (35-46°F). **DO NOT FREEZE**. Freezing destroys the potency of these biologics.
- Special care should be taken to avoid waste because of the high cost of the biologics. If biologics on hand are provided to your clinic by the Texas Vaccines for Children Program (TVFC) and are due to expire within 90 days, please contact your DSHS PHR or LHD for assistance in transferring the product.

Be sure to also refer to the package inserts for additional detailed storage and handling procedures.

If your vaccine is provided by the Texas Vaccines for Children (TVFC) Program, be sure to follow all TVFC Program requirements. For more information on TVFC Program Requirements and Vaccine Storage and Handling, please visit

[www.dshs.state.tx.us/immunize/tvfc/ProviderResources.shtm](http://www.dshs.state.tx.us/immunize/tvfc/ProviderResources.shtm).

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## Chapter 4: Learning Check

1. True or False: HBIG needs to be given to infants born to HBsAg-positive women within 12 hours of birth because they are too young for the Hepatitis B vaccine.

**Answer:** False! Both HBIG and the hepatitis B vaccine are given within 12 hours of birth in this case to help prevent perinatal HBV transmission. HBIG provides short-term protection against HBV that the infant may have been exposed to during birth. Because HBIG does not provide long-term protection, the infant must also receive the hepatitis B vaccine at birth and complete the vaccine series by 6 months of age.

2. Infants born to HBsAg-negative mothers should receive the Hepatitis B birth dose vaccine...
  - A. Before hospital discharge
  - B. At 1 month of age at their pediatrician's office
  - C. Within 24 hours of birth
  - D. Only if requested by the parents

**Answer:** C: The current CDC recommendation is to give the birth dose of the hepatitis B vaccine to all stable infants (weighing  $\geq 2,000$  grams/ $\geq 4.4$  pounds) within 24 hours of birth. All infants meeting the minimum weight should receive a birth dose, regardless of the mother's HBsAg status.

3. You are reviewing the vaccine history for an infant born to a HBsAg-positive woman and find that the infant has received the following vaccines:

Birth: Energix-B<sup>®</sup>

Two Months: Pediarix<sup>®</sup>

Four Months: Pediarix<sup>®</sup>

6 Months: Pediarix<sup>®</sup>

How do you interpret this vaccine history?

- A. The infant has completed the Hepatitis B vaccine series.
- B. The infant received an extra dose of Hepatitis B vaccine and there is a vaccine error.

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- C. The infant should repeat the Hepatitis B vaccine series since a different formulation was given after birth.

**Answer:** A: The infant has completed the Hepatitis B vaccine series. No additional doses are needed and, although infants who receive Pediarix® on the appropriate schedule will get four (4) total doses of the Hepatitis B vaccine; this is considered safe and is not a vaccine error.

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## **Chapter 5**

# **Serology Testing and Reporting**

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### Diagnostic Tests for Hepatitis B Virus

Diagnosis of hepatitis B virus (HBV) infection (acute vs. chronic) is based on clinical, laboratory, and epidemiological findings. HBV infection cannot be differentiated from types of viral hepatitis from clinical symptoms alone, and definitive diagnosis depends on the results of laboratory testing. Serologic markers of HBV infection vary depending on whether the infection is acute, chronic, or resolved. Commercial tests for hepatitis B, as summarized in Table 5.1, are widely available and are used for various clinical purposes:

**Hepatitis B Surface Antigen (HBsAg)** is the most commonly used test for HBV screening for infection. However, it does not differentiate between an acute and a chronic infection. HBsAg can be detected between one (1) and 12 weeks after exposure to HBV. The presence of HBsAg indicates that a person is infectious, regardless of whether the HBV infection is acute or chronic. If the infection is self-limited (an acute infection), HBsAg disappears in most patients within a few weeks to several months after infection. People with chronic HBV infection continue to have circulating HBsAg.

**Hepatitis B Surface Antibody (anti-HBs)** is a protective, neutralizing antibody. The presence of anti-HBs following acute HBV infection generally indicates recovery and immunity against reinfection. Anti-HBs can also be acquired as an immune response to hepatitis B vaccine or passively transferred temporarily by administration of HBIG.

**Total Hepatitis B Core Antibody (anti-HBc):** The presence of this marker indicates a current or past infection with hepatitis B. It is recommended that this test be ordered with HBsAg and Anti-HBs to determine if an individual has an ongoing or previous infection with hepatitis B.

**Hepatitis B “little e” Antigen (HBeAg)** is a marker associated with HBV infection and, when present, indicates active viral replication within the liver, higher concentrations of HBV, and high infectivity. Testing for HBeAg is useful in identifying candidates for antiviral therapy and to monitor therapy response.

**IgM Antibody to Hepatitis B Core Antigen (IgM anti-HBc):** The presence of this marker indicates a new hepatitis B infection (within the last six [6] months). A positive result indicates an acute infection.

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**Hepatitis B DNA (HBV DNA):** HBV DNA is one of the first tests that can detect HBV in the bloodstream after initial infection. It can be detected as early as one (1) week after infection. The amount of HBV DNA in the patient's blood indicates how fast the virus is replicating within the liver. This test measures the patient's viral load, or how much virus is present in the patient. High viral loads indicate rapid viral replication while low or undetectable levels indicate inactive infections. The Centers for Disease Control and Prevention (CDC) recommends all HBsAg positive pregnant women be tested for HBV DNA to guide antiviral therapy as needed.

Refer to Appendix D for additional CDC resources on ordering and interpreting hepatitis B serology.

**Table 5.1 Quick Reference for Ordering HBV Diagnostic Testing**

Factor	HBV Antigen or Antibody	Purpose	CPT Code
<b>HBsAg</b>	Hepatitis B surface antigen	Detection of acutely or chronically infected persons.	87340 Confirmatory test: 87341
<b>Anti-HBs</b>	Antibody to HBsAg	Identification of persons who have resolved infections with HBV; determination of immunity after immunization	Quantitative (preferred): 86317 Qualitative: 86706
<b>Anti-HBc</b>	Total Hepatitis B antibody	To determine a current or past Hepatitis B infection	86704
<b>HBeAg</b>	Hepatitis B e antigen	Identification of infected persons at increased risk for transmitting HBV	87350
<b>HBV DNA</b>	Hepatitis B DNA	HBV DNA measures the amount of HBV present. HBV DNA levels guide anti-viral therapy.	87517

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## Maternal Screening

According to Chapter 81, §81.090 of the Texas Health and Safety Code, providers who care for pregnant women are required to perform screening for hepatitis B at the first prenatal visit and at delivery. Providers should **not** select a viral hepatitis serology panel for testing; instead, they should select and order the individual hepatitis B serology markers. The serology markers are HBsAg, anti-HBs, and anti-HBc. The CDC also recommends that providers order an HBV DNA test for any pregnant woman who has a positive HBsAg result.

HBsAg screening should occur when other routine prenatal testing is done. The HBsAg test is widely available and can be added to the routine prenatal panel of tests without requiring additional patient visits. The advantages of routine HBsAg testing at the first prenatal visit are:

- determining early in the pregnancy if the mother is HBsAg-positive so HBV carrier status can be better established at the time of delivery
- determining HBV DNA viral load early in the pregnancy to guide antiviral therapy as needed
- ensuring that the infant receives appropriate and timely Post-Exposure Prophylaxis (PEP) immediately after birth
- providing appropriate counseling to families before delivery
- obtaining the name of contacts  $\leq 24$  months of age for case management
- referral of household contacts  $> 24$  months of age and sexual partner(s) to a health care provider for evaluation of susceptibility, vaccination status, and/or HBV infection

Hepatitis B identified prenatally and/or at time of delivery is a reportable condition in Texas, as outlined in Chapter §81.041 of the Texas Health and Safety Code within one (1) week of identification. All women identified as being HBsAg-positive while pregnant or at the time of delivery must be reported to their local or regional health department.

## Investigational Form

If maternal screening was not performed during pregnancy and/or at delivery, documentation of the reason(s) as to why the mother was not screened should be stated on the *Investigational Report* form. Specific training regarding the identified issues in lack of screening should be

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provided to the provider/delivery hospital by the Texas Department of State Health Services (DSHS) Public Health Region (PHR) or Local Health Department (LHD) office.

### **Medical Records**

Maternal HBsAg results, along with dates of testing, should be documented in all infant medical records. If HBsAg testing was not done prenatally or at delivery, it is the responsibility of the hospital and obstetrical care provider to ensure that the test is done before hospital discharge. If HBsAg results are positive, the hospital and obstetrical care provider are also responsible for administering the appropriate PEP to the infant in addition to reporting the positive result to the LHD as soon as possible, but no later than one (1) week after results are obtained.

### **Standing Delegation Orders (SDOs)**

Hospitals should develop written policies to ensure screening of all pregnant women and administration of PEP to all at-risk neonates. These policies should be assessed by the DSHS PHR and LHD each time the hospital receives training from the Perinatal Hepatitis B Prevention Program (PHBPP) case manager and any time there is a gap in HBsAg screening or PEP. These policies should include standing orders for the following key elements:

- Review prenatal HBsAg results of all pregnant women
- Test all mothers for HBsAg at each delivery
- Provide the first dose of the hepatitis B vaccine to all infants  $\geq 2,000$  grams ( $\geq 4.4$  pounds) at birth:
  - within 12 hours of birth for HBsAg positive mothers or mothers with unknown status, OR
  - within 24 hours of birth, regardless of mother's HBsAg status.
- Provide appropriate PEP\* (HBIG and birth dose of the hepatitis B vaccine) to all infants of HBsAg-positive mothers (prenatally and/or at delivery)
- If the mother's HBsAg status is unknown at the time of delivery, the mother's blood should be drawn as soon as possible to determine her HBsAg status. If positive, the infant should receive HBIG as soon as possible, but no later than seven days after birth\* and

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- Report all HBsAg-positive mothers to the DSHS PHR or LHD within one (1) week of identification.
- \* For additional guidance on PEP of infants born to women who are HBsAg-positive or HBsAg-unknown status, please refer to Chapter 4 of this manual.

## Serologic Testing of Infants and Children

### Pre-vaccination Serologic Testing

Serologic testing is not recommended before routine vaccination of infants and children, nor is it recommended for infants born to HBsAg-positive women immediately after birth. *See guidelines and recommendations below for the appropriate timing of serology testing of at-risk infants.*

### Serologic Testing for Immunity of Infants and Contacts ≤24 Months of Age

Testing for immunity following vaccination is routinely recommended for infants who are born to HBsAg-positive women. **These infants should complete PVST and be tested for infection (HBsAg) and immunity (Anti-HBs).** The CDC's recommendations and general guidance for PVST can be found in the January 12, 2018 Morbidity and Mortality Weekly Report (MMWR) titled *Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices*, accessible at <https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>.

The MMWR states that PVST should be done one to two (1-2) months after completion of the vaccine series. However, **testing is not recommended before age nine (9) months** to avoid possible detection of anti-HBs from HBIG administered during infancy and to maximize the likelihood of detecting late HBV infection. Therefore, infants who received their final dose of hepatitis B vaccine at 6 months of age must wait three (3) months for PVST to be done; ideally at the next well-child visit at nine (9) months to determine the success of PEP. It is important to test for both HBsAg **and** anti-HBs to determine the success or failure of vaccination, as up to five (5%) percent of infants may not respond adequately to vaccination.

**Important note: Testing delays after series completion can lead to false-negative anti-HBs results.**

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Providers should order the individual serology markers **HBsAg** and **anti-HBs**. Providers should not order a hepatitis panel when performing PVST, as it typically does not include testing for immunity, but rather only screens for acute hepatitis infection. Most commercial labs are able to add additional lab testing to existing specimens within a few days of specimen collection. Case managers can prevent additional lab draws by verifying serology orders within a few days of specimen collection and adding appropriate serology markers as needed.

For contacts  $\leq 24$  months of age, the same serologic testing (HBsAg and anti-HBs) should be done, at least one (1) month after the final dose of the hepatitis B vaccine series is completed, and as long as the child is at least nine (9) months of age.

### Post-Vaccination Serologic Testing Interpretation

**Table 5.3 Response to Infant Serologic Test Results**

Test Results	Interpretation	Action
HBsAg (-) Anti-HBs (+)	Immune due to vaccination	1. Notify the DSHS PHR or LHD 2. No additional action needed
HBsAg (-) Anti-HBs (-)	Susceptible / Non-responder	1. See guidance below 2. Notify the DSHS PHR or LHD
HBsAg (+) Anti-HBs (-)	Infant infected with Hepatitis B Virus	1. Notify the DSHS PHR or LHD 2. Provide education/counseling 3. Refer for evaluation

### Susceptible/Non-responder

The CDC recently updated its guidelines for at-risk infants who do not respond to the first hepatitis B vaccine series. Children that fail to respond to the first complete hepatitis B vaccine series need to receive a single dose of hepatitis B vaccine immediately and have PVST repeated one to two months later. Infants who have repeat anti-HBs  $< 10$  mIU/mL should receive the next two (2) vaccines in the series, followed by PVST 1-2 months after the final dose. Alternatively, providers and families may skip the booster dose of

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hepatitis B vaccine and repeat the entire three-dose vaccine series, followed by repeat PVST 1-2 months later. Single-dose revaccination has many advantages, including fewer vaccine doses, shorter duration of case management, and lower cost. Please see the January 12, 2018 MMWR titled *Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices*, accessible at <https://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm>, for more details.

Note that children who fail to respond to two (2) complete series of the hepatitis B vaccine are considered non-responders and parents/guardians should be counseled regarding susceptibility and prevention of virus transmission.

### Serologic Testing for Immunity on Contacts >24 Months of Age

Services are not provided through the PHBPP for contacts >24 months of age. These contacts should be referred to a provider for health care evaluation. Document the referral on the mother's case management form.

### Serologic Testing of Mothers with unknown HBsAg status

**Table 5.4 Testing Response to Mothers' Serologic Test Status**

Prenatal HBsAg Status	Delivery HBsAg Status	Action
Unknown	Unknown	Test for HBsAg immediately
Positive	Unknown	
Unknown	Positive	In six (6) months, patient should be referred for the following tests: HBsAg, anti-HBs, and anti-HBc.

Should the patient not have health insurance (or their health insurance is refusing to pay), serology testing for HBsAg, anti-HBs, and anti-HBc is provided by DSHS at no cost to the client.

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If the mother's HBsAg status is unknown at delivery, the mother, her infant, and contacts  $\leq 24$  months of age must receive appropriate case management until the mother's status is determined. If determined to be positive, case management services shall be continued until completion of the program. Contacts  $> 24$  months of age should be referred to a healthcare provider for testing and vaccination if susceptible. Additionally, the new MMWR states that PVST should be completed for any infants whose mother's HBsAg status remains unknown indefinitely (e.g., infants who are safely surrendered after birth).

### Discrepant HBsAg Results

Discrepant results occur when the mother's HBsAg tests during the current pregnancy yield conflicting results.

**Table 5.4 Hospital Response at Delivery to Mothers' Discrepant Serologic Test Status**

HBsAg Test Results	Prenatally	At Delivery	Hospitals
	Positive (+)	Negative (-)	<ul style="list-style-type: none"><li>• Administer HBIG and hepatitis B vaccine-birth dose within 12 hours of birth</li><li>• Report case to DSHS PHR or LHD</li></ul>
	Negative (-)	Positive (+)	

All infants born to mothers with discrepancies in their HBsAg test results should receive HBIG and Hepatitis B vaccine within 12 hours of birth. It is the role of the delivery hospital to administer appropriate PEP within 12 hours of birth to all infants born to mothers with discrepant HBsAg results and to report results to the DSHS PHR or LHD. Refer to Chapter 4 for further guidelines on PEP.

Any positive HBsAg result should undergo confirmation by neutralization. If the sample is confirmed, the result is considered positive for HBsAg. If the sample is negative upon confirmation, then the HBsAg is considered negative even though the preliminary result was positive.

It is necessary to gather more information when there are discrepant HBsAg results during the pregnancy. First, verify that the HBsAg positive result was



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confirmed by neutralization. Also, determine if the client had any prior testing or has received hepatitis B vaccines. Additionally, it is helpful to have providers order HBsAg, Anti-HBs, and Anti-HBc to help determine Hepatitis B status.

### **The Role of the DSHS Health Service Region (PHR) and Local Health Department (LHD)**

The LHDs must report the mother's discrepant HBsAg results directly to their DSHS PHBPP Coordinator using the *Mother Case Management Report* form **within one (1) week** of notification.

The *Mother Case Management Report* form should contain the following information:

- Name
- Date of birth (DOB)
- Country of birth information
- Type(s) of tests
- Laboratories that performed the tests
- Hepatitis B vaccination dates (if applicable)
- Type(s) of vaccines (if applicable)
- Other pertinent health information

**NOTE:** Cases can be opened and submitted using the *Mother Case Management Report* form with only the information the case manager currently has (e.g., with just name, DOB, and lab result). Case managers should not delay submitting cases due to limited information or while waiting to interview the client. The case management form can be updated with additional information as it comes available and re-submitted immediately to their DSHS PHBPP coordinator.

### **Case Management of Discrepant Hepatitis B serology results**

Case managers should ensure that six (6) months have passed between HBsAg-positive results to determine the mother's status.

Repeat testing should include HBsAg, Anti-HBs, and Anti-HBc to help determine status.

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Note that all cases should remain open, and follow-up of the infant and contacts  $\leq 24$  months of age should be continued, until the mother's status can be determined.

### **Hepatitis B Immunity Laboratory Parameters**

A positive anti-HBs of  $\geq 10$  mIU/mL indicates adequate immunity to hepatitis B. This immunity may be from either a past hepatitis B infection or a hepatitis B vaccination. After receiving a primary hepatitis B vaccine series, individuals with anti-HBs levels of  $\geq 10$  mIU/mL are considered protected and immune to the HBV, in accordance with CDC guidelines.

A negative result indicates a lack of recovery from acute or chronic hepatitis B or inadequate immune response to hepatitis B vaccination. Infants with a negative anti-HBs and a negative HBsAg should be revaccinated (refer to chapter 4 for details). The ACIP does not recommend more than two (2) hepatitis B vaccine series for non-responders.

Indeterminate results indicate an inability to determine if anti-HBs are present at levels consistent with immunity. Repeat testing is recommended in one to three (1-3) months.

Refer to Appendix D for Interpretation of PVST.

### **Inconclusive Laboratory Results**

Contact the reporting laboratory to clarify reports of inconclusive laboratory results, such as equivocal anti-HBs, and obtain appropriate follow-up instructions for re-testing. Contact the ordering provider to confirm which labs were ordered to help determine Hepatitis B status and check Hepatitis B vaccine history.

### **Reporting Sources**

One of the most difficult challenges for a PHBPP is obtaining reports of HBsAg-positive pregnant women. To have a successful reporting system, a PHBPP should have several overlapping sources of information to identify HBsAg-positive pregnant women. Three (3) main reporting sources are laboratories, prenatal care providers, and delivery hospitals. Additional sources for reporting may include:

- Midwife centers/home births,
- Pediatricians/Family Practices,

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- Planned Parenthood,
- Federally Qualified Health Clinics (FQHCs), and
- Rural Health Clinics (RHCs).

### **Laboratory Reports**

A primary reporting source for the PHBPP is the laboratory. Nationwide, there are 260,000 certified laboratories under the 1988 Clinical Laboratory Improvement Amendments (CLIA). The objective of CLIA is to ensure quality laboratory testing for all lab testing performed on humans, except for research purposes. Laboratory reporting is more consistent and reliable than provider reporting and is often automatic or electronic. Additionally, reporting by laboratories can be made a condition of licensure, but non-laboratory reporting sources require constant reminders and education.

Several problems may be encountered using laboratory reporting as a source of perinatal cases, including:

- Provider information, including contact information, may be omitted;
- Appropriate serology tests markers may not have been ordered; and/or
- Pregnancy status is often not indicated.

Having alternate reporting sources can compensate for the deficiencies or periodic problems that may occur in laboratory reporting. When information is missing on the electronic lab report (ELR), the reporting laboratory should be educated on the information that is required by law for reporting of certain conditions. Refer to Chapter 3 for information pertaining to the statutes and rules of reporting.

### **Labor and Delivery Hospital Reports**

The PHBPP also uses hospital reports to identify infants born to HBsAg-positive women. For a labor and delivery hospital to be an effective reporting source, it is necessary to educate the individuals responsible for determining a pregnant woman's HBsAg status, administering HBIG, and vaccinating the newborn. To achieve this, the program must collaborate with staff physicians, labor and delivery nursing staff, newborn nursery staff, pharmacy staff, and infection control staff. When possible, program assistance should be offered to develop hospital policies and procedures regarding screening and treatment standards that are reflected in Appendix E.

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The PHBPP staff should encourage reporting by making the process as easy as possible and by helping the collaborating facilities in identifying what works best for them (e.g., whether reporting will be done by nursing staff or by infection control staff). Hospital staff designated to identify, and report cases should either call to report a case or fax in the completed case report form: *Hospital/Provider Report of HBsAg-Positive Mother* (Stock #EF11-11015). This form is available at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

The PHR and LHD program staff are responsible for completing the paperwork on all cases that are reported by hospitals. Instructions and form samples can be found online at <https://www.dshs.texas.gov/immunize/perinatal-hepatitis-B/publications.aspx>.

Refer to flow charts located in Appendix C for the flow of information on serology testing and case management of HBsAg-positive women that must occur for the PHBPP to be successful.

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## Chapter 5 Learning Check

1. You are reviewing hepatitis B lab results for pregnant women. Which of the following lab results are you most concerned about?
  - A. A woman with a positive HBsAg, positive HBeAg, and a HBV DNA of 250,000 IU/ml.
  - B. A woman with a history of Hepatitis B vaccination and positive anti-HBs.
  - C. A woman with fatigue who is HBsAg-negative.

**Answer:** A. The positive HBsAg, positive HBeAg, and high HBV DNA viral load indicate a high level of circulating HBV and increased infectiousness. It is imperative this woman be educated, and that the delivery facility is prepared to administer appropriate PEP to her infant at delivery.

2. An infant born to a HBsAg-positive woman received three (3) doses of hepatitis B vaccine and completed PVST, with the below results. How do you interpret the results and what is your recommendation?

HBsAg: Negative

Anti-HBs: Negative

- A. The infant is not infected with HBV and is protected from the virus.
- B. The infant is not immune to hepatitis B and should be considered a non-responder.
- C. The infant is not immune to hepatitis B and should receive a booster dose of hepatitis B vaccine, followed by PVST 1-2 months after vaccination. Or, if preferred, the infant can repeat the entire three-dose series.

**Answer:** C. The infant did not respond to the first hepatitis B vaccine series and is susceptible. The infant should immediately receive a booster dose of hepatitis B vaccine and have PVST repeated 1-2 months later. Alternatively, the provider & family can decide to repeat the entire three-dose hepatitis B series and repeat PVST 1-2 months after the second series is complete.

3. A delivery hospital calls to ask for help in interpreting HBsAg lab results. A woman admitted for delivery was HBsAg-negative prenatally, but at her delivery HBsAg is now positive. What should the hospital do?

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- A. Repeat the HBsAg before discharge to determine hepatitis B status.
- B. The result is most likely a false positive and the hospital does not need to do anything else.
- C. The infant needs HBIG and the hepatitis B birth dose within 12 hours of birth and be reported to the appropriate DSHS PHR or LHD.

**Answer:** C. The positive HBsAg at delivery indicates a potential HBV infection that could be transmitted to the infant without appropriate PEP. This is true regardless of the prenatal HBsAg results. The PHBPP case manager can help determine true hepatitis B status by asking to see the results of the HBsAg confirmation by neutralization and by requesting other hepatitis B labs (anti-HBs, Anti-HBc, & IgM anti-HBc).

## **Chapter 6**

### **Conducting Interviews, Counseling, and Education**

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## Initialization of Interview

The client interview is crucial to the case management process. It includes educating the client patient on her condition and reassuring her that competent healthcare providers and public health staff will coordinate case management services for her, her infant(s), and her contacts  $\leq 24$  months of age. Contacts  $>24$  months of age will be referred to a provider for health care evaluation. In addition, the personal information that she shares with public health staff will be kept confidential, as required by law. The case manager should first verify with the ordering provider that the client has been informed of the positive HBsAg result prior to contacting the client. The case manager **should not** be the first person to inform the client of the positive results. When a case manager initially contacts the client, they should ask if the client has time to talk and, if she makes it known that it is an inconvenient time for her, the case manager should inquire about a more convenient day/time to reach her to conduct the interview. The initial interview must include the following:

- Introduction of public health staff
- Role of the public health staff and the public health department, including the Texas Department of State Health Services (DSHS) Public Health Region (PHR) or Local Health Department (LHD) office that will be managing her case
- Discussion with the client that her case managers are trained public health professionals and have experience assisting persons with hepatitis B in understanding and managing their disease
- Overview of hepatitis B, perinatal transmission, and the risks to her infant
- Review the Perinatal Hepatitis B Prevention Program (PHBPP), including the phases of the program and the timeframe of case management services provided by the program
- Discuss with the client that public health staff will ensure that her medical information remains confidential, as required by law

## Providing Patient Assessment, Counseling, and Education

The purpose for patient assessment and education is to establish rapport, get the client accustomed to talking comfortably with you, addressing the client's concerns, gathering information, and giving the client sufficient

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information to support disease intervention behaviors. Targeted medical information presented by the provider or program staff can reduce or eliminate inappropriate strategies the client may develop to handle the diagnosis. To conduct the assessment, the following should be done:

- First ask the client what she knows about hepatitis B.
- Provide information and education to the client regarding the disease, including:
  - Signs and symptoms of disease progression\*
  - Preventing progression of liver disease
    - Avoiding or limiting alcohol consumption
    - Consulting a healthcare provider before beginning any medicine, including herbal remedies and over-the-counter (OTC) medications
    - Obtaining vaccination against hepatitis A
  - Transmission\* and preventing transmission
  - Work and school exclusions are not necessary
  - Testing and treatment options
- Ask the client about problems or questions regarding hepatitis B and clarify any misconceptions.
- Discuss the meaning of the client's test result(s), and the possible need for additional testing. Give time to ask questions.
- Encourage the client to get involved with a support group to help her cope with her HBV infection.
- Explain that all household members  $\leq 24$  months of age will be tested for hepatitis B, vaccine will be given if there is no valid vaccine record, and the contact is susceptible. In addition, these contacts will be case managed by the PHBPP until the vaccination series and PVST have been completed (may require two (2) series of vaccine).
- Explain that all contacts  $> 24$  months of age should be referred to providers for medical evaluation.

\* More detailed information regarding transmission can be found in Chapter 2 of this manual.

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### **Supporting Program Compliance**

It is important that the client understands the importance of the hepatitis B vaccine series and PVST to prevent infection of her infant(s). The case manager should reinforce messages expressed by the healthcare provider and verify that the patient understands and intends to comply with the program. The case manager should:

- Instruct the client to remind the delivery facility and care providers that she is a carrier of the HBV and that her infant(s) needs to receive HBIG and the hepatitis B vaccine at birth.
- Educate the client regarding the importance for the newborn(s) and other children in the household  $\leq 24$  months of age to comply with timely completion of the hepatitis B vaccine series and subsequent PVST.
- Encourage the client to keep scheduled appointments and to notify the case manager when it is necessary to cancel or reschedule appointments.
- Encourage the client to contact the case manager with any changes to contact information or care providers (infant or mother).
- Obtain emergency contact information and complete disaster questionnaire. Ask if the client has any plans to move out of the state or out of the country during pregnancy or after delivery.

### **Providing Additional Patient Education Sources**

- A critical aspect of the PHBPP is patient education. It is extremely important that program staff thoroughly explain to HBsAg-positive pregnant women and new mothers the serious consequences of HBV infection (found in Chapter 2), the lifesaving importance that hepatitis B biologics (HBIG and the hepatitis B vaccine) be administered to their infants, and the necessity of PVST after completing the vaccine series.
- The DSHS Immunization Section PHBPP has developed educational materials for HBsAg-positive women and their healthcare providers. These materials can be found at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

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- The CDC and the organization Hep B Moms have information about hepatitis B and perinatal hepatitis B available to order for free or to download in many different languages from:
  - <https://www.cdc.gov/hepatitis/hbv/perinatalxmtm.htm#eduTools>
  - <https://www.hepbmoms.org/brochures>

### Concluding the Interview

- Ask the client what questions or concerns remain.
- Briefly review and reinforce all components of the PHBPP.
- Reinforce the need to communicate her HBsAg status to her household and recent sexual contacts and the need for a medical evaluation.
- Arrange for the next communication, if indicated.
- Remind the client to update the case manager if she changes providers or moves.
- Give the client contact information for you and a back-up.
- Provide culturally sensitive and easy-to-understand educational information on hepatitis B, along with your contact information in case she has any further questions for you.

**Tip:** To build a trusting relationship with the client, follow up within a week of your initial interview to answer any questions or address any concerns she may have. Make note of this in your case management notes.

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## Chapter 6 Learning Check

1. True/False: Conducting an interview with a hepatitis B-positive pregnant or postpartum woman is optional.

True or False?

**Answer:** False. The initial interview is a crucial part of case management. Attempts at contacting the woman for her initial interview should be done within seven (7) days of notification, but ONLY after the case manager confirms the woman has been informed of the results by the ordering provider.

2. All the following are ways to facilitate rapport during the interview **except**:
  - A. Identifying the woman's preferred language prior to the interview and using translation services as needed.
  - B. Introducing yourself and asking if this is a good time to talk before beginning the interview.
  - C. Demanding the client answer all questions immediately since you have other work to do.
  - D. Informing the client that all information will be kept confidential, as required by law.

**Answer:** C. Clients that refuse to answer questions should be respected but still case-managed using information from their provider and the delivery hospital. Case managers should ask the clients if it is a good time to talk before starting the interview, and be respectful of clients' time, language needs, and concerns for privacy.

3. True/False: One good way to start the interview process is to ask, "What do you know about Hepatitis B?"

True or False?

**Answer:** True. Some women may have chronic hepatitis B or have been previously enrolled in PHBPP and may not need as much education. Other women may have never heard of hepatitis B prior to their positive result and will need more details. It saves time and improves the interview process to tailor education for each individual client.

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# Chapter 7

## Case Management

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## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

### What is Case Management?

Case management is a systematic process to ensure disease prevention through coordination of medical services and education. Case management uses an organized and coordinated service delivery approach, tailoring individualized and specific services to the needs of the client to facilitate continued support. The goal of Perinatal Hepatitis B Prevention Program (PHBPP) case management is to prevent perinatal hepatitis B transmission. Case managers achieve this goal through active disease surveillance, providing education to clients and healthcare providers, coordinating interventions needed to prevent transmission, and ensuring appropriate testing to determine the outcomes of cases.

The Texas Department of State Health Services (DSHS) Public Health Region (PHR) and Local Health Department (LHD) office case managers should conduct case management for HBsAg-positive mothers, their infant(s), and household contacts  $\leq 24$  months of age. Case management activities should occur according to the PHBPP guidelines.

Case management in the PHBPP involves:

- Interviewing HBsAg-positive mothers and providing education and information (e.g., brochures, handouts, and online resources) on hepatitis B and the Perinatal Hepatitis B Prevention Program (PHBPP).
- Educating providers, facilities, contacts, and family members on hepatitis B and its prevention and control.
- Recommending that all women with chronic hepatitis B follow up with their primary care provider or specialist to monitor their hepatitis B.

**NOTE:** Case managers do not need to obtain a physical referral but do need to remind women of the importance of regular hepatitis B evaluation.

- Collecting contact information (sexual and household) for appropriate referrals.

There are varying degrees of case management and each case may require different levels of involvement from DSHS. If the mother decides to follow up with her private physician, this is acceptable and should be encouraged. However, the case manager still has the responsibility of gathering all medical information from the provider, such as dates of vaccine administration (if applicable) and serology testing results. There can be

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many challenges and obstacles to case management, such as refusal of services by the client. Any problems encountered, and efforts made to overcome those obstacles, should be documented in case management notes.

Some clients may prefer or require more direct services, which may involve home visits to administer vaccines or to draw blood for testing. These services are provided by the PHBPP at no cost to the client. Services that are available to the HBsAg-positive pregnant woman, infant, and contacts will be discussed further in this chapter.

The DSHS PHR PHBPP Coordinators should review all case reports for completion prior to submission to the DSHS Immunization Section PHBPP.

All current case management forms along with detailed instructions, can be found at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org). For additional guidance, contact your DSHS PHR PHBPP Coordinator.

### **Timeline for Management of Cases**

Upon receiving notification of a positive HBsAg result in a pregnant woman, timing is important to ensure the appropriate steps are taken to maximize the health and safety of both the mother and child. A general outline for when certain steps need to be taken is as follows:

#### **Immediately:**

- Contact the ordering provider to verify pregnancy status, get estimated due date (EDD) and planned delivery hospital.
- Verify client has been informed of hepatitis B status prior to contacting client.
- Contact client to interview or to set up a time for an interview.
- Send "Initial Provider Letter" to prenatal provider.

#### **Within one week of notification:**

- Open and submit mother case management form
  - Send in CMR within seven (7) days, even if interview is not done. CMR can be completed with all available information and updated after interview is complete.

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### **Within 15 days of notification:**

- Complete interview/ or attempts to make interview have been done and documented.
- Open and submit Contact Case Management form, as needed
  - Complete contact case management as needed until contact is closed.
- Send “follow up” letter to client after initial interview is completed.
- Create reminder to contact delivery hospital two months before EDD

### **Two months before EDD:**

- Contact the mother to check in. Confirm EDD and planned delivery hospital. Remind the mother to inform the hospital of her hepatitis B status and that the infant needs HBIG and the hepatitis B vaccine immediately after birth.
- Contact planned delivery hospital and inform them of the hepatitis B-positive client coming for delivery.
  - Confirm the hospital has HBIG and the hepatitis B vaccine available, standing delegation orders (SDOs) for administering the vaccines, and SDOs to test every woman admitted for delivery for HBsAg.
  - Remind hospital to complete the “Hospital Reporting Form” and send it to case manager after delivery.
- Update and submit “Mother case management form,” as needed.
- Set up reminder to check with delivery hospital one week after EDD.

### **Upon notification of delivery:**

- Review hospital reporting form and request additional information, as needed.
  - Make sure infant received appropriate Post-Exposure Prophylaxis (PEP). If infant did not receive appropriate PEP, contact facility to make plans to provide it and/or complete the “investigational report” and make plans to provide training.
- Update mother’s case management form, and open and submit infant case management form.
  - **Pay special attention to Low Birth Weight (LBW) Infants and infants who do not receive the appropriate PEP. LBW infants need to re-initiate the hepatitis B series at one (1) month of**

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**age. The birth dose does not count toward series completion.**

Infants that do not receive appropriate PEP, lag in program outcomes (PVST, completing the vaccine series on time) and may need more frequent follow-up.

### **Within 2 weeks of delivery:**

- Contact mother/guardian to say congratulations and obtain the infant's name and pediatrician.
- Send patient and provider reminder of the second hepatitis B vaccine dose.
- Set up reminder to contact both the provider and mother/guardian one week before next vaccine is due.

### **One week before the second hepatitis B vaccine dose is due:**

- Remind both the provider and the mother/guardian that the vaccine is due. Make note of next appointment. If the infant does not have an appointment, help the mother/guardian make one and offer Local Health Department (LHD) office/home-visit services, as needed.
- Ask provider to send a copy of the vaccine record after administration with the date of administration, formulation, manufacturer, and lot number.

### **Upon notification of second vaccine dose:**

- Review vaccine record and verify the dose. If there are any problems, immediately contact the provider.
- Update and submit the infant case management form.
- Set up reminder to contact both the provider and mother/guardian one week before the next vaccine is due.

### **One week before the third hepatitis B vaccine dose is due:**

- Remind both the provider and the mother/guardian that the vaccine is due. Make note of next appointment. If the infant does not have an appointment, help the mother/guardian make one and offer Local Health Department (LHD) office/home-visit services, as needed.

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- Ask provider to send a copy of the vaccine record after administration with the date of administration, formulation, manufacturer, and lot number.

### **Upon notification of 3<sup>rd</sup> Vaccine Dose:**

- Review vaccine record and verify the dose. If there are any problems, immediately contact the provider.
- Update and submit the infant case management form.
- Set up reminders to contact both the provider and mother/guardian one week before PVST is due.

### **One week before PVST due:**

- Remind both the provider and the mother/guardian that PVST is due. Make note of next appointment. If the infant does not have an appointment, help index case make one and offer LHD/home visit services as needed.
- Ask provider to send a copy of the lab results as soon as they receive them.

### **One day after scheduled PVST:**

- Contact ordering provider to ask for PVST results. If they have not yet returned, verify the provider ordered HBsAg (CPT code: 87340) and Anti-HBs (Quantitative CPT code: 86317).
- Review lab results. Verify correct labs were ordered and determine if the infant is immune, susceptible, or infected.
  - **If the infant is infected, report the infant to PHBPP within one working day.**
  - **If the infant is susceptible, contact the provider to discuss the booster dose and repeat testing protocol.** (See Chapter 7 for more information.)
- Update and submit case management report with a copy of the PVST lab results.
- If the child is immune, case management is complete. Notify the mother/guardian of the results and send “reminder of program completion”.

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## How to Manage Cases

### Assigning a Case to the Appropriate Jurisdiction by Federal Information Processing Standards Code

Determining case jurisdiction is done via Federal Information Processing Standard (FIPS) codes. FIPS codes can be found using the zip code or the patient's street address and city at: <https://www.zipinfo.com/cgi-local/zipsrch.exe>.

- Click on "County Name and FIPS code".
- Enter the zip code and click "Go".
- The FIPS code is displayed with the county name.

See Figure 7.1 below for help identifying results. For more information on FIPS codes for your jurisdiction, contact the DSHS Immunization Section PHBPP team at [TxPeriHepB@dshs.texas.gov](mailto:TxPeriHepB@dshs.texas.gov) or 800-252-9152.

**Figure 7.1 FIPS Code Look-up**

Mailing State	ZIP	County	FIPS
Name	Code	Name	Code
Austin TX	78756	Travis	48453

Are you looking for the ZIP code for a particular street address? If so, [click here](#).

**Search Again...**

For a valid ZIP code, find the city and state, plus:

☒ county name and FIPS code ☐ area code

☐ time zone ☐ latitude and longitude

☐ MSA/PMSA ☐ population

Enter a ZIP code or a city and state

Data Source: [ZIPLIST5 Product Line](#) July 2019

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### Assigning a Case Identification Number (PHBPP Use Only)

A new identification number (ID#) must be assigned to each pregnancy by program staff at the DSHS PHR or LHD level. This information should be documented in the top right corner of all case management forms.

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The format for the ID# is: *yr/county/mother/hh##*, and is assigned as following:

- **yr:** The four-digit year the client was first identified in the PHBPP (i.e., 2019).
- **county:** The three-digit FIPS\* county code.
- **mother:** The three-digit individual code, as assigned by the case manager (this is a chronological number unique to every individual).
- **hh##:** The two-digit number identifying the relationship to the mother. The mother's ID must end with "00".
  - Infant: 01-09 (based on current pregnancy only)
  - Contacts  $\leq 24$  months of age:  $\geq 10$

### Examples of client identification (ID) numbers:

- 2014/000/001/00 – mother (index case)
- 2014/000/001/01 – infant born to HBsAg-positive mom
- 2014/000/001/10 – first contact  $\leq 24$  months of age
- 2014/000/001/11 – second contact  $\leq 24$  months of age

### The Initial Record

Upon opening a case, the mother's case management form should be filled out with all available information and submitted to the DSHS PHR PHBPP Coordinator **within one (1) weekday**. All forms can be found online at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org). When initially submitting the form, the **required information** for opening a case is:

- Case identification (ID) number
- Initial report date
- Initial contact date
- Mother's full name
- Mother's DOB
- Mother's address
- Provider information (name and contact info)
- Estimated Date of Delivery/Estimated Due Date (EDD) *or* infant DOB and pregnancy outcome
- HBsAg-positive lab report with confirmation

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Requested information that may be gained from the client interview, but not required for the initial submission of the form to open a case, is:

- Phone number
- Country of birth
- Mother's maternal grandmother's country of birth
- Planned delivery hospital
- Race
- Preferred language
- Insurance information
- Alternate contacts
- Disaster Questionnaire
- Vaccine history as applicable
- Prior hepatitis B lab results

### Contacting the HBsAg-Positive Pregnant or Postpartum Woman

Establishing contact and developing a trusting relationship with the HBsAg-positive client is critical and is the first step in the case management process. She should be contacted as soon as possible following identification, preferably by phone.

**Important note:** The case manager **should not** be the first person to inform the client of the positive results. Contact the provider **first** to determine whether they have notified the client and provided any counseling or education. If they have not, request they notify her of the results and that the DSHS PHR or LHD will be contacting her to follow up. Call the provider again later to verify it has been done.

To establish a trusting relationship with the client, advise her that all information she provides will be kept confidential, as required by law. If the client is reluctant to provide information, the physician's office can be contacted to provide additional needed information. Remember, **client consent is not required to obtain laboratory confirmed HBsAg test results from the provider.**

If you are encountering challenges while attempting to contact the client for case management services, refer to Table 7.1 on pages 133, 134, and 135 for related actions.



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### Best Practices:

- Notification(s) may be in any of these forms:
  - Phone call(s), with messages if there is no answer – *preferred method*,
  - Letter(s) sent to parent(s), and
  - Computer/phone system that automatically calls or texts patients.
- Remind parents and provider one (1) week before immunization visit(s).
- **Contact provider within one (1) day after scheduled appointment to ensure that patient received necessary vaccine(s)/PVST.**
  - Verify the provider ordered the correct PVST labs and ask them to correct the lab orders, as needed. Many labs can add testing to existing samples within five (5) days, to prevent additional lab draws.
- **If the appointment is missed, contact parent(s) immediately to arrange for a follow-up visit or a home visit.**

**Table 7.1 Challenges Contacting the HBsAg-positive Mother**

Challenges Contacting the HBsAg-positive Mother	
Challenge	Follow-up Action
No answer of telephone calls.	Make at least five (5) attempts to call on different days of the week, at different times of the day. If possible, attempt at least one (1) evening call.
Telephone number is disconnected.	Contact the provider to verify contact information. Inquire how they have been contacting her. Check Immtrac2 and NEDSS for other possible numbers. If no new number can be obtained, a first-class letter should be sent to the client's home address. It should include contact information and request the client contact case management directly regarding a recent health issue (do not disclose HBsAg results in letter).

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<b>Challenges Contacting the HBsAg-positive Mother</b>	
<b>Challenge</b>	<b>Follow-up Action</b>
No response to first-class United States Postal Service (USPS) letter.	Send a certified letter, signature required, to the client's home address. It should include contact information and request the client contact case management directly regarding a recent health issue (do not disclose HBsAg results in letter).
Certified letter returned with "Forwarding Address Requested" stamp.	Send a certified letter, signature required, to the client's forwarding address. It should include contact information and request the client contact case management directly regarding a recent health issue (do not disclose HBsAg results in letter).
No response after certified letter sent to forwarding address.	Attempt to visit the last known residence to conduct a home visit and provide education. Know the patient's preferred language or arrange for interpretation.
Unsuccessful home visit/no one home.	Work directly with the provider's office to manage the case. Request the provider educate the client on the importance of the case manager's role in preventing transmission of the virus to her infant.
Inability to contact client after exhausting all above options.	Do not close as "lost to follow-up." If the patient cannot be contacted, but you have an EDD and planned delivery hospital, attempts must still be made to locate the infant around the time of delivery. More information may become available after delivery (e.g., Vital Statistics records).
Client moved to a known address in another jurisdiction/state.	Obtain accurate location information, complete the appropriate transfer form and submit to the DSHS Immunization Section, PHBPP Central Office. PHBPP will forward the transfer information to the new jurisdiction. All out-of-state transfers should be sent to Central Office for the coordinator to transfer.

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Challenges Contacting the HBsAg-positive Mother	
Challenge	Follow-up Action
Client moved to an unknown address in another state.	Contact Central Office for assistance. They will attempt to coordinate with the new state for the new address and transfer of case. If the new address is unable to be identified and the client cannot be located, the new state may not accept the transfer. The case is then closed as "Lost to follow-up".

Other methods that may be used to locate the client include:

- Check ImmTrac2 to check for additional/updated demographic information and to find current pediatric provider.
- Contact the post office to see if there is a forwarding request for the client.
- Make a home visit to the last known address, if there is no response to certified letters.

**NOTE:** Find out from the provider what the patient's preferred language is and arrange for interpretation, if needed, to avoid any barriers when first contacting the patient.

- Check NEDSS for new labs or demographic information and/or contact the laboratory providing the test results for contact information on the patient.
- Access Accurint, an online searchable database available to law enforcement, and government agencies. Accurint includes postal addresses, driver's licenses, property ownership, and criminal records. To use this database, you must request the assistance of DSHS PHR or LHD Sexually Transmitted Disease (STD) program staff.
- Contact Medicaid and WIC programs, as up-to-date addresses are required for these services.

**A case cannot be closed as 'lost to follow-up' until all avenues have been exhausted.** Additionally, the patient must no longer be receiving any known services from an OB/GYN due to the physician's inability to locate or contact the client for services, however, if the patient cannot be contacted but you have an EDD and a planned delivery hospital (from client or

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physician), attempts must still be made to locate the infant around the time of delivery before the case can be closed.

After the EDD has passed and the planned delivery hospital does not have record of the birth, contact Central Office PHBPP staff to see if the mother/infant's birth hospital or contact information can be located in Vital Statistics records.

### Patient Education

A critical aspect of the PHBPP is patient education. It is extremely important that PHBPP staff explain to HBsAg-positive pregnant women and new mothers about the serious consequences of HBV infection (refer to Chapter 2), the lifesaving importance of hepatitis B biologics (HBIG and the hepatitis B vaccine) being administered to their infants, and the necessity of PVST after completing the vaccine series. The DSHS Immunization Section PHBPP has developed educational materials for HBsAg-positive women and their health care providers. Materials can be found at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

### Case Management of HBsAg-Positive Pregnant and Postpartum Women

Each DSHS PHR and LHD staff involved with the interviewing of clients should explain the services provided by the PHBPP and assure the client that her medical history (including her household contacts  $\leq 24$  months of age) will be handled confidentially by the PHBPP staff. Complete the *Mother Case Management Report* (Stock # EF11-10932), which can be accessed at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org). It should be completed and submitted within **one (1) week** to the DSHS PHR PHBPP Coordinators for review who will submit the completed forms by email to [TxPeriHepB@dshs.texas.gov](mailto:TxPeriHepB@dshs.texas.gov) (preferred) or by fax at 512-776-7544.

Every time the form is updated, it should be **immediately submitted** to the DSHS PHR PHBPP Coordinator who will send to the DSHS Immunization Section PHBPP Database Manager. The procedures outlined below should be followed when a pregnant or postpartum woman is identified as HBsAg-positive. You may receive the report from the provider, the laboratory, or through National Electronic Disease Surveillance System (NEDSS).

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1. Contact the provider first to obtain the following information\*:
  - OB/GYN medical records
    - HBsAg lab result(s) with positive confirmatory test
    - Any additional hepatitis B lab results
    - EDD
    - Planned delivery hospital
    - Vaccination history (if available)
    - Pregnancy history (if applicable)
    - Treatment(s) and/or medication(s) for hepatitis B
    - Any referrals to specialist(s) for hepatitis B
2. Face sheet showing patient's contact and insurance information.

**NOTE:** Occasionally, the LHD will be notified of new hepatitis B-positive woman by a delivery hospital. Request the hospital complete the *Provider/Hospital Report of HBsAg-Positive Mother* (Stock # E11-11015), which can be accessed at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org), the delivery lab, and the name of the prenatal provider. Contact the prenatal provider to obtain all information listed above.
3. Verify that the provider has notified the client of her positive HBsAg result. Establish the client's preferred language before contacting her. Utilize translation language services when appropriate.
4. Contact the client to obtain pertinent medical history, personal information, and type of insurance (Medicaid, private insurance, no insurance). All efforts should be made to obtain patient insurance information, otherwise, the reason for not obtaining the insurance status should be documented.

**Tip:** *Insurance information is normally noted on the "face sheet," obtained from the client's provider*

5. Educate the client about HBV, communicability of the virus, and the importance of protecting her infant from HBV transmission using HBIG and the hepatitis B vaccine.

**Tip:** *HBV education regarding routes of HBV transmission should be done prior to requesting information on all sexual partners and household contacts.*

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6. Services that will be provided by the DSHS PHR and/or LHD should be explained to the client and, if needed, a face-to-face visit should be arranged. If the client is unable to travel to a DSHS PHR or LHD, the PHBPP staff can conduct home visits to provide these services, in accordance with their LHD policies.
7. Provide patient educational brochure to the client, the bilingual *Hepatitis B Vaccine Can Save Your Baby's Life Brochure*, (Stock # 11-11444), available through the DSHS Immunization Section PHBPP at <https://secure.immunizetexasorderform.com/default.asp>. Ensure that all educational materials are provided in a culturally sensitive manner.

**Tip:** The group *Hep B Moms* has hepatitis B and perinatal hepatitis B information available in many different languages and available free on their website at: <https://www.hepbmoms.org/brochures>.

8. Refer the HBsAg-positive pregnant woman to her usual healthcare provider (PCP or OB/GYN) if she needs a referral for additional hepatitis B care.

**NOTE:** The healthcare provider or OB/GYN might refer the HBsAg-positive pregnant woman to a Gastroenterologist, Hepatologist, or an Infectious Disease Specialist. Her case should continue to be managed, regardless of which specialty is following her.

- If the HBsAg-positive pregnant woman receives antiviral medications for hepatitis B, document the following information on her case management report:
  - treatment or antiviral agents (brand and dose)
  - date antivirals were initiated
- 9. Notify the client's healthcare provider (or other specialty provider) of the role of the DSHS PHR and/or LHD, including the case management services, that will be provided to the newborn and household contacts ≤24 months of age.
- 10. Complete and submit the *Mother Case Management Report* to the DSHS PHR PHBPP Coordinator **within one (1) week**. This form is available at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

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11. Identify all household contacts who are  $\leq 24$  months of age, sexual partner(s), and household contacts  $> 24$  months of age.
  - PHBPP Case Management services should be provided for all household contacts  $\leq 24$  months of age.
  - All sexual partners and contacts  $> 24$  months of age should be referred to a healthcare provider for follow-up and evaluation. Adult contacts without health insurance who are found to be susceptible to hepatitis B can be vaccinated through the Adult Safety Net (ASN) Program. Susceptible children may be eligible for Texas Vaccines for Children program. Please contact your DSHS PHR or LHD for additional information.
12. After the initial interview with the pregnant woman, direct program involvement with her may be minimal. However, because the client may be newly diagnosed, program personnel should remain available to offer counseling or advice and to answer any questions or concerns she may have.
13. If possible, notify the delivery hospital where the client plans to deliver her infant(s) **at least two (2) months prior** to her estimated date of delivery.
14. Ensure that the hospital has both HBIG and hepatitis B vaccine available in advance, **at least seven (7) days before her estimated date of delivery**.
15. Review with the Newborn Nursery their standing orders and written policies pertaining to both the administration of HBIG and hepatitis B vaccine birth dose, and the testing of the infected mother for HBsAg on delivery.
16. Periodically contact the hospital (delivery unit or newborn nursery) to determine whether the mother has yet delivered.
17. Once the infant has been born, complete and submit the initial *Infant Case Management Report* within **15 days of the infant's birth** to the DSHS PHR PHBPP Coordinator. The form is available at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

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**NOTE:** Case management on HBsAg-positive women with a stillbirth or miscarriage will still be case managed by the program, however, they should be referred to a healthcare provider for healthcare to delay further injury to the liver. The case management report is coded as “referred to medical follow-up,” and the status code is noted as “infected.”

### **Provider Education**

Patients with acute and chronic HBV infections require medical evaluation and regular monitoring. PHBPP case managers should refer all HBsAg-positive pregnant women to medical providers for supportive and/or therapeutic treatment to prevent the progression of liver damage. PHBPP case managers do NOT need to get a physical referral, but only need to educate the client to follow-up with their specialist or primary care physician for regular monitoring. If they are not already familiar in doing so, the provider should also be educated as to:

- interpretation of serology results (refer to Appendix D)
- monitoring patients for disease progression and prevention
- identifying the need for specialized consultation

If the pregnant woman’s infection has been verified as being chronic, the PHBPP staff should identify available medical resources for chronic hepatitis B infections and ensure the medical providers are knowledgeable about risk factors for HBV infection in pregnant women, their infants, sexual partners, and household contacts. If needed, staff should provide training to the providers. Pregnant women, infants, sexual partners, and household contacts >24 months of age should be referred to a FQHC or a RHC for appropriate medical management if they do not already have a healthcare provider.

### **Client and Provider Reminders**

Due to the critical need to complete the hepatitis B vaccine series and PVST on time, reminders are required to remind parents as to when vaccinations and serology testing for their infants are due. It should never be assumed that parents will use effective methods of reminders for themselves, and physicians’ offices should not be relied on for notification of appointments. To be effective, the system should be set up to make it easy to remind the



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coordinators, who can then notify clients, when an immunization or test is due. Notifications to parents and providers should occur at least one (1) week prior to any hepatitis B vaccine and/or PVST due dates.

### **Case Management of Infants Born to HBsAg-Positive Women**

Case management of infants born to HBsAg-positive women can be labor intensive. Adequate case management should require no more than nine (9) months to complete perinatal hepatitis B prevention case management services once the infant has been born. (Refer to Guideline 3 in Appendix C.) For children who do not adequately respond to the vaccine series and who are also not infected with HBV, case management services may take up to 17 months to complete. Infants born to women whose hepatitis B status remains unknown indefinitely (e.g., safe surrender) also need to be case managed to ensure they receive the hepatitis B vaccine series and PVST.

1. It is imperative that the case manager inform labor and delivery staff at the planned delivery hospital of the woman's HBsAg-positive status at least two (2) months prior to her expected delivery date.
  - Staff should ensure that the delivery hospital has both HBIG and hepatitis B vaccine ready for administration to the newborn immediately after delivery, to be given within 12 hours.
  - Hospitals should order HBIG and hepatitis B vaccine directly from the distributor. HBIG can be ordered through the DSHS Immunization Section only in emergency situations. Refer to guidelines provided later in this chapter.
2. Appropriate Post-Exposure Prophylaxis (PEP) treatment should be administered, based on the mother's HBsAg status:
  - Born to HBsAg-positive woman:
    - Administer HBIG within 12 hours.
    - Administer first dose (birth dose) of hepatitis B vaccine within 12 hours.
  - Born to HBsAg-unknown status woman:
    - Administer first dose (birth dose) of hepatitis B vaccine within 12 hours.
    - If mother's hepatitis B status is still unknown at discharge, administer HBIG before discharging infant.

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- If HBIG was not given before discharge and the HBsAg result later comes back as positive, administer HBIG no later than seven (7) days after delivery.
  - If the infant has already been discharged, it is the delivery facility's responsibility to recall the infant and administer HBIG as soon as possible.
- Born to a woman with discrepant prenatal and delivery HBsAg results:
  - If **any** HBsAg test has been positive, administer:
    - HBIG within 12 hours
    - First dose (birth dose) of hepatitis B vaccine within 12 hours

**NOTE:** Infants born to HBsAg-positive women do not need placement in special isolation. (For additional guidance on PEP and vaccine schedules, refer to Appendix B.) It is generally safe for HBsAg-positive mothers to breastfeed their infants. For additional information, refer to the Perinatal Transmission section in Chapter 2.

3. The case manager should obtain all necessary information below about the first dose of the HBIG and Hepatitis B vaccine from the delivery hospital.
  - Lot number
  - Manufacturer/Brand
  - Dose
  - Date and time of administration
4. Information should be documented on the *Infant Case Management Report* (Stock # EF11-10931) which can be found at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org). The form must be completed and submitted **within 15 days** of infant birth to the DSHS PHR PHBPP Coordinator for review, who must submit the *Infant Case Management Report* by either email to [TxPeriHepB@dshs.texas.gov](mailto:TxPeriHepB@dshs.texas.gov) (preferred) or by fax to 512-776-7544.
5. Before the infant leaves the hospital, discharge planning should begin. The case manager should find out from the delivery hospital which pediatrician the infant is being discharged to. Once that information is

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known, arrangements should begin to ensure the timely administration of the second and third doses of hepatitis B vaccine.

6. Reminders should be sent to the family and pediatric healthcare provider to notify them when vaccines and PVST are due. For additional information, please refer to the earlier *Client and Provider Reminders* section of this chapter.
7. The infant should complete the hepatitis B vaccine series on time.
8. Dose #2: at 1 month of age (no later than 2 months of age).
9. Dose #3: at 6 months of age.
  - Refer to Appendix B for further guidance on vaccine schedules. The infant should be vaccinated through his/her pediatrician. If the child is unable to be vaccinated by the pediatrician, the case manager should arrange with the DSHS PHR PHBPP Coordinator and/or the DSHS Immunization Section to obtain the vaccine. Infants born to HBsAg-positive mothers can receive DSHS Immunization Section-supplied vaccine, even if they receive health care in the private sector.
10. The immunization information should be obtained from the infant's healthcare provider and be documented on the *Infant Case Management Report form*. If the parents consented to ImmTrac2, vaccine information can also be obtained from this system. Every time the form is updated, it should be **immediately submitted** to the DSHS PHR PHBPP Coordinator who will send to the DSHS Immunization Section PHBPP Database Manager. Information to be documented:
  - date administered,
  - dose administered,
  - formulation (ie., Pediarix<sup>®</sup>, Engerix-B<sup>®</sup>, Recombivax HB<sup>®</sup>, etc.),
  - manufacturer,
  - lot number, and
  - provider/clinic that administered the dose.
11. Contact the parent or guardian by phone or mail to remind him/her about PVST at the child's 9-month wellness visit.

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12. Results of the PVST is needed to determine the success of PEP.

- **Perform no earlier than 9 months of age**
- **Perform at least one to two (1-2) months after completion of the hepatitis B vaccine series**
- Two lab tests are required:
  - HBsAg, CPT Code: 87340
  - anti-HBs, CPT Code: 86317

- Test at the 9-month-old well-child visit, if all doses of the vaccine were completed at least one to two (1-2) months prior.

**NOTE:** Request that the provider annotates and flags the child's medical record to indicate that the PVST (HBsAg and anti-HBs) is due at the next well-child visit (see guidance above for timing). If an appointment date has not yet been scheduled, also follow up with the parent or guardian to schedule an appointment with the provider.

**NOTE:** Follow up with the provider one (1) day after the appointment for PVST is scheduled to verify the child attended and that the correct lab tests were ordered. If ordered incorrectly, many laboratories can add the correct testing to existing specimens for up to five (5) days to prevent needing to do additional blood draws on the infant.

- A release of information is not needed from a parent or guardian to request that the provider perform PVST on the infant. Hepatitis B, identified prenatally or at delivery, is a reportable condition and is protected under Texas statutes and rules. Because of the significant health risks posed to the infant if proper care is not obtained, a release of information is not required to provide this information to the infant's care provider. Ideally, the hospital and/or DSHS PHR or LHD should notify the infant's care provider immediately after birth.
- PVST is not recommended before the age of 9 months to avoid possible detection of anti-HBs from HBIG administered during infancy, and to maximize the likelihood of detecting late HBV infection. **Quantitative antibodies for surface antigen are preferred because they give a level of immunity with which to measure the immunity of the infant.** Anti-HBc testing of infants is not recommended because passively acquired maternal

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anti-HBc may be detected up to age 24 months in infants born to HBV-infected mothers.

13. The results of the tests should be recorded on the *Infant Case Management Report form* and the form should be **immediately submitted** to the DSHS Immunization Section PHBPP, along with a copy of the infant's results.

### Perinatal Hepatitis B Virus Infection Case Definition

Perinatal hepatitis B infection in infants ages 1-24 months is a nationally notifiable condition, and Texas is required to report all cases to the CDC. **These cases are reported through NEDSS AND PHBPP.** The case definition for perinatal hepatitis B virus infection is HBsAg positivity in an infant aged 1-24 months, or an infant aged 9-24 months who is positive for HBeAg or HBV DNA, born in the US or US territories to a hepatitis B-positive mother. An infant who is determined to be HBsAg-positive will be classified as a case of perinatal hepatitis B virus infection. Perinatal hepatitis B infection in the newborn may range from asymptomatic to fulminant hepatitis. All laboratory-confirmed perinatal hepatitis B virus infections must be reported to the DSHS through NEDSS and through the Perinatal Hepatitis B Program. It is the responsibility of the DSHS PHR and LHD program staff to obtain a copy of the laboratory report, update the *Infant Case Management Report form*, and submit both forms to the DSHS Immunization Section PHBPP Coordinator **within one (1) working day of notification.**

### CASE MANAGEMENT OF CONTACT(S) $\leq 24$ MONTHS OF AGE TO HBSAG-POSITIVE PREGNANT WOMEN

Household contacts are defined as persons  $\leq 24$  months of age currently residing in the home of the HBsAg-positive pregnant woman. Household contacts  $> 24$  months of age and sexual contacts are not eligible for the program and should be referred to a healthcare provider. The *Contact  $\leq 24$  Months Case Management Report form* should be completed for all contacts identified who are  $\leq 24$  months of age, and case management should be completed.

These case management procedures should be followed when a contact  $\leq 24$  months of age is identified as born to a positive HBsAg mother.

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- 1) Educate parent/guardian on the consequences and risks of HBV infection.
- 2) Complete the *Contact ≤24 months of age Case Management Report* Form (Stock # EF11-10934) for each contact ≤24 months of age identified **within 15 days** of identification. This form, along with the instructions, is available at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).
- 3) Obtain vaccine and serology history on all contacts ≤24 months of age. A reliable vaccination history for each dose administered to complete the hepatitis B vaccine series should be obtained, if applicable. Serology history consists of a written and dated laboratory report; verbal reports are not acceptable. Case management is initiated based on vaccine results and serology history.
  - If contact ≤24 months of age has no documentation of immunity by serology, the contact should be tested for HBsAg and anti-HBs. Once the results are obtained, follow guidance identified on Chart 7.2. HBsAg-positive results must have confirmatory testing performed.

**Chart 7.2 Actions after First PVST Results**

Actions After First PVST Results			
HBsAg	Anti-HBs	Status	Action
Negative	Negative	Susceptible	Proceed to Step # 4 below
Negative	Positive	Immune	Submit form and documentation to DSHS PHR PHBPP Coordinator
Positive	Negative	Infected	Refer to physician for follow-up and evaluation

- 4) If needed, ensure initiation and completion of the hepatitis B vaccine series. If the contact is susceptible after a complete hepatitis B vaccine series, give a booster dose of the hepatitis B vaccine and then repeat PVST 1-2 months later. If the contact is still susceptible after the booster dose, give dose 2 and 3 of the second Hepatitis B vaccine

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series and then repeat PVST 1-2 months later. Alternatively, the provider and family can choose to not do a booster dose and just repeat the entire three-dose hepatitis B vaccine second series, with PVST repeated 1-2 months after the last vaccine. The CDC does not recommend further vaccination after completion of two (2) complete hepatitis B vaccine series. These “non-responders” should be referred to their physician for follow up.

- 5) All updates to the *Contacts ≤24 months of age Case Management* form should be **submitted immediately**. DSHS PHR PHBPP Coordinators must submit reports to the DSHS Immunization Section PHBPP Coordinator.
- 6) Perform PVST 1-2 months after completing the vaccine series to determine if adequate protection has been achieved with one (1) complete series of vaccine, keeping in mind that PVST should not be done before 9 months of age. Refer to Chart 7.3 for relevant actions for each type of PVST result.

**Chart 7.3 Actions After Second PVST Results**

Actions After 2nd PVST Results6.0			
HBsAg	Anti-HBs	Status	Action
Negative	Negative	Susceptible / Non-responder	Provide counseling and refer to provider
Negative	Positive	Immune	Submit form and documentation to DSHS PHR PHBPP Coordinator
Positive	Negative	Infected	Refer to provider for follow-up and evaluation

- 7) Record all information on the Contact Case Management Report form. Any updates should be submitted immediately to the DSHS PHR PHBPP Coordinator.

**NOTE:** Reporting of adequate and inadequate is acceptable only if your lab is using mIUs as the measurement for anti-HBs and the cut

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off is  $<10$  for reporting inadequate anti-HBs, and  $\geq 10$  for reporting adequate anti-HBs. Check with your lab to be certain of results.

### Case Management Report Submission Guidelines

Initial identification of cases should be submitted on their respective case management reporting forms **within 15 days** to the DSHS PHR PHBPP Coordinator.

All case management report updates must be **submitted immediately** to the DSHS PHR PHBPP Coordinator for any the following events:

- Administration of *any* dose of hepatitis B vaccine
- Completion of PVST
- Any added or updated information to *any* part of the form
- Closure of a case



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### Chapter 7 Learning Check

1. A HBsAg positive pregnant women lives with her 32-year-old husband, 1-year-old daughter, and 3-year-old son. How do you case manage the members in the household?
  - A. Each household contact should be referred to their PCP for vaccination and testing as needed.
  - B. Only the 1-year-old should have a case management report opened and complete the hepatitis B vaccine series and PVST.
  - C. All household contacts should have a case management report opened and complete the hepatitis B vaccine series and PVST.
  - D. Both children need to have a case management report opened and complete the hepatitis B vaccine series and PVST.

**Answer:** B. PHBPP case management services are provided for all household contacts under  $\leq 24$  months of age. Only the daughter is under  $< 24$  months of age and eligible for case management services. She should be vaccinated and receive PVST as needed. All other contacts should be referred to their PCP for evaluation, vaccination, and testing as needed.

2. True/False: In order to close out a PHBPP case as “referred for medical follow-up,” the case manager needs to give the client an official referral for a specialist.

True or False?

**Answer:** False. Case managers do not need to obtain an official referral but do need to remind women of the importance of regular evaluation. Instructing the client to have regular hepatitis B evaluations done with their primary care provider or specialist is sufficient to close as “referred for medical follow-up.”

3. PVST requires which of the following the following lab tests?
  - A. HBsAg
  - B. Anti-HBs
  - C. Both A and B
  - D. Hepatitis Panel

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**Answer:** C. PVST consists of HBsAg and Anti-HBs. A hepatitis panel is not recommended because it usually only tests for markers of an acute infection and not immunity. Note that Anti-HBc is also not recommended because infants can passively acquire it from their HBsAg positive mothers for up to 24 months.

## Chapter 8

### Contacts and Resources

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### **Contact Information**

For a complete list of names and email addresses, please visit the DSHS Immunization Section PHBPP website at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org). Refer to Appendix A for a map defining the borders of each Texas region.

#### **DSHS Immunization Section PHBPP Coordinator:**

Ph. (800) 252-9152  
Fax (512) 776-7544

#### **DSHS Immunization Section PHBPP Database Manager:**

Ph. (512) 776-6813  
Fax: (512) 776-7544

#### **DSHS PHBPP Coordinators:**

##### **Regions 1 / 9 / 10**

Ph. (432) 571-4146  
Fax (432) 571-4162

##### **Regions 2 / 3 / 7**

Ph. (817) 264-4769  
Fax (817) 264-4895

##### **Regions 4 / 5 / 6**

Ph. (903) 533-5361  
Fax (903) 533-9502

##### **Region 8**

Ph. (830) 591-4386  
Fax (830) 278-1831

##### **Region 11**

Ph. (956) 423-0130 - Ext. 5549  
Fax (956) 444-3216

### **DSHS Resources**

DSHS Home page: [www.dshs.texas.gov](http://www.dshs.texas.gov)

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DSHS Adult Safety Net Program: <http://www.dshs.state.tx.us/asn/>

DSHS Perinatal Hepatitis B Prevention Program (PHBPP):  
[www.texasperinatalhepb.org](http://www.texasperinatalhepb.org)

Emerging and Acute Infectious Disease Unit: [www.dshs.texas.gov/idcu/](http://www.dshs.texas.gov/idcu/)

Immunization Section: [www.ImmunizeTexas.com](http://www.ImmunizeTexas.com)

Immunization Section Literature Order Form:  
[secure.immunizetexasorderform.com/default.asp](http://secure.immunizetexasorderform.com/default.asp)

ImmTrac2: [www.dshs.texas.gov/immunize/immtrac/](http://www.dshs.texas.gov/immunize/immtrac/)

Texas National Electronic Disease Surveillance System (NEDSS):  
[txnedss.dshs.state.tx.us:8009/login/login.asp](http://txnedss.dshs.state.tx.us:8009/login/login.asp)

## **Centers for Disease Control and Prevention (CDC) Resources**

Home page: [www.cdc.gov](http://www.cdc.gov)

Advisory Committee on Immunization Practices (ACIP):  
[www.cdc.gov/vaccines/acip/index.html](http://www.cdc.gov/vaccines/acip/index.html)

Annual Statistics and Surveillance Reports:  
[www.cdc.gov/hepatitis/statistics/SurveillanceRpts.htm](http://www.cdc.gov/hepatitis/statistics/SurveillanceRpts.htm)

Hepatitis B Virus information: [www.cdc.gov/hepatitis/hbv/index.htm](http://www.cdc.gov/hepatitis/hbv/index.htm)

Morbidity and Mortality Weekly Reports (MMWR): [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)

National Health and Examination Survey: [www.cdc.gov/nchs/nhanes.htm](http://www.cdc.gov/nchs/nhanes.htm)

Recommended Immunization Schedule: [www.cdc.gov/vaccines](http://www.cdc.gov/vaccines)

Vaccine Information Statement: [www.cdc.gov/vaccines/hcp/vis/index.html](http://www.cdc.gov/vaccines/hcp/vis/index.html)

Center for Disease Control and Prevention, 2021. Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course

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Textbook 14<sup>th</sup> Ed. (2021). Taken from  
[www.cdc.gov/vaccines/pubs/pinkbook/hepb.html](http://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html)

Prevention of Hepatitis B Virus Infection in the United States:  
Recommendations of the Advisory Committee on Immunization Practices,  
Sarah Schillie, MD; Claudia Vellozzi, MD; Arthur Reingold, MD; et al., *MMWR*,  
January 12, 2018, Vol 67,(1);1-31  
[www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm](http://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm)

### **Other Resources**

American Academy of Pediatrics (AAP): [www.aap.org](http://www.aap.org)

American College of Obstetrician and Gynecologist (ACOG): [www.acog.org](http://www.acog.org)

American Liver Foundation: [www.liverfoundation.org](http://www.liverfoundation.org)

Asian Liver Center at Stanford University: [www.med.stanford.edu/liver.html](http://www.med.stanford.edu/liver.html)

GlaxoSmithKline: [www.gskvaccines.com](http://www.gskvaccines.com)

Healthfinder: [www.healthfinder.gov](http://www.healthfinder.gov)

Hepatitis B Foundation: [www.hepb.org](http://www.hepb.org)

Hep B United: [www.hepbunited.org](http://www.hepbunited.org)

HepBMoms: [www.hepbmoms.org](http://www.hepbmoms.org)

Hepatitis Foundation International: [hepatitisfoundation.org/](http://hepatitisfoundation.org/)

Immunization Action Coalition (IAC): [www.immunize.org](http://www.immunize.org)

IAC Hepatitis B Birth Dose Honor Roll:  
[www.immunize.org/honor-roll/birthdose/](http://www.immunize.org/honor-roll/birthdose/)

Institute for Vaccine Safety (Johns Hopkins School of Public Health):  
[www.vaccinesafety.edu](http://www.vaccinesafety.edu)

Medscape: [www.medscape.com](http://www.medscape.com)

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Merck & Co., Inc.: [www.merck.com](http://www.merck.com)

National Library of Medicine (links to MedlinePlus and PubMed):  
[www.nlm.nih.gov](http://www.nlm.nih.gov)

Parents of Kids with Infectious Diseases (PKIDS): [www.pkids.org](http://www.pkids.org)

Sanofi Pasteur ImmYOUity Vaccine Information: [www.vaccines.com](http://www.vaccines.com)

Vaccinate Your Family (formerly Every Child by Two):  
[www.vaccinateyourfamily.org](http://www.vaccinateyourfamily.org)

Viral Hepatitis Prevention Board: [www.vhpb.org](http://www.vhpb.org)

World Health Organization (WHO) Hepatitis B Key Facts:  
[www.who.int/en/news-room/fact-sheets/detail/hepatitis-b](http://www.who.int/en/news-room/fact-sheets/detail/hepatitis-b)

Zip Info FIPS Code Search: <https://www.zipinfo.com/cgi-local/zipsrch.exe>

### **Free Newsletters and Publications**

The following resources about immunization and hepatitis B may be downloaded or ordered directly from the organizations listed:

CDC Morbidity and Mortality Weekly Report (MMWR): [www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)

CDC Pink Book-Epidemiology and Prevention of Vaccine-Preventable Diseases: <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

IAC Publications: [www.immunize.org/publications](http://www.immunize.org/publications)

Prevention of Hepatitis B Virus Infection in the United States:  
Recommendations of the Advisory Committee on Immunization Practices:  
[www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm](http://www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm)

### **Suggested Publications**

Red Book 2018: [redbook.solutions.aap.org/Book.aspx?bookid=2205](http://redbook.solutions.aap.org/Book.aspx?bookid=2205)



## Appendix A

### Program Terms, Definitions, and Regions

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

### TERMS AND DEFINITIONS

#### Serology Tests

**Anti-HBc:** Hepatitis B Core Antibody

**Anti-HBe:** Hepatitis B “little e” Antibody

**Anti-HBs:** Hepatitis B Surface Antibody (HBsAb)

**HBcAg:** Hepatitis B Core Antigen

**HBeAg:** Hepatitis B “little e” Antigen

**HBsAg:** Hepatitis B Surface Antigen

**IgM:** M-class Immunoglobulin Antibody

#### Symbols

( $<$ ): less than/younger than

( $>$ ): greater than/older than

( $\leq$ ): less than or equal to/younger than or equal to

( $\geq$ ): greater than or equal to/older than or equal to

#### Terms and Acronyms

**AAFP:** American Academy of Family Physicians

**AAP:** American Academy of Pediatrics

**ACIP:** Advisory Committee on Immunization Practices

**ACOG:** American College of Obstetricians and Gynecologists

**CDC:** Centers for Disease Control and Prevention

**CFR:** Code of Federal Regulations

**CLIA:** Clinical Laboratory Improvement Amendments

**DNA:** Deoxyribonucleic Acid

**DSHS:** Texas Department of State Health Services

**EDD:** Estimated Date of Delivery/Estimated Due Date

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

**EMR:** Electronic Medical Record

**FDA:** Food and Drug Administration

**FIPS:** Federal Information Processing Standard

**FQHC:** Federally Qualified Health Center

**GSK:** GlaxoSmithKline

**HB:** Hepatitis B

**HBIG:** Hepatitis B Immune Globulin

**HBV:** Hepatitis B Virus

**HIPAA:** Health Insurance Portability and Accountability Act

**HIV:** Human Immunodeficiency Virus

**IIS:** Immunization Information System

**IM:** Intramuscular

**ImmTrac2:** Texas Immunization Registry

**IT:** Information Technology

**ITEAMS:** Inventory Tracking Electronic Assets Management System

**IV:** Intravenous

**LHD:** Local Health Department

**MSM:** Men who have sex with men

**NAM:** National Academy of Medicine (formerly IOM, Institute of Medicine)

**NEDSS:** National Electronic Disease Surveillance System

**NHANES:** National Health and Nutrition Examination Survey

**NIS:** National Immunization Survey

**NPI:** National Provider Identifier

**OB-GYN:** Obstetrician/Gynecologist

**OTC:** Over-the-counter

**PCR:** Polymerase Chain Reaction

**PEP:** Post-Exposure Prophylaxis

**PHBPP:** Perinatal Hepatitis B Prevention Program

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

**PHR:** Public Health Region

**PIN:** Provider Identification Number

**PVST:** Post-Vaccination Serologic Testing

**RHC:** Rural Health Clinic

**SST:** Serum Separator Tube

**TAC:** Texas Administrative Code

**TVFC:** Texas Vaccines for Children

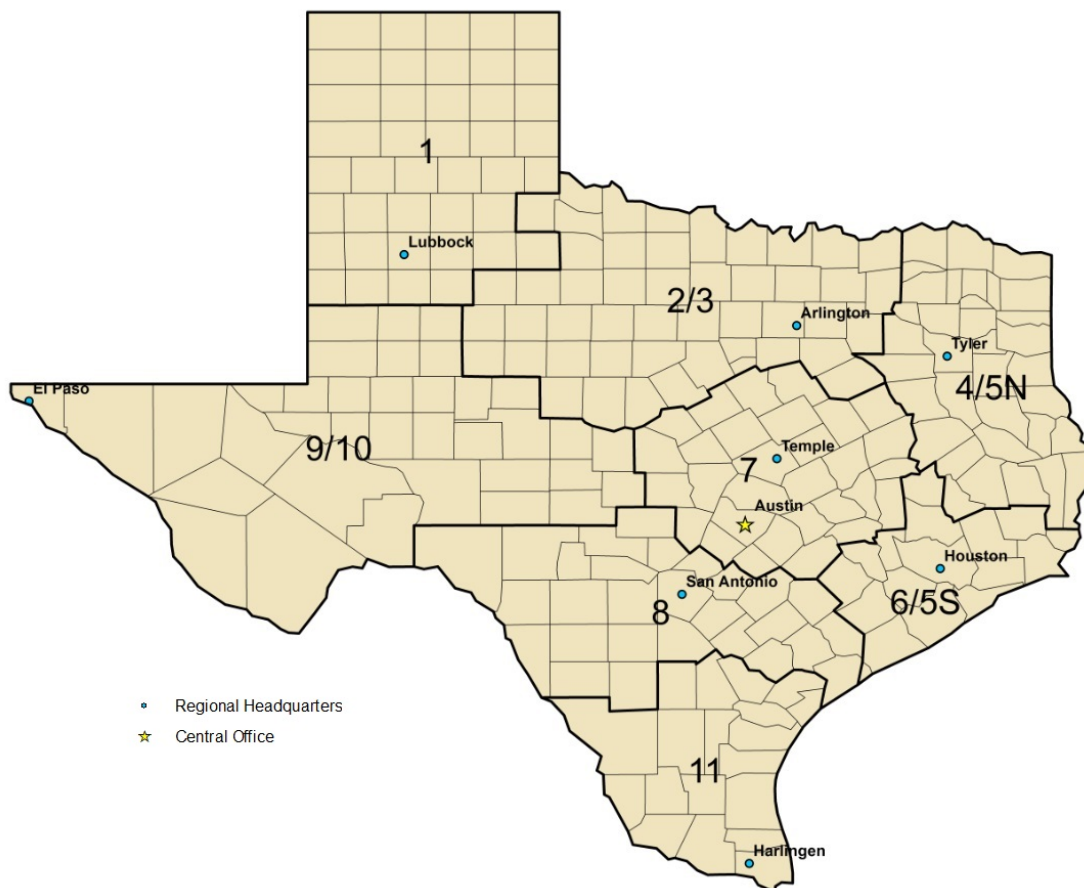
**WHO:** World Health Organization

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Perinatal Hepatitis B Virus Infection Case Definition

The case definition for perinatal hepatitis B virus infection is Hepatitis B Surface Antigen (HBsAg) positivity in an infant aged 1-24 months born in the United States (U.S.) or U.S. territories to an HBsAg-positive mother. An infant who is determined to be HBsAg-positive will be classified as a case of perinatal hepatitis B virus infection. Perinatal hepatitis B infection in the newborn may range from asymptomatic to fulminant hepatitis. All laboratory-confirmed perinatal hepatitis B virus infections must be reported to the Texas Department of State Health Services (DSHS) **within one (1) working day** of notification.

## Texas Program Regions



# Appendix B

## Vaccine Schedule

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

**Table B.1.**

**Table 1** Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger  
United States, 2019

These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Table 1. To determine minimum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs				
Hepatitis B (HepB)	1 <sup>st</sup> dose	2 <sup>nd</sup> dose			← 3 <sup>rd</sup> dose →																
Rotavirus (RV) RV1 (2-dose series); RV5 (3-dose series)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See Notes																
Diphtheria, tetanus, & acellular pertussis (DTaP: <7 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose			← 4 <sup>th</sup> dose →				5 <sup>th</sup> dose									
Haemophilus influenzae type b (Hib)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	See Notes		← 3 <sup>rd</sup> or 4 <sup>th</sup> dose, See Notes →														
Pneumococcal conjugate (PCV13)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	3 <sup>rd</sup> dose		← 4 <sup>th</sup> dose →														
Inactivated poliovirus (IPV: <18 yrs)			1 <sup>st</sup> dose	2 <sup>nd</sup> dose	← 3 <sup>rd</sup> dose →							4 <sup>th</sup> dose									
Influenza (IIV)					Annual vaccination 1 or 2 doses									Annual vaccination 1 dose only							
OR													OR								
Influenza (LAIV)												Annual vaccination 1 or 2 doses		Annual vaccination 1 dose only							
Measles, mumps, rubella (MMR)					See Notes		← 1 <sup>st</sup> dose →					2 <sup>nd</sup> dose									
Varicella (VAR)							← 1 <sup>st</sup> dose →					2 <sup>nd</sup> dose									
Hepatitis A (HepA)					See Notes		2-dose series, See Notes														
Meningococcal (MenACWY-D ≥9 mos; MenACWY-CRM ≥2 mos)			See Notes															1 <sup>st</sup> dose		2 <sup>nd</sup> dose	
Tetanus, diphtheria, & acellular pertussis (Tdap: ≥7 yrs)														Tdap							
Human papillomavirus (HPV)															See Notes						
Meningococcal B														See Notes							
Pneumococcal polysaccharide (PPSV23)												See Notes									

Range of recommended ages for all children
Range of recommended ages for catch-up immunization
Range of recommended ages for certain high-risk groups
Range of recommended ages for non-high-risk groups that may receive vaccine, subject to individual clinical decision-making
No recommendation

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Give the Birth Dose... Hepatitis B Vaccine at Birth Saves Lives!

■ By Deborah L. Wexler, MD

Executive Director, Immunization Action Coalition

*In December 2005, CDC issued updated recommendations on hepatitis B vaccination for infants. The recommendations strongly support (1) giving the hepatitis B vaccine birth dose to every newborn prior to hospital discharge and (2) using standardized admission orders for administering the birth dose. In addition, it is recommended that a copy of the **original** maternal hepatitis B lab report be sent to the hospital—not a transcribed result. The recommendations also state that the hepatitis B vaccine birth dose may be delayed until after hospital discharge only “in rare circumstances.” When doing so, a physician’s order to withhold the birth dose and a copy of the original lab report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant’s medical record. The most recent CDC estimates indicate only 70% of newborns receive the hepatitis B vaccine birth dose by 3 days of age. Clearly, there is much work left to do to fully protect newborns.*

**Leading health organizations – CDC, AAP, AAFP, and ACOG** – recommend that all hospitals and healthcare professionals protect newborns from hepatitis B virus (HBV) infection by administering the first dose of hepatitis B vaccine to every baby at birth, no later than hospital discharge.

Approximately 24,000 women with chronic HBV infection give birth in the U.S. each year, and many do not know they are infected. Up to 95% of perinatal infections can be prevented by post-exposure prophylaxis given within 12 hours of birth. Tragically, many babies are exposed to HBV at birth and do not receive appropriate postexposure prophylaxis. Infants infected at birth have a 90% chance of becoming chronically infected with HBV. Chronic HBV infection in infants leads to liver cancer, cirrhosis, and liver failure in up to 25% of these infants when they become adults.

### Why is a universal birth dose policy necessary in hospitals?

Following are some of the ways newborns can be infected if they do not receive a dose of hepatitis B vaccine, ideally within 12 hours of birth:

- The pregnant woman is tested and found to be hepatitis B surface antigen (HBsAg) positive, but her “infected” status is not communicated to the newborn nursery. The infant receives neither hepatitis B vaccine nor hepatitis B immune globulin (HBIG) protection at birth.

### Healthcare professionals:

**Urge your patients to protect their newborns with hepatitis B vaccine before hospital discharge.**

**Your recommendation to vaccinate is a strong patient motivator!**

**The birth dose saves lives!**

**To obtain CDC’s recommendations for hepatitis B immunization of infants, children, and adolescents, visit [www.cdc.gov/mmwr/pdf/rr/rr5416.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5416.pdf).**



- A chronically infected pregnant woman receives the wrong test. For example, antibody to hepatitis B surface antigen (antiHBs) is ordered in error, instead of HBsAg. This can happen because some labs use the confusing abbreviation HBsAb instead of anti-HBs. This misordering of a test is relatively common since the two abbreviations (HBsAg and HBsAb) differ by only one letter. However, when her incorrectly ordered test comes back “negative,” the woman may actually be HBsAg positive and her infant would not receive appropriate postexposure prophylaxis.
- The pregnant woman is HBsAg positive, but her test results are misinterpreted or mistranscribed into her prenatal record or her infant’s chart. As a result, her infant does not receive HBIG or hepatitis B vaccine.

CONTINUED ON THE NEXT PAGE ►

immunization  
action coalition  
**IAC**  
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Technical content reviewed by the Centers for Disease Control and Prevention

[www.immunize.org/catg.d/p2125.pdf](http://www.immunize.org/catg.d/p2125.pdf) • Item #P2125 (2/14)

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

Give the Birth Dose... **Hepatitis B Vaccine at Birth Saves Lives!** (continued)

page 2 of 2



- The pregnant woman is not tested for HBsAg either prenatally or in the hospital at the time of delivery. In one study, women who didn't receive prenatal care were eight times more likely to be HBsAg positive than women who received prenatal care. When a woman does not receive prenatal care and is not tested at the time of delivery, her infant is in danger of being infected with HBV at birth – unless he or she is born in a hospital that adheres to a policy of administering hepatitis B vaccine within 12–24 hours of birth to every newborn **without fail**. This provides the greatest effectiveness in preventing HBV infection.
- She develops HBV infection later in pregnancy, but it is not clinically detected. Because her initial HBsAg test result is negative, she is not retested later in pregnancy as CDC recommends for high-risk women, and her infant does not receive hepatitis B vaccine or HBIG at birth.
- The mother is HBsAg negative, but the infant is exposed to HBV postnatally from another family member or caregiver. This occurs in two-thirds of the cases of childhood transmission.

In 2001, 2002, and 2008, the Immunization Action Coalition surveyed perinatal hepatitis B coordinators at every state health department, as well as at city and county CDC projects to assess their views about providing hepatitis B vaccine in the hospital. Their responses contained hundreds of reports of newborns who were unprotected or inadequately protected because healthcare professionals failed to order or misordered hepatitis B blood tests or misinterpreted, mistranscribed, or miscommunicated the test results of the children's mothers. (See *States Report Hundreds of Medical Errors in Perinatal Hepatitis B Prevention*, at [www.immunize.org/catg.d/p2062.pdf](http://www.immunize.org/catg.d/p2062.pdf).)

These state coordinators' reports tell us that no matter how well healthcare providers think they are doing in screening all pregnant women for HBsAg, mistakes continue to occur. Newborns are unnecessarily being exposed without the benefit of postexposure prophylaxis. At least one baby has died of fulminant hepatitis B; hundreds have become chronically infected and are doomed to preventable hepatocellular carcinoma or cirrhosis later in life. To overcome these failures, perinatal hepatitis B vaccine coordinators overwhelmingly endorse providing a hepatitis B vaccine birth dose as the first step in developing a safety net to protect all infants from HBV infection, regardless of the circumstances.

To maximally protect every newborn, CDC, AAP, AAFP, and ACOG recommend all infants be vaccinated with a hepatitis B vaccine birth dose prior to hospital discharge. Delaying hepatitis B vaccination until a follow-up office visit will be too late to prevent perinatal HBV transmission.\*

Hepatitis B vaccine is a highly effective vaccine. Studies have shown that infants of the most highly infectious mothers (women who are both HBsAg and HBeAg positive) who receive postexposure prophylaxis with hepatitis B vaccine alone (without HBIG) at birth are protected in 70%–95% of cases. Please read the hepatitis coordinators' survey results ([www.immunize.org/birthdose/birthdose\\_survey.asp](http://www.immunize.org/birthdose/birthdose_survey.asp)), including descriptions of their experiences with failures of the system – failures that largely will be prevented by administering hepatitis B vaccine to infants before they go home from the hospital, ideally within 12 hours of birth.

Your support for providing a birth dose to newborns while they are still in the hospital will protect and save lives that are now being put at risk.

\*For subsequent doses of hepatitis B vaccine in infants, use monovalent hepatitis B vaccine or hepatitis B-containing combination vaccines. If using a hepatitis B-containing combination vaccine, you will be giving 3 more doses of hepatitis B vaccine. Giving a total of 4 doses of hepatitis B vaccine to infants is acceptable practice according to CDC, AAP, and AAFP. These vaccine doses are covered under the Vaccines For Children (VFC) program for VFC-eligible children.



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Technical content reviewed by the Centers for Disease Control and Prevention

[www.immunize.org/catg.d/p2125.pdf](http://www.immunize.org/catg.d/p2125.pdf) • Item #P2125 (2/14)

## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

**Table B.2. Routine Infant Hepatitis B Vaccine Schedule Using Monovalent Vaccine**

Dose	Recommended Age
1	Birth
2	1-2 months
3	6-18 months*

Both the ACIP and CDC recommend that all children born to women who are HBsAg-positive receive their final dose of the hepatitis B vaccine series at 6 months of age, as long as all minimum intervals (below) are met.

**Table B.3. Infant Hepatitis B Vaccine Schedule Using Combination Vaccines**

Pediarix <sup>®</sup> Vaccine Schedule		
Biologic	Dose	Age of Infant
Hepatitis B Vaccine dose 1	0.5 mL	Birth ( <b>Monovalent vaccine ONLY</b> )
Hepatitis B Vaccine dose 2	0.5 mL	2 months*
Hepatitis B Vaccine dose 3	0.5 mL	4 months
Hepatitis B Vaccine dose 4	0.5 mL	6 months**
<p>* Not approved for use in infants &lt;6 weeks of age.</p> <p>** Final dose of vaccine <u>should not</u> be administered before 6 months (24 weeks) of age.</p>		

## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

**Table B.4. Minimum Dosing Intervals for Hepatitis B Vaccines**

Minimum Dosing Intervals	
Dose 1 to 2	Four (4) weeks
Dose 2 to 3	Eight (8) weeks
Dose 3	16 weeks after 1 <sup>st</sup> dose*
* Dose three <u>should not</u> be administered before 6 months (24 weeks) of age.	

## Guidance for Postexposure Prophylaxis (PEP) Treatment of Infants

**Table B.5. PEP for Infants of HBsAg-Positive Mothers**

Infant Born to an HBsAg-Positive mothers		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*±
Hepatitis B Vaccine dose 1	0.5 mL	Within 12 hours of birth*±
Hepatitis B Vaccine dose 2	0.5 mL	1 month
Hepatitis B Vaccine dose 3	0.5 mL	6 months**
<p>* Administer at separate anatomical sites. Preferred site: anterolateral thighs.</p> <p>** Dose three <u>should not</u> be administered before 6 months (24 weeks) of age.</p> <p>± Regardless of infant's birth weight.</p>		

## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

**Table B.6. PEP for Infants of HBsAg-Unknown Mothers**

<b>Infant Born to an HBsAg–Unknown Status mother±</b>		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	If <2,000g - within 12 hours of birth*
		If ≥2,000g – ASAP, but no later than 7 days if mother is positive
Hepatitis B Vaccine dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine dose 2	0.5 mL	1 to 2 months
Hepatitis B Vaccine dose 3	0.5 mL	6 months**
<p>* Administer at separate anatomical sites. Preferred site: anterolateral thigh</p> <p>** Dose three should not be administered before 6 months (24 weeks) of age.</p> <p>± In the event a mother’s HBsAg status is initially unknown but her HBsAg delivery result comes back negative, the infant does not need to receive HBIG. However, it will not harm the infant if HBIG is administered before the result is received.</p>		

## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

**Table B.7. PEP of Infants Weighing <2,000g (4.4 lbs.)**

Infant Born to an HBsAg–Positive OR HBsAg–Unknown mother		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B Vaccine dose 1	0.5 mL	Within 12 hours of birth* <b>Do not count birth dose as part of series.</b>
Hepatitis B Vaccine dose 2	0.5 mL	1 month
Hepatitis B Vaccine dose 3	0.5 mL	2 months
Hepatitis B Vaccine dose 4	0.5 mL	6 months**
<p>* Administer at separate anatomical sites. Preferred site: anterolateral thighs.</p> <p>** Dose three should not be administered before 6 months (24 weeks) of age.</p> <p>± All preterm infants weighing &lt;2,000g at birth should reinstitute the series beginning at 1 month of age.</p>		

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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## Appendix C

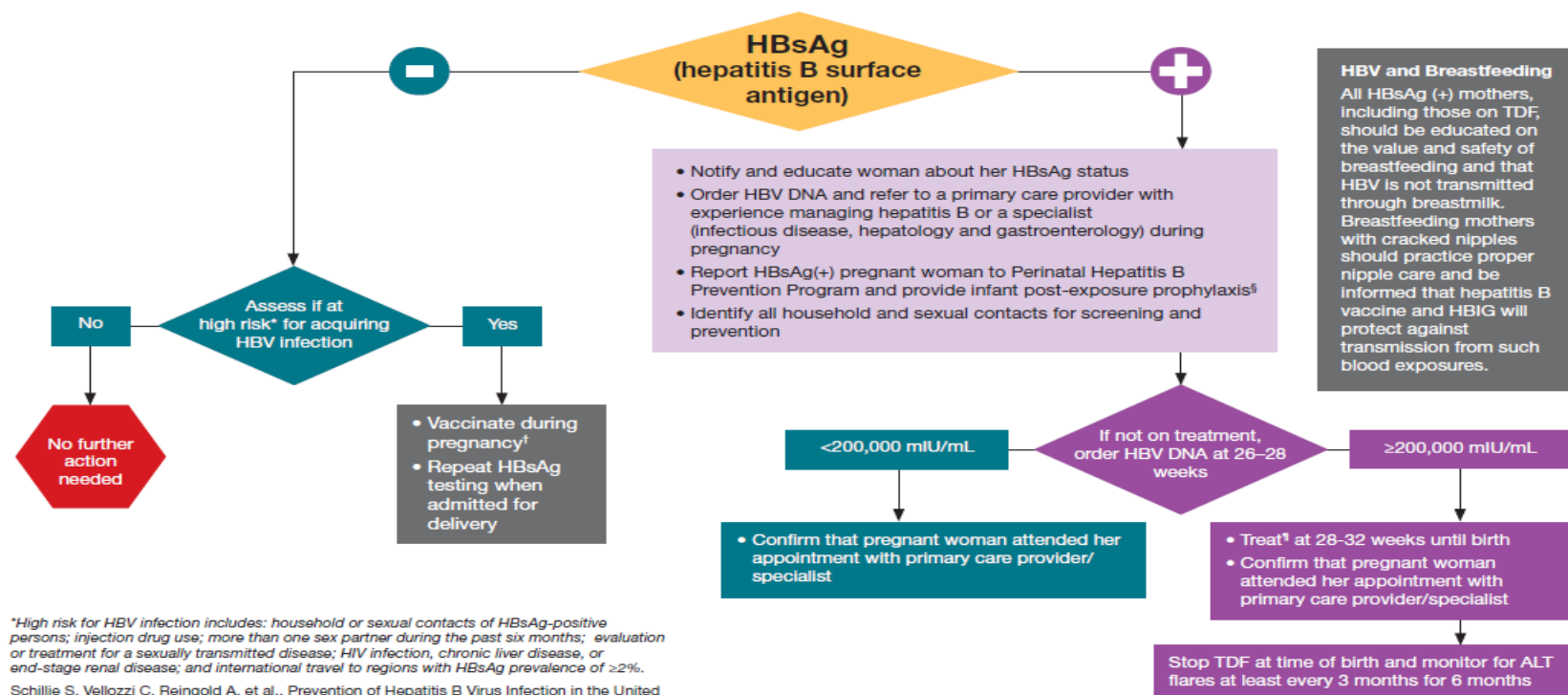
### Flowcharts and Diagrams

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

### Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection Among Pregnant Women



\*High risk for HBV infection includes: household or sexual contacts of HBsAg-positive persons; injection drug use; more than one sex partner during the past six months; evaluation or treatment for a sexually transmitted disease; HIV infection, chronic liver disease, or end-stage renal disease; and international travel to regions with HBsAg prevalence of ≥2%.

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):1-34.

Originally adapted with permission from the Hepatitis B Foundation, from Apuzzio et. al, 2012. <http://www.hepb.org/assets/Uploads/Final-OB-publications-The-Female-Patient.pdf>

¹Vaccinate if not previously vaccinated with a complete hepatitis B vaccine series (refer to Schillie et. al. for more information).

§Hepatitis B vaccine birth dose and Hepatitis B immune globulin (HBIG) (refer to Schillie et. al. for more information).

³Tenofovir disoproxil fumarate (TDF) should be used for the treatment of pregnant women.



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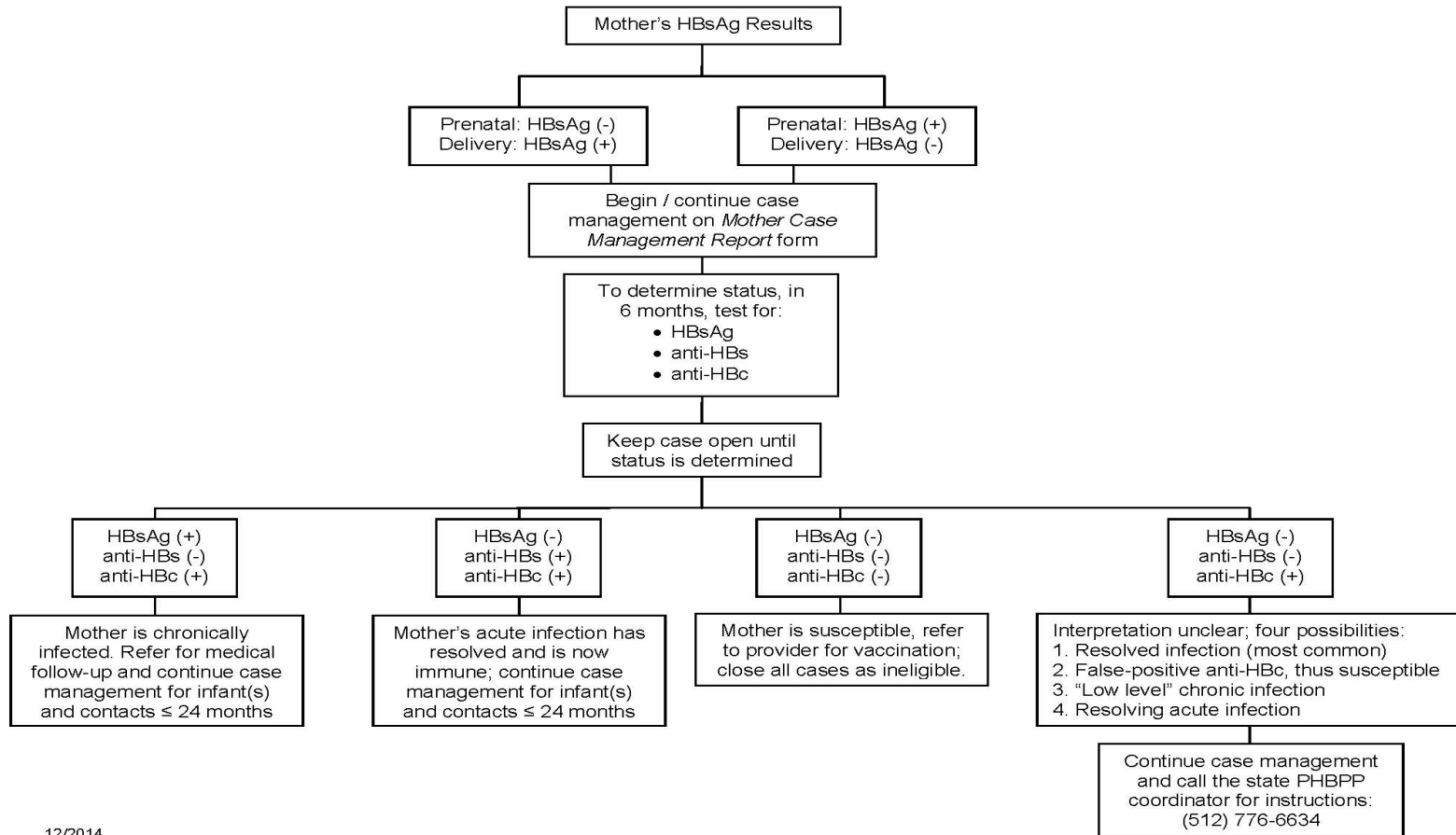
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[www.cdc.gov/hepatitis](http://www.cdc.gov/hepatitis)

Updated 2020

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

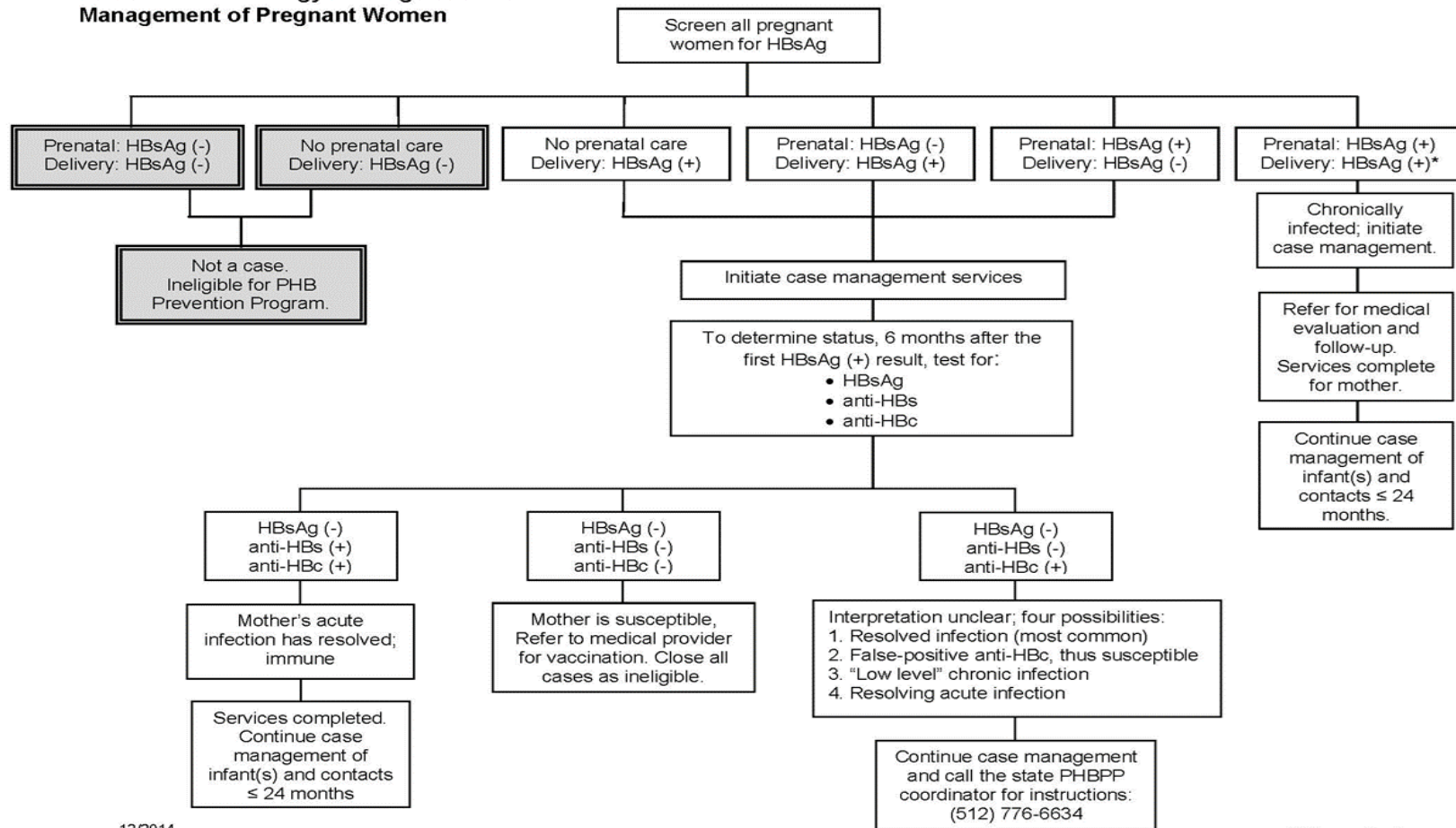
## Guideline 1: Case Management of Mothers with Discrepant HBsAg Results



12/2014

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Guideline 2: Serology Testing and Case Management of Pregnant Women

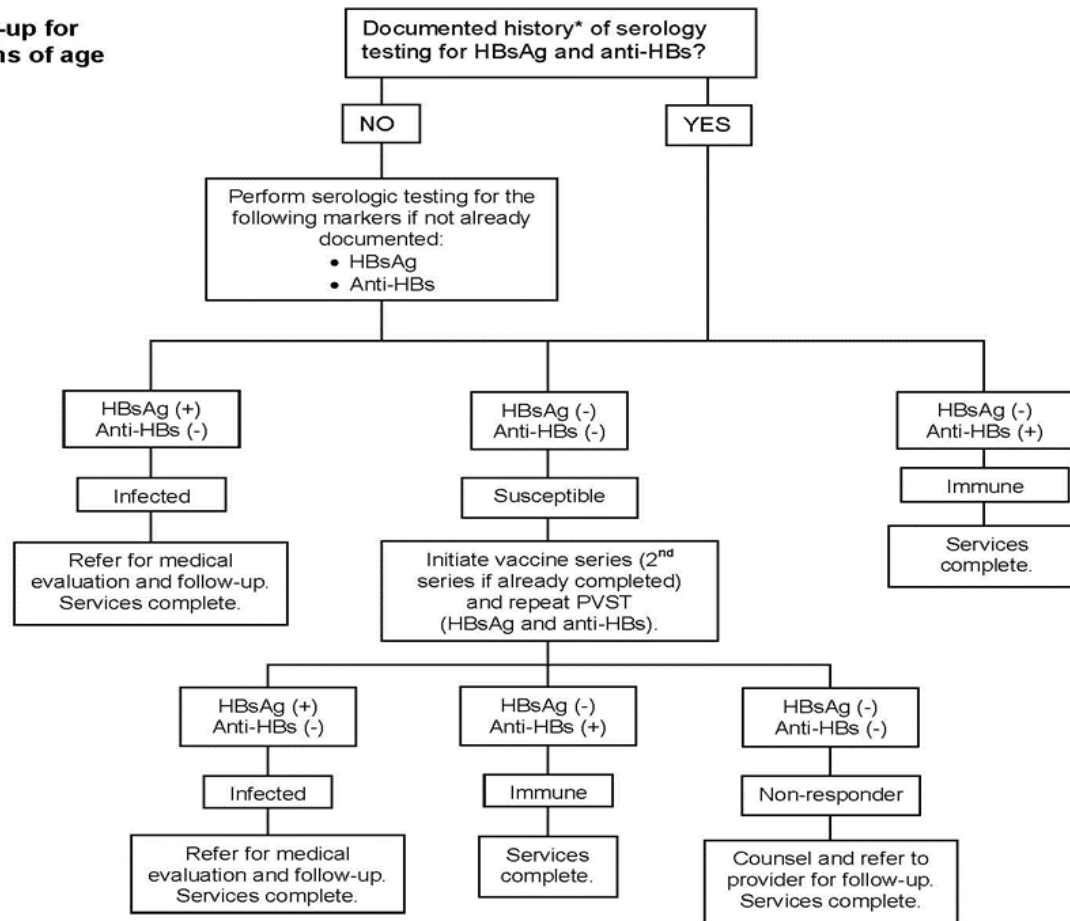


12/2014

\*If 6 months have not passed, follow guidance to retest.

## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

### Guideline 4: Follow-up for Contacts ≤ 24 months of age



12/2014

\* Serologic testing history is defined as a written and dated laboratory report.

## Appendix D

### Lab Ordering and Serology Interpretation

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

### **Hepatitis B Antigens and Markers**

#### **Hepatitis B DNA (HBV DNA)**

HBV DNA is one of the first tests that can be detected in the bloodstream after initial infection. It can be detected as early as one (1) week after infection. The amount of HBV DNA in the patient's blood indicates how fast the virus is replicating within the liver. This test measures the patient's viral load. High viral loads indicate rapid viral replication while low or undetectable levels indicate inactive infections. The CDC recommends all HBsAg positive pregnant women be tested for HBV DNA to guide antiviral therapy.

#### **HBV-DNA genotype**

HBV DNA genotype testing identifies which of the genetic strains of hepatitis B virus a patient is infected with. It is most often used to predict or monitor therapy, detect mutations, or in epidemiologic investigations to assess transmission linkages.

#### **Hepatitis B Surface Antigen (HBsAg)**

HBsAg is found on the surface of the virus and can be identified approximately 30-60 days after exposure to the virus. The presence of HBsAg indicates that the person is infectious. HBsAg testing is the current standard to indicate current infection with hepatitis B. If HBsAg is present for more than six (6) months this generally indicates a chronic infection.

#### **Hepatitis B "little e" Antigen (HBeAg or 'e' antigen)**

HBeAg is contained within the core of the virus rather than on the surface. When the virus replicates, HBeAg is produced in excess. The "little e" antigen is only detectable when the hepatitis B virus is actively reproducing. HBeAg indicates high infectivity due to the active replication of the virus and indicates a greater risk of progression to liver disease. HBeAg and HBsAg are generally detectable at the same time, however, HBeAg disappears before HBsAg.

Mutant strains of HBV do exist that replicate without producing HBeAg. In many cases, infection with one of these mutant strains is more aggressive than HBe-producing strains.

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

### **Hepatitis B “little e” Antibody (anti-HBe)**

Antibodies to HBeAg only become detectable when the HBeAg is no longer present, indicating there is no active viral replication. Serology that is anti-HBe positive would indicate low infectivity.

### **Hepatitis B Core Antigen (HBcAg)**

The core antigen (HBcAg) is a viral protein that is produced and contained within the infected hepatocyte and is the most antigenic component of the virus. It does not freely circulate in a detectable amount within the blood, therefore, there is no specific lab test to detect the core antigen. However, it can be detected in a sample of liver cells taken after a liver biopsy. Because of the antigenicity of the core antigen, the immune system does produce antibodies to HBcAg (anti-HBc) that are detectable.

### **Hepatitis B Core Antibody (anti-HBc)**

Anti-HBc positive serum indicates that the individual has been infected with the hepatitis B virus at some point, but it is not possible to determine when the infection occurred. Any individual who has been infected with the virus will test positive for anti-HBc for life.

### **Hepatitis B Immunoglobulin M (IgM anti-HBc)**

IgM anti-HBc is detectable approximately six to eight weeks after infection occurs and indicates acute infection. It is generally not detectable after six months and therefore generally indicates a recent infection. This is the best serologic marker of acute HBV infection.

### **Hepatitis B Surface Antibody (anti-HBs)**

This is a protective antibody. The presence of anti-HBs following a known acute infection indicates recovery and immunity against reinfection. Anti-HBs can also be acquired as an immune response to the hepatitis B vaccine, indicating that the individual adequately responded to the vaccine and is protected from infection.

# Screening All Pregnant Women for Hepatitis B Virus (HBV) Infection:

## Ordering Prenatal Hepatitis B Surface Antigen (HBsAg) Tests from Major Commercial Laboratories

Laboratory	Test Option	Test Name	Reflex to Confirmation Test*	Test Code/ID	CPT Code	Web Link
ARUP Laboratories	Panel	Prenatal Reflexive Panel	✓	0095044	87340**	<a href="http://ltd.aruplab.com/Tests/Pub/0095044">http://ltd.aruplab.com/Tests/Pub/0095044</a>
	Standalone	Hepatitis B Virus Surface Antigen with Reflex to Confirmation, Prenatal	✓	2007573	87340	<a href="http://ltd.aruplab.com/Tests/Pub/2007573">http://ltd.aruplab.com/Tests/Pub/2007573</a>
LabCorp	Panel	Prenatal Profile I with Hepatitis B Surface Antigen	✓	202945	87340**	<a href="https://www.labcorp.com/wps/portal/provider/testmenu/">https://www.labcorp.com/wps/portal/provider/testmenu/</a> (Enter test code or CPT code to search for test)
	Panel	Hepatitis Profile XIII (HBV Prenatal Profile)	✓	265397	87340**	<a href="https://www.labcorp.com/wps/portal/provider/testmenu/">https://www.labcorp.com/wps/portal/provider/testmenu/</a> (Enter test code or CPT code to search for test)
	Standalone	N/A	N/A	N/A	N/A	
Mayo Medical Laboratories	Panel	Prenatal Hepatitis Evaluation	✓	PHSP	87340**	<a href="http://www.mayomedicallaboratories.com/test-catalog/Overview/5566">http://www.mayomedicallaboratories.com/test-catalog/Overview/5566</a>
	Standalone	Hepatitis B Surface Antigen Prenatal, Serum	✓	HBAGP	87340	<a href="http://www.mayomedicallaboratories.com/test-catalog/Overview/86185">http://www.mayomedicallaboratories.com/test-catalog/Overview/86185</a>
Quest Diagnostics	Panel	Obstetric Panel	✓	20210	80055	<a href="http://www.questdiagnostics.com/testcenter/TestDetail.action?ntc=20210&amp;fromFlyOut=true">http://www.questdiagnostics.com/testcenter/TestDetail.action?ntc=20210&amp;fromFlyOut=true</a>
	Standalone	N/A	N/A	N/A	N/A	

\*When an HBsAg test result is reactive, laboratories may automatically perform a confirmatory test without additional provider order.

\*\*This CPT code corresponds only to the HBsAg screening component of this laboratory panel; additional CPT codes might be associated with other component tests in this laboratory panel.

**Notes:** CDC recommends healthcare providers use prenatal HBsAg tests (vs. non-specific tests) for pregnant women, which allows for reporting of positive results along with pregnancy status to public health jurisdictions. Refer all HBsAg positive pregnant women to Perinatal Hepatitis B Prevention Program coordinators for case management of mother and infant: <https://www.cdc.gov/vaccines/vpd/hepb/hcp/perinatal-contacts.html>.

Laboratories reserve the right to add, modify, or stop performing tests at any time – providers should review any test notifications from laboratories for changes.



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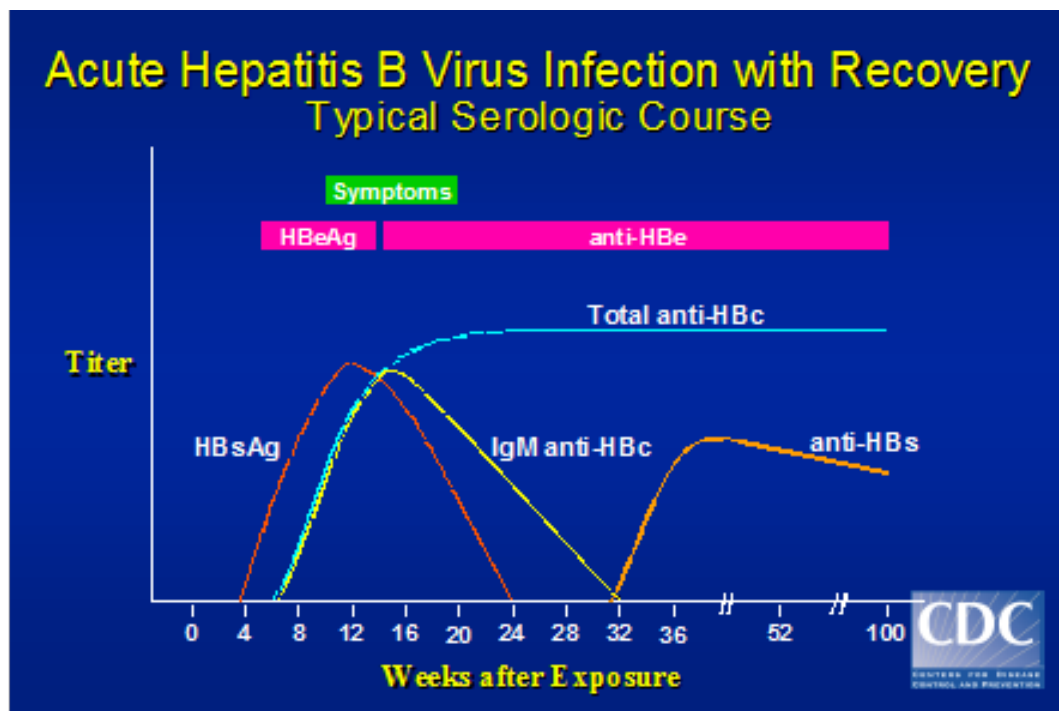
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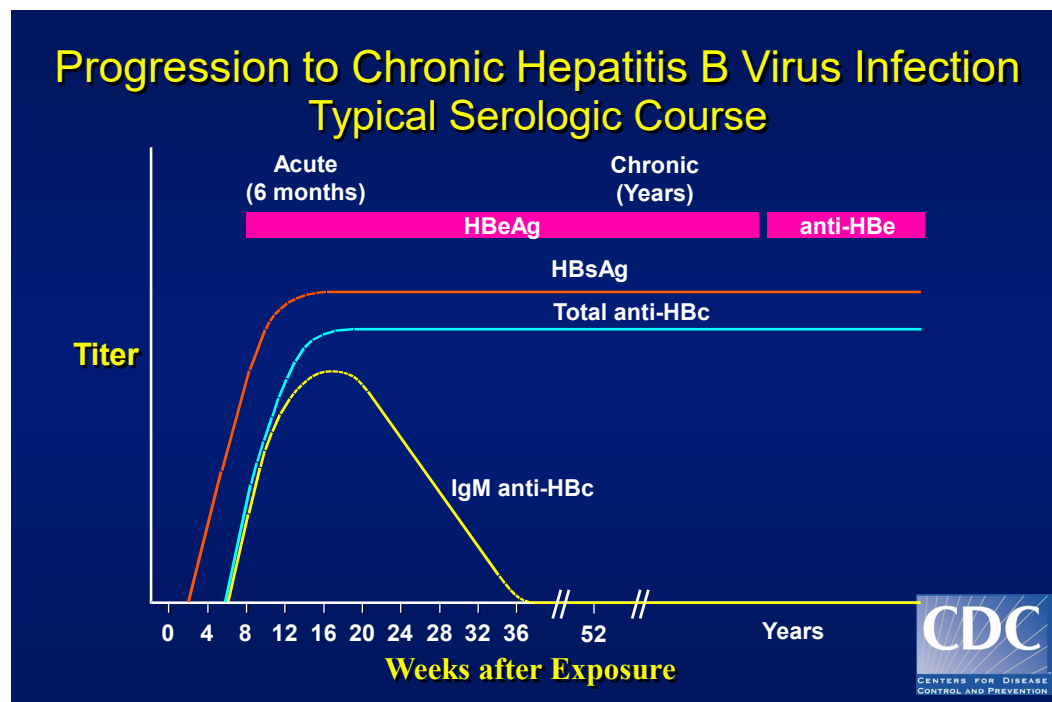
Updated 2020

## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

**Figure D.1. Acute Hepatitis B Virus Infection with Recovery**



**Figure D.2. Progression to Chronic Hepatitis B Virus Infection**



## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

**Table D.1. Interpretation of Infant Post-Vaccination Serologic Testing and Related Actions**

HBsAg	Anti-HBs	Interpretation and Necessary Action
-	+	The infant is immune to HBV. Case management services are considered complete.
-	-	The infant is NOT immune to hepatitis B. The infant must receive a second dose of the hepatitis B vaccine as soon as post-vaccination serology results are known. The infant can then repeat PVST 1-2 months after the booster dose of the hepatitis B vaccine. If still not immune after the booster dose, the child should complete the 2 <sup>nd</sup> and 3 <sup>rd</sup> hepatitis B vaccine dose and repeat PVST 1-2 months later. Alternatively, providers and parents may decide to repeat the entire three-dose vaccine series and then repeat PVST 1-2 months later. See Chapter 5 for more detail.
+	-	<p>The vaccination effort failed. The infant is infected with HBV (<b>perinatal hepatitis B infection</b>) and is likely to become a chronic carrier. All confirmed cases of perinatal HBV infection should be reported to the state through NEDSS as soon as they are identified, and to the perinatal hepatitis B coordinator through the submission of the <i>Infant Case Management Form</i>, along with a copy of the laboratory report. Refer the child for clinical follow-up. Case management services are considered complete.</p> <p><b>NOTE:</b> The surveillance case definition for perinatal hepatitis B virus infection is HBsAg positivity in any infant aged 1-24 months or positive for HBeAg or HBV DNA aged 9-24 months who was born in the US or in US territories to an HBsAg-positive mother.</p>

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Interpretation of Hepatitis B Serologic Test Results

Hepatitis B serologic testing involves measurement of several hepatitis B virus (HBV)-specific antigens and antibodies. Different serologic “markers” or combinations of markers are used to identify different phases of HBV infection and to determine whether a patient has acute or chronic HBV infection, is immune to HBV as a result of prior infection or vaccination, or is susceptible to infection.

HBsAg anti-HBc anti-HBs	negative negative negative	Susceptible
HBsAg anti-HBc anti-HBs	negative positive positive	Immune due to natural infection
HBsAg anti-HBc anti-HBs	negative negative positive	Immune due to hepatitis B vaccination
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	Acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	Chronically infected
HBsAg anti-HBc anti-HBs	negative positive negative	Interpretation unclear; four possibilities: 1. Resolved infection (most common) 2. False-positive anti-HBc, thus susceptible 3. “Low level” chronic infection 4. Resolving acute infection

Adapted from: A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices. Part I: Immunization of Infants, Children, and Adolescents. MMWR 2005;54(No. RR-16).



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### ■ Hepatitis B surface antigen (HBsAg):

A protein on the surface of hepatitis B virus; it can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make hepatitis B vaccine.

### ■ Hepatitis B surface antibody (anti-HBs):

The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully vaccinated against hepatitis B.

### ■ Total hepatitis B core antibody (anti-HBc):

Appears at the onset of symptoms in acute hepatitis B and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame.

### ■ IgM antibody to hepatitis B core antigen (IgM anti-HBc):

Positivity indicates recent infection with hepatitis B virus ( $\leq 6$  mos). Its presence indicates acute infection.

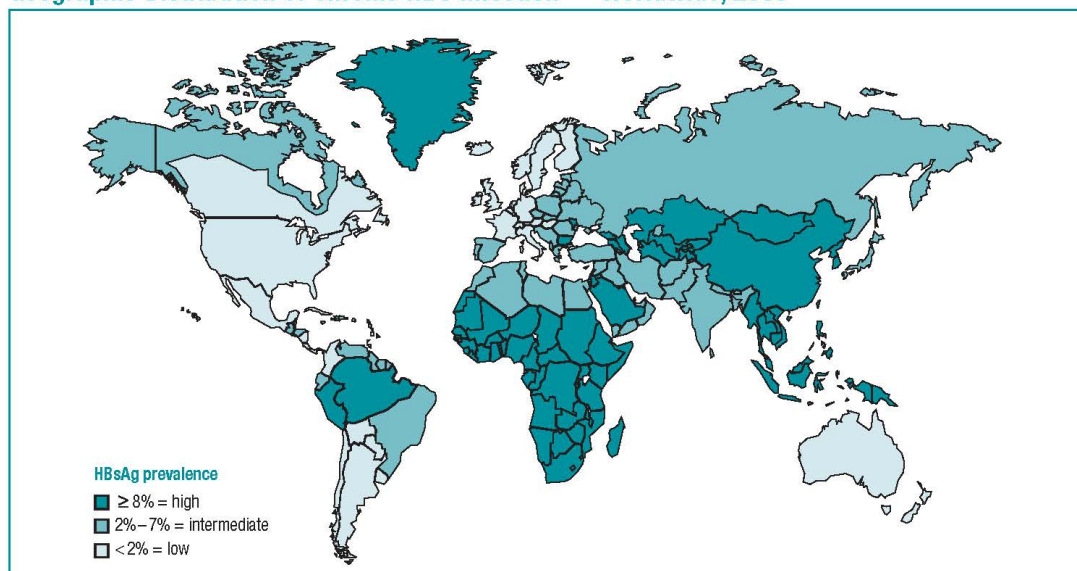
# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Recommendations for Routine Testing and Follow-up for Chronic Hepatitis B Virus (HBV) Infection

Population	Recommendation	
	Testing	Vaccination/Follow-up
Persons born in regions of high and intermediate HBV endemicity (HBsAg prevalence $\geq 2\%$ )	Test for HBsAg, regardless of vaccination status in their country of origin, including <ul style="list-style-type: none"> <li>– immigrants</li> <li>– refugees</li> <li>– asylum seekers</li> <li>– internationally adopted children</li> </ul>	If HBsAg-positive, refer for medical management. If negative, assess for on-going risk for hepatitis B and vaccinate if indicated.
US born persons not vaccinated as infants whose parents were born in regions with high HBV endemicity ( $\geq 8\%$ )	Test for HBsAg regardless of maternal HBsAg status if not vaccinated as infants in the United States.	If HBsAg-positive, refer for medical management. If negative, assess for on-going risk for hepatitis B and vaccinate if indicated.

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### Geographic Distribution of Chronic HBV Infection — Worldwide, 2006\*



\* For multiple countries, estimates of prevalence of hepatitis B surface antigen (HBsAg), a marker of chronic HBV infection, are based on limited data and might not reflect current prevalence in countries that have implemented childhood hepatitis B vaccination. In addition, HBsAg prevalence might vary within countries by subpopulation and locality.

Source: CDC. Travellers' Health; Yellow Book. <http://wwwn.cdc.gov/travel/yellowbookch4-HepB.aspx>.



# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Routine Testing and Follow-up for Chronic HBV Infection (continued)

Population	Recommendation	
	Testing	Vaccination/Follow-up
Injection-drug users	Test for HBsAg, as well as for anti-HBc or anti-HBs to identify susceptible persons.	First vaccine dose should be given at the same visit as testing. Susceptible persons should complete a 3-dose hepatitis B vaccine series to prevent infection from ongoing exposure.
Men who have sex with men	Test for HBsAg, as well as for anti-HBc or anti-HBs to identify susceptible persons.	First vaccine dose should be given at the same visit as testing. Susceptible persons should complete a 3-dose hepatitis B vaccine series to prevent infection from ongoing exposure.
Persons needing immunosuppressive therapy, including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders	Test for all markers of HBV infection (HBsAg, anti-HBc, and anti-HBs).	Treat persons who are HBsAg-positive. Monitor closely persons who are anti-HBc positive for signs of liver disease.
Persons with elevated ALT/AST of unknown etiology	Test for HBsAg along with other appropriate medical evaluation.	Follow-up as indicated.
Donors of blood, plasma, organs, tissues, or semen	Test for HBsAg, anti-HBc, and HBV-DNA as required.	
Hemodialysis patients	Test for all markers of HBV infection (HBsAg, anti-HBc, and anti-HBs). Test vaccine nonresponders monthly for HBsAg. HBsAg-positive hemodialysis patients should be cohorted.	Vaccinate against hepatitis B to prevent transmission and revaccinate when serum anti-HBs titer falls below 10mIU/mL.
All pregnant women	Test for HBsAg during each pregnancy, preferably in the first trimester. Test at the time of admission for delivery if prenatal HBsAg test result is not available or if mother was at risk for infection during pregnancy.	If HBsAg-positive, refer for medical management. To prevent perinatal transmission, infants of HBsAg-positive mothers and unknown HBsAg status mothers should receive vaccination and postexposure immunoprophylaxis in accordance with recommendations and within 12 hours of delivery.
Infants born to HBsAg-positive mothers	Test for HBsAg and anti-HBs 1–2 mos after completion of at least 3 doses of a licensed hepatitis B vaccine series (i.e., at age 9–18 months, generally at the next well-child visit to assess effectiveness of postexposure immunoprophylaxis). Testing should not be performed before age 9 months or within 1 month of the most recent vaccine dose.	Vaccinate in accordance with recommendations.
Household, needle-sharing, or sex contacts of persons known to be HBsAg positive	Test for HBsAg, as well as anti-HBc or anti-HBs to identify susceptible persons.	First vaccine dose should be given at the same visit as testing. Susceptible persons should complete a 3-dose hepatitis B vaccine series to prevent transmission from ongoing exposure.
Persons who are the sources of blood or body fluids resulting in an exposure (e.g., needlestick, sexual assault) that might require postexposure prophylaxis	Test source for HBsAg.	Vaccinate healthcare and public safety workers with reasonably anticipated occupational exposures to blood or infectious body fluids. Provide postexposure prophylaxis to exposed person if needed.
HIV-positive persons	Test for HBsAg, as well as for anti-HBc or anti-HBs to identify susceptible persons.	Vaccinate susceptible persons against hepatitis B to prevent transmission.

Adapted from: Centers for Disease Control and Prevention. Recommendations for Identification and Public Health Management of Persons with Chronic Hepatitis B Virus Infection. MMWR 2008; 57 (No. RR-8).



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## Appendix E

### Policies, Standing Orders, and HIPAA

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission

*The guidelines in this document were developed to help hospitals establish policies and standing orders in their labor and delivery (L&D) and newborn units.*

*During 2005, the Centers for Disease Control and Prevention (CDC) published updated recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in children which includes the recommendation to administer hepatitis B vaccine to **all newborns before hospital discharge**. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have all endorsed the birth dose recommendation. To obtain a copy, go to [www.cdc.gov/mmwr/PDF/rr/rr5416.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf).*

*To protect infants from HBV infection, CDC recommends that all delivery hospitals institute standing orders or admission orders, and protocols to ensure healthcare professionals do the following:*

- 1. Administer hepatitis B vaccine to **all newborns** before they are discharged from the hospital.*
- 2. Identify all infants born to mothers who are hepatitis B surface antigen (HBsAg) positive or to mothers with unknown HBsAg status. Administer appropriate immunoprophylaxis to these infants.*

### Admission orders and procedures for women admitted to a birthing facility

**For pregnant women who have a HBsAg lab report included in their prenatal records, do the following:**

1. Examine a copy of the *original* laboratory report of the pregnant woman's HBsAg<sup>1</sup> test result to verify that the correct test (i.e., HBsAg) was performed and to verify that the testing date was during *this* pregnancy not a previous one. *Do not rely on a handwritten or transcribed HBsAg test result!*
2. Place a copy of the original HBsAg lab report into (1) the pregnant woman's L&D record and (2) the infant's hospital record.
3. If the pregnant woman is HBsAg positive, alert the nursery staff that the newborn is high risk and will need postexposure prophylaxis—both hepatitis B immune globulin (HBIG) and hepatitis B vaccine—within 12 hours of birth.
4. Perform a repeat blood test for HBsAg<sup>1</sup> if the pregnant woman was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., not in a long-term, mutually monogamous relationship; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drugs).
5. Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

**For pregnant women who do not have an HBsAg lab report on their prenatal record, do the following:**

1. Perform HBsAg<sup>1</sup> testing ASAP on women who do not have a copy

of an original HBsAg laboratory report from the current pregnancy included in their prenatal record.

2. Instruct the lab to call L&D and the nursery units with the newly obtained HBsAg test result ASAP.

### Admission orders and procedures for newborns

**Hospital procedures to follow for ALL newborns**

1. Review a copy of the mother's *original* HBsAg<sup>1</sup> lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
2. Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg status and the newborn's birth weight. If the newborn weighs less than 2 kg (4.4 lb), see the descriptions below and footnotes 2, 5, 6.
3. Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement.

**For newborns of HBsAg-negative mothers**

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before hospital discharge to **all** newborns weighing 2 kg (4.4 lb) or more at birth.<sup>2,3,4</sup>
2. Document the hepatitis B vaccine dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.

**For newborns of mothers with unknown HBsAg status, do the following:**

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.<sup>3,5</sup> Do not wait for test results to return before giving this dose of vaccine.
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, and site of administration, as well as the vaccine lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.
4. Confirm that the laboratory has received blood for the mother's HBsAg<sup>1</sup> test.

*(continued on next page)*

[www.immunize.org/catg.d/p2130.pdf](http://www.immunize.org/catg.d/p2130.pdf) • Item #p2130 (9/12)

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

*Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units*

*continued from page 1*

5. Verify when the mother's HBsAg result will be available and that it will be reported to L&D and the newborn unit ASAP.
6. If the nursery does not receive the report of the mother's HBsAg test at the expected time, call the laboratory for the result.
7. If the laboratory test indicates the mother's HBsAg<sup>1</sup> test result is positive, do the following:
  - a. Administer HBIG (0.5 mL, IM) to the newborn ASAP. (Hepatitis B vaccine should have been given within 12 hours of birth.)
  - b. Document the HBIG dose in the newborn's medical record. There is little benefit in administering HBIG to the newborn if more than 7 days have elapsed since birth.
  - c. Alert the mother's and newborn's physician(s) of the test result.
  - d. Follow the instructions below "For newborns of HBsAg-positive mothers," steps 3–7.
8. If the newborn must be discharged before the mother's HBsAg result is known:
  - a. Document the parents' contact information (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed for the infant.
  - b. Obtain the name, address, and phone number of the mother's and the newborn's healthcare providers.
  - c. Notify the mother's and newborn's healthcare providers that the mother's HBsAg test result is pending.

## **For newborns of HBsAg-positive mothers**

1. Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine<sup>3,6</sup> (0.5 mL, IM) at separate injection sites within 12 hours of birth.
2. Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.
4. Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
5. Obtain the name, address, and phone number of the newborn's primary care provider.
6. Notify the provider of the newborn's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination and postvaccination testing of the infant for HBsAg and antibody to HBsAg after completion of the hepatitis B vaccine series.
7. Provide advice to the mother. Tell her the following:
  - a. That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
  - b. That it is critical for her infant to complete the full hepatitis B vaccine series on the recommended schedule;
  - c. That blood will need to be drawn from the child after completion of at least 3 doses of the hepatitis B vaccine series at age 9–18 months (usually done at a well-child visit) to determine if the child developed a protective immune response to vaccination or needs additional management;
  - d. About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
  - e. That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is a candidate for antiviral treatment.

## **Footnotes**

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was/is ordered. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs or HBsAb) and antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg (4.4 lb) at birth and whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge, whichever comes first. The mother's HBsAg test result must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the IAC website at [www.immunize.org/vis](http://www.immunize.org/vis).
4. According to the CDC recommendations, exceptions to administering the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. If the hepatitis B vaccine birth dose is not administered, a copy of the mother's negative HBsAg test result from the current pregnancy must be placed in the infant's medical record and the attending physician must write a specific order directing staff not to administer the birth dose in the hospital. Infants who do not receive the first dose of hepatitis B vaccine before hospital discharge should receive the first dose no later than age 2 months.
5. An infant weighing less than 2 kg (4.4 lb) whose mother's HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
6. An infant weighing less than 2 kg (4.4 lb) whose mother is HBsAg positive should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.

**For "Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Birth Dose" go to [www.immunize.org/catg.d/p2131.pdf](http://www.immunize.org/catg.d/p2131.pdf)**

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

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## Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Vaccine Birth Dose

### General orders for all newborns

1. Review a copy of the mother's original lab report to ensure that the correct serologic test (HBsAg) was ordered and that it was ordered during this pregnancy. Perform a repeat HBsAg blood test on the pregnant woman (mother) if she was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., not in a long-term, mutually monogamous relationship; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drugs).
2. Determine if the newborn is high risk and needs immediate postexposure prophylaxis within 12 hours of birth. The infant is high risk if the mother's HBsAg status is positive or unknown.

### For routine newborn hepatitis B vaccination: the mother is HBsAg negative

1. Administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, intramuscular (IM), in anterolateral thigh no later than hospital discharge. Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. Give the parent a record of the vaccination. If parent unwilling to give consent, notify physician ASAP. Document vaccine administration or vaccine refusal in hospital record.

### For highest-risk infants: the mother is HBsAg positive

1. Administer Hepatitis B Immune Globulin (HBIG) 0.5 mL, IM, in anterolateral thigh in the delivery room or ASAP within 12 hours of birth. Document HBIG administration in hospital record. Give parent a record of the HBIG dose.
2. At same time and in opposite anterolateral thigh, administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, IM, ASAP within 12 hours of birth. Document vaccine administration in hospital record. Give parent a record of the vaccination.
3. Prior to administering both HBIG and hepatitis B vaccine, give parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. If parent unwilling to give consent, notify physician ASAP. Consider notifying Child Protective Services if parent continues to refuse despite discussion with physician.
4. Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
5. Obtain the name, address, and phone number of the newborn's primary care provider.
6. Notify primary care provider of newborn's birth, the date and time that HBIG and hepatitis B vaccine doses were administered, and the importance of additional on-time vaccination (infants weighing less than 2 kg (4.4 lbs) will require 4 doses of vaccine as the first dose does not "count") and postvaccination testing of the infant for HBsAg and antiHBs (antibody to HBsAg) after completion of the hepatitis B vaccine series at age 9–18 months.
7. Provide advice to the mother. Tell her the following:
  - a. That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
  - b. It is critical for her infant to complete the full hepatitis B vaccine series on the recommended schedule;
  - c. Blood will need to be drawn from the infant following completion of the hepatitis B vaccine series (usually done at a well-child visit at age 9–18 months) to determine if the infant developed a protective immune response to vaccination or needs additional management;
  - d. About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
  - e. She and other infected contacts need to have medical evaluations for chronic hepatitis B, including assessment to determine if they are candidates for antiviral treatment.

### For high-risk infants: the mother's HBsAg status is unknown

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth. For infants weighing less than 2 kg (4.4 lbs) at birth, also administer hepatitis B immune globulin (HBIG 0.5 mL, IM) within 12 hours. Do not wait for test results to return before giving this dose of vaccine (and HBIG for infants weighing less than 2 kg [4.4 lb]). Document vaccine administration in the hospital record. Give the parent a record of the vaccination.

*(continued on next page)*

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

2. Confirm that the laboratory has received blood for the mother's HBsAg test.
3. Verify when the mother's HBsAg result will be available and that it will be reported to the newborn unit ASAP.
4. If the laboratory test indicates the mother's HBsAg test result is positive, do the following:
  - a. Administer HBIG 0.5 mL, IM, ASAP to the newborn weighing 2 kg (4.4 lb) or more. (Those weighing less than 2 kg (4.4 lb) at birth should have already received HBIG.) (Hepatitis B vaccine should have been given within 12 hours of birth to all infants of mothers with unknown HBsAg status.)
  - b. Follow steps 4–7 of previous section (The Mother Is HBsAg Positive).

For additional detailed information about text that you might incorporate into newborn admission orders, including orders for premature infants, refer to “*Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission*” available at [www.immunize.org/catg.d/p2130.pdf](http://www.immunize.org/catg.d/p2130.pdf).

## Reference

*A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Part 1: Immunization of Infants, Children and Adolescents. MMWR*, December 23, 2005, Vol. 54(RR-16):1-39, at [www.cdc.gov/mmwr/pdf/rr/rr5416.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5416.pdf).

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## Public Health

### *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*

U.S. Department of Health and Human Services  
Office of the Secretary

#### **THE PRIVACY RULE** 45 CFR Parts 160 and 164

Related Excerpts from the Final Regulation Text  
Amended as of August 14, 2002

#### **§ 160.102 APPLICABILITY**

- (a) Except as otherwise provided, the standards, requirements, and implementation specifications adopted under this subchapter apply to the following entities:
- (1) A health plan.
  - (2) A health care clearinghouse.
  - (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

#### **§ 164.504 USES AND DISCLOSURES: ORGANIZATIONAL REQUIREMENTS**

- (b) *Standard: health care component.* If a covered entity is a hybrid entity, the requirements of this subpart, other than the requirements of this section, apply only to the health care component(s) of the entity, as specified in this section.
- (g) *Standard: requirements for a covered entity with multiple covered functions [or hybrid entity]*
- (1) A covered entity that performs multiple covered functions that would make the entity any combination of a health plan, a covered health care provider, and a health care clearinghouse, must comply with the standards, requirements, and implementation specifications of this subpart, as applicable to the health plan, health care provider, or health care clearinghouse covered functions performed.
  - (2) A covered entity that performs multiple covered functions may use or disclose the protected health information of individuals who receive the covered entity's health plan or health care provider services, but not both, only for purposes related to the appropriate function being performed.

#### **Does HIPAA apply to public health?**

HIPAA applies to *any* entity that performs certain covered functions (the performance of which would by definition make the entity a health plan, health care provider, or health information clearinghouse). Any part of a public health system that answers affirmative to all of the following questions may be subject to HIPAA and its requirements.

<b>(1) Does the entity (in whole or in part) perform any of the following covered functions...?</b>	<ul style="list-style-type: none"><li>• provide [for] or pay the cost of medical care;</li><li>• provide [direct] medical or health services (or furnish, bill, or receive payment for health care in the normal course of business); or</li><li>• receive, process, or facilitate the processing of health information received from another entity into standard or nonstandard formats.</li></ul>	
<b>(2) Does the entity receive or transmit individually identifiable health information pertaining to...?</b>	<ul style="list-style-type: none"><li>• health plan enrollment (or disenrollment);</li><li>• health plan eligibility determinations;</li><li>• health plan premium payments;</li><li>• referral certification, authorization;</li></ul>	<ul style="list-style-type: none"><li>• claim submissions (encounter info);</li><li>• health plan benefit coordination;</li><li>• claim status inquiries;</li><li>• payment and remittance advices;</li><li>• first report of injury; and/or</li><li>• health claim attachments.</li></ul>
<b>(3) Does the entity conduct any or all of these standard transactions electronically...?</b>		

*This document contains selected text from the HIPAA Privacy Rule [45 CFR Parts 160 and 164]. It is not a complete analysis nor is it legally binding. Covered entities are advised to seek legal counsel for answers to legal questions.*

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

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45 CFR Parts 160 and 164

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## § 164.512(b) STANDARD: USES AND DISCLOSURES FOR PUBLIC HEALTH ACTIVITIES

- (1) *Permitted disclosures.* A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:
  - (i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;
  - (ii) A public health authority or other appropriate government authority authorized by law to receive reports of child abuse or neglect;
  - (iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include:
    - (A) To collect or report adverse events (or similar activities with respect to food or dietary supplements), product defects or problems (including problems with the use or labeling of a product), or biological product deviations;
    - (B) To track FDA-regulated products;
    - (C) To enable product recalls, repairs, or replacement, or lookback (including locating and notifying individuals who have received products that have been recalled, withdrawn, or are the subject of lookback); or
    - (D) To conduct post marketing surveillance;
  - (iv) A person who may have been exposed to a communicable disease or may otherwise be at risk of contracting or spreading a disease or condition, if the covered entity or public health authority is authorized by law to notify such person as necessary in the conduct of a public health intervention or investigation; or
  - (v) An employer, about an individual who is a member of the workforce of the employer, if:
    - (A) The covered entity is a covered health care provider who is a member of the workforce of such employer or who provides health care to the individual at the request of the employer:
      - (1) To conduct an evaluation relating to medical surveillance of the workplace; or
      - (2) To evaluate whether the individual has a work-related illness or injury;
    - (B) The protected health information that is disclosed consists of findings concerning a work-related illness or injury or a workplace-related medical surveillance;
    - (C) The employer needs such findings in order to comply with its obligations, under 29 CFR parts 1904 through 1928, 30 CFR parts 50 through 90, or under state law having a similar purpose, to record such illness or injury or to carry out responsibilities for workplace medical surveillance; and
    - (D) The covered health care provider provides written notice to the individual that protected health information relating to the medical surveillance of the workplace and work-related illnesses and injuries is disclosed to the employer:
      - (1) By giving a copy of the notice to the individual at the time the health care is provided; or
      - (2) If the health care is provided on the work site of the employer, by posting the notice in a prominent place at the location where the health care is provided.
- (2) *Permitted uses.* If the covered entity also is a public health authority, the covered entity is permitted to use protected health information in all cases in which it is permitted to disclose such information for public health activities under paragraph (b)(1) of this section.



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## **§ 164.506 USES AND DISCLOSURES TO CARRY OUT TREATMENT, PAYMENT, OR HEALTH CARE OPERATIONS**

- (a) *Standard: Permitted uses and disclosures.* Except with respect to uses or disclosures that require an authorization under § 164.508(a)(2) and (3), a covered entity may use or disclose protected health information for treatment, payment, or health care operations as set forth in paragraph (c) of this section, provided that such use or disclosure is consistent with other applicable requirements of this subpart.
- (c) *Implementation specifications: Treatment, payment, or health care operations.*
  - (1) A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.
  - (2) A covered entity may disclose protected health information for treatment activities of a health care provider.
  - (3) A covered entity may disclose protected health information to another covered entity or a health care provider for the payment activities of the entity that receives the information.
  - (4) A covered entity may disclose protected health information to another covered entity for health care operations activities of the entity that receives the information, if each entity either has or had a relationship with the individual who is the subject of the protected health information being requested, the protected health information pertains to such relationship, and the disclosure is:
    - (i) For a purpose listed in paragraph (1) or (2) of the definition of health care operations; or
    - (ii) For the purpose of health care fraud and abuse detection or compliance.
  - (5) A covered entity that participates in an organized health care arrangement may disclose protected health information about an individual to another covered entity that participates in the organized health care arrangement for any health care operations activities of the organized health care arrangement.

## **§ 164.512(a) USES AND DISCLOSURES REQUIRED BY LAW**

- (1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.
- (2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

## **§ 164.512(d) USES AND DISCLOSURES FOR HEALTH OVERSIGHT ACTIVITIES**

- (1) *Permitted disclosures.* A covered entity may disclose protected health information to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight of:
  - (i) The health care system;
  - (ii) Government benefit programs for which health information is relevant to beneficiary eligibility;
  - (iii) Entities subject to government regulatory programs for which health information is necessary for determining compliance with program standards; or
  - (iv) Entities subject to civil rights laws for which health information is necessary for determining compliance.

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## § 164.512(d) USES AND DISCLOSURES FOR HEALTH OVERSIGHT ACTIVITIES (cont'd)

- (2) *Exception to health oversight activities.* For the purpose of the disclosures permitted by paragraph (d)(1) of this section, a health oversight activity does not include an investigation or other activity in which the individual is the subject of the investigation or activity and such investigation or other activity does not arise out of and is not directly related to:
  - (i) The receipt of health care;
  - (ii) A claim for public benefits related to health; or
  - (iii) Qualification for, or receipt of, public benefits or services when a patient's health is integral to the claim for public benefits or services.
- (3) *Joint activities or investigations.* Notwithstanding paragraph (d)(2) of this section, if a health oversight activity or investigation is conducted in conjunction with an oversight activity or investigation relating to a claim for public benefits not related to health, the joint activity or investigation is considered a health oversight activity for purposes of paragraph (d) of this section.
- (4) *Permitted uses.* If a covered entity also is a health oversight agency, the covered entity may use protected health information for health oversight activities as permitted by paragraph (d) of this section.

### The Public Health Exception

HIPAA expressly permits covered entities to disclose protected health information for the following purposes:

**EXCEPTIONS**—A provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall not supersede a contrary provision of State law, if the provision of State law—

- (A) is a provision the Secretary determines—
  - (i) is necessary—
    - (I) to prevent fraud and abuse;
    - (II) to ensure appropriate State regulation of insurance and health plans;
    - (III) for State reporting on health care delivery or costs; or
    - (IV) for other purposes; or
  - (ii) addresses controlled substances; or
- (B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

**PUBLIC HEALTH**—Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

**STATE REGULATORY REPORTING**—Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

Source: Public Law 191, 110 Stat. 2030, 104<sup>th</sup> Congress, 2<sup>nd</sup> Session (21 August 1996), *Health Insurance Portability and Accountability Act*.

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## **§ 164.512(j) USES AND DISCLOSURES TO AVERT A SERIOUS THREAT TO HEALTH OR SAFETY**

- (1) *Permitted disclosures.* A covered entity may, consistent with applicable law and standards of ethical conduct, use or disclose protected health information, if the covered entity, in good faith, believes the use or disclosure:
  - (i)
    - (A) Is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public; and
    - (B) Is to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat; or
  - (ii) Is necessary for law enforcement authorities to identify or apprehend an individual:
    - (A) Because of a statement by an individual admitting participation in a violent crime that the covered entity reasonably believes may have caused serious physical harm to the victim; or
    - (B) Where it appears from all the circumstances that the individual has escaped from a correctional institution or from lawful custody, as those terms are defined in § 164.501.
- (2) *Use or disclosure not permitted.* A use or disclosure pursuant to paragraph (j)(1)(ii)(A) of this section may not be made if the information described in paragraph (j)(1)(ii)(A) of this section is learned by the covered entity:
  - (i) In the course of treatment to affect the propensity to commit the criminal conduct that is the basis for the disclosure under paragraph (j)(1)(ii)(A) of this section, or counseling or therapy; or
  - (ii) Through a request by the individual to initiate or to be referred for the treatment, counseling, or therapy described in paragraph (j)(2)(i) of this section.
- (3) *Limit on information that may be disclosed.* A disclosure made pursuant to paragraph (j)(1)(ii)(A) of this section shall contain only the statement described in paragraph (j)(1)(ii)(A) of this section and the protected health information described in paragraph (f)(2)(i) of this section.
- (4) *Presumption of good faith belief.* A covered entity that uses or discloses protected health information pursuant to paragraph (j)(1) of this section is presumed to have acted in good faith with regard to a belief described in paragraph (j)(1)(i) or (ii) of this section, if the belief is based upon the covered entity's actual knowledge or in reliance on a credible representation by a person with apparent knowledge or authority.

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## DEFINITIONS

### **Business associate<sup>\*</sup>:**

- (1) Except as provided in paragraph (2) of this definition, *business associate* means, with respect to a covered entity, a person who:
  - (i) On behalf of such covered entity or of an organized health care arrangement (as defined in § 164.501 of this subchapter) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, performs, or assists in the performance of:
    - (A) A function or activity involving the use or disclosure of individually identifiable health information, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, billing, benefit management, practice management, and repricing; or
    - (B) Any other function or activity regulated by this subchapter; or
  - (ii) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in § 164.501 of this subchapter), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.
- (2) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement, does not, simply through the performance of such function or activity or the provision of such service, become a business associate of other covered entities participating in such organized health care arrangement.
- (3) A covered entity may be a business associate of another covered entity.

### **Covered entity<sup>\*</sup> means:**

- (1) A health plan.
- (2) A health care clearinghouse.
- (3) A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter.

**Covered functions<sup>†</sup>** means those functions of a covered entity the performance of which makes the entity a health plan, health care provider, or health care clearinghouse.

**Direct treatment relationship<sup>†</sup>** means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

**Disclosure<sup>†</sup>** means the release, transfer, provision of access to, or divulging in any other manner of information outside the entity holding the information.

**Health care clearinghouse<sup>\*</sup>** means a public or private entity, including a billing service, repricing company, community health management information system or community health information system, and “value-added” networks and switches, that does either of the following functions:

- (1) Processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction.
- (2) Receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

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\* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504

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**Health care component<sup>‡</sup>** means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with paragraph (c)(3)(iii) of this section.

**Health care provider<sup>\*</sup>** means a provider of services (as defined in section 1861(u) of the Act, 42 U.S.C. 1395x(u)), a provider of medical or health services (as defined in section 1861(s) of the Act, 42 U.S.C. 1395x(s)), and any other person or organization who furnishes, bills, or is paid for health care in the normal course of business.

**Health information<sup>\*</sup>** means any information, whether oral or recorded in any form or medium, that:

- (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

**Health oversight agency<sup>†</sup>** means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is authorized by law to oversee the health care system (whether public or private) or government programs in which health information is necessary to determine eligibility or compliance, or to enforce civil rights laws for which health information is relevant.

**Health plan<sup>\*</sup>** means an individual or group plan that provides, or pays the cost of, medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

- (1) *Health plan* includes the following, singly or in combination:
  - (i) A group health plan, as defined in this section.
  - (ii) A health insurance issuer, as defined in this section.
  - (iii) An HMO, as defined in this section.
  - (iv) Part A or Part B of the Medicare program under title XVIII of the Act.
  - (v) The Medicaid program under title XIX of the Act, 42 U.S.C. 1396, et seq.
  - (vi) An issuer of a Medicare supplemental policy (as defined in section 1882(g)(1) of the Act, 42 U.S.C. 1395ss(g)(1)).
  - (vii) An issuer of a long-term care policy, excluding a nursing home fixed-indemnity policy.
  - (viii) An employee welfare benefit plan or any other arrangement that is established or maintained for the purpose of offering or providing health benefits to the employees of two or more employers.
  - (ix) The health care program for active military personnel under title 10 of the United States Code.
  - (x) The veterans health care program under 38 U.S.C. chapter 17.
  - (xi) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)(as defined in 10 U.S.C. 1072(4)).
  - (xii) The Indian Health Service program under the Indian Health Care Improvement Act, 25 U.S.C. 1601, et seq.
  - (xiii) The Federal Employees Health Benefits Program under 5 U.S.C. 8902, et seq.
  - (xiv) An approved State child health plan under title XXI of the Act, providing benefits for child health assistance that meet the requirements of section 2103 of the Act, 42 U.S.C. 1397, et seq.
  - (xv) The Medicare + Choice program under Part C of title XVIII of the Act, 42 U.S.C. 1395w-21 through 1395w-28.
  - (xvi) A high risk pool that is a mechanism established under State law to provide health insurance coverage or comparable coverage to eligible individuals.
  - (xvii) Any other individual or group plan, or combination of individual or group plans, that provides or pays for the cost of medical care (as defined in section 2791(a)(2) of the PHS Act, 42 U.S.C. 300gg-91(a)(2)).

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\* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504

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(2) *Health plan* excludes:

- (i) Any policy, plan, or program to the extent that it provides, or pays for the cost of, excepted benefits that are listed in section 2791(c)(1) of the PHS Act, 42 U.S.C. 300gg-91(c)(1); and
- (ii) A government-funded program (other than one listed in paragraph (1)(i)-(xvi) of this definition):
  - (A) Whose principal purpose is other than providing, or paying the cost of, health care; or
  - (B) Whose principal activity is:
    - (1) The direct provision of health care to persons; or
    - (2) The making of grants to fund the direct provision of health care to persons.

**Hybrid entity<sup>†</sup>** means a single legal entity:

- (1) That is a covered entity;
- (2) Whose business activities include both covered and non-covered functions; and
- (3) That designates health care components in accordance with paragraph (c)(3)(iii) of this section.

**Indirect treatment relationship<sup>†</sup>** means a relationship between an individual and a health care provider in which:

- (1) The health care provider delivers health care to the individual based on the orders of another health care provider; and
- (2) The health care provider typically provides services or products, or reports the diagnosis or results associated with the health care, directly to another health care provider, who provides the services or products or reports to the individual.

**Individually identifiable health information<sup>\*</sup>** is information that is a subset of health information, including demographic information collected from an individual, and:

- (1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and
- (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and
  - (i) That identifies the individual; or
  - (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

**Plan administration functions<sup>‡</sup>** means administration functions performed by the plan sponsor of a group health plan on behalf of the group health plan and excludes functions performed by the plan sponsor in connection with any other benefit or benefit plan of the plan sponsor.

**Protected health information<sup>†</sup>** means individually identifiable health information:

- (1) Except as provided in paragraph (2) of this definition, that is:
  - (i) Transmitted by electronic media;
  - (ii) Maintained in any medium described in the definition of *electronic media* at § 162.103 of this subchapter; or
  - (iii) Transmitted or maintained in any other form or medium.
- (2) *Protected health information* excludes individually identifiable health information in:
  - (i) Education records covered by the Family Educational Rights and Privacy Act,
  - (ii) as amended, 20 U.S.C. 1232g;
  - (iii) Records described at 20 U.S.C. 1232g(a)(4)(B)(iv); and
  - (iv) Employment records held by a covered entity in its role as employer.

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\* 45 CFR § 160.103  
† 45 CFR § 164.501  
‡ 45 CFR § 164.504

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**Public health authority<sup>†</sup>** means an agency or authority of the United States, a State, a territory, a political subdivision of a State or territory, or an Indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

**Research<sup>‡</sup>** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

**Required by law<sup>‡</sup>** means a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or an administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing public benefits.

**Trading partner agreement<sup>‡</sup>** means an agreement related to the exchange of information in electronic transactions, whether the agreement is distinct or part of a larger agreement, between each party to the agreement. (For example, a trading partner agreement may specify, among other things, the duties and responsibilities of each party to the agreement in conducting a standard transaction.)

**Treatment<sup>‡</sup>** means the provision, coordination, or management of health care and related services by one or more health care providers, including the coordination or management of health care by a health care provider with a third party; consultation between health care providers relating to a patient; or the referral of a patient for health care from one health care provider to another.

**Use<sup>‡</sup>** means, with respect to individually identifiable health information, the sharing, employment, application, utilization, examination, or analysis of such information within an entity that maintains such information.

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\* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504



# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual



THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

## About the Notice

When you receive treatment or benefits from any Department of State Health Services (DSHS) facility, we will obtain and/or create information about your health and treatment. Protected Health Information (PHI) includes any information that relates to:

- Your past, present, or future physical or mental health or condition;
- Health care provided to you; and,
- Past, present, or future payment for your health care.

The following notice tells you about DSHS' duty to protect your PHI, your privacy rights, and how we may use or disclose your health information.

## DSHS Duties and Responsibilities

The law requires us to protect the privacy of your PHI. This means that we will:

- Not use or let other people see your PHI without your permission except in the ways we tell you in this notice; and,
- Safeguard your PHI and keep it private. (This protection applies to all PHI we have about you, regardless of when or where you received or requested services.)

If you receive direct health care or dental care from DSHS, DSHS will:

- Not allow any unauthorized person to interview, photograph, film, or record you without your written permission;
- Ask you for your written permission (authorization or consent) to use or disclose your PHI (with the exception of uses and disclosures for treatment, payment and/or health care operations.)
- If you give such authorization, you may revoke it at any time, but DSHS will not be liable for uses or disclosures made before you revoked your authorization.
- Not tell anyone if you requested, are receiving, or have ever received services from DSHS, unless the law allows us to disclose that information.

We are required to give you this notice of our legal duties and privacy practices, and we must do what this notice says. We will also provide you with a copy of this notice upon request. We can change the contents of this notice and, if we do, we will have copies of the new notice at our facilities and on the DSHS website - [www.dshs.state.tx.us/hipaa](http://www.dshs.state.tx.us/hipaa). The new notice will apply to all PHI we have, regardless of when we received or created the information.

Our employees must protect the privacy of your PHI as part of their jobs. We do not let our employees see your PHI unless they need it as part of their jobs. Employees who do not protect the privacy of your PHI will be disciplined.

We will not disclose information about you related to testing for Human Immunodeficiency Virus or Acquired Immune Deficiency Syndrome without your specific written permission, unless otherwise provided by law.

## Your Privacy Rights at DSHS

You can read or get a copy of your PHI. There are some reasons why we may not let you see or get a copy of your PHI, and if we deny your request we will tell you why. You can appeal our decision in some situations. You can choose to get a summary of your PHI instead of a copy. If you want a summary or a copy of your PHI, you may have to pay a reasonable fee for it.

You can request that we correct information in your records if you think the information is incorrect. We will not destroy or change our records, but we will add the correct information to your records and make a note in your records that you have provided the information. If DSHS denies your request, you can have your written disagreement placed in your record.

You can get a list of the disclosures of your PHI that we made to other people in the last six years. The list will not include disclosures for treatment, payment, health care operations, national security, law enforcement, or disclosures where you gave your permission.

You can ask us to limit some of the ways we use or share your PHI. We will consider your request, but the law does not require us to agree to it. If we do agree, we will put the agreement in writing and follow it, except in case of emergency. We cannot agree to limit the uses or sharing of information that are required by law.

You can ask us to contact you at a different place or in some other way. You must put this request in writing and be specific about how to contact you. We will agree to your request as long as it is reasonable.

You may exercise any of the rights described above by contacting the DSHS office or program that has PHI about you, or by contacting the DSHS Privacy Officer.



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## Treatment, Payment, and Health Care Operations

We may use or disclose your PHI to provide care to you, to obtain payment for that care, or for our own health care operations.

Health information about you may be exchanged between DSHS facilities and DSHS contractors, for purposes of treatment, payment, or health care operations, without your permission. If DSHS shares your PHI with a contractor, the contractor must agree to protect the privacy of the PHI.

### *Treatment*

We can use or disclose your PHI to provide, coordinate, or manage health care or related services. This includes providing care to you, consulting with another health care provider about you, and referring you to another health care provider. For example, we can use your PHI to refer you to a community program for services. Unless you ask us not to, we may also contact you to remind you of an appointment or to offer treatment alternatives or other health-related information that may interest you.

### *Payment*

We can use or disclose your PHI to obtain payment for providing health care to you or to provide benefits to you under a health plan such as the Medicaid program. For example, we can use your PHI to bill your insurance company for health care provided to you.

### *Health Care Operations*

We can also use your PHI for:

- Activities to improve health care;
- Evaluating programs and developing procedures;
- Case management and care coordination;
- Reviewing the competence, qualifications, or performance of health care professionals and others;
- Conducting training programs;
- Resolving internal grievances;
- Conducting accreditation, quality assessment, certification, licensing, or credentialing activities;
- Providing medical review, legal services, or auditing functions;
- Carrying out activities related to the creation, renewal, or replacement of a contract for health insurance or health benefits; and
- Engaging in business planning and management or general administration.

For example, DSHS may use or disclose your PHI to make sure providers bill only for care you receive.

**Unless you are receiving treatment for alcohol or drug abuse DSHS is permitted to use or disclose your PHI without your permission for the following purposes:**

### *When required by law*

We may use or disclose your PHI when a law requires the use or disclosure.

### *Serious threat to health or safety*

We may use or disclose your PHI to medical or law enforcement personnel if you or others are in danger and the information is necessary to prevent physical harm.

### *Victims of abuse, neglect or violence*

If DSHS believes you are the victim of abuse, neglect, or domestic violence, DSHS may disclose PHI about you to a person legally authorized to investigate a report that you have been abused, neglected, or have been denied your rights. If DSHS does this, DSHS will tell you or your legally authorized representative (LAR) about the report unless DSHS believes that doing so could harm you.

### *To a correctional institution*

If you are in the custody of a correctional institution, we may disclose your PHI to the institution in order to provide health care to you, or for the health and safety of other inmates or employees of the institution.

### *If you are in the criminal justice system*

We may disclose your PHI to other state agencies involved in your treatment, rehabilitation, or supervision.

### *For other law enforcement purposes*

DSHS may disclose PHI about you to a law enforcement official:

- To comply with a grand jury subpoena, summons, investigation, or similar lawful process;
- To identify and locate a suspect, fugitive, witness, or missing person;
- In response to a request for information about an actual or suspected crime victim;
- To alert a law enforcement official of a death that DSHS suspects is the result of criminal conduct;
- To report evidence of a crime on DSHS property; or
- To provide information learned while providing emergency treatment to an individual regarding criminal activity.

### *To locate you if you are missing from a facility*

If you are a patient in a state hospital, we may disclose some information about you to law enforcement personnel so that they can find you and return you to the hospital if you are missing.

# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

## ***Public health activities***

We will disclose your PHI to:

- A public health authority for purposes of preventing or controlling disease, injury, or disability, or to report vital statistics;
- A government agency allowed to receive reports of child abuse or neglect;
- The Food and Drug Administration (FDA) to report problems with medications, products, or activities regulated by the FDA;
- A person who may have been exposed to a contagious disease or who is at risk of contracting or spreading a disease or condition; or,
- A person or agency investigating work-related illness or injury or conducting workplace medical surveillance.

## ***Health oversight activities***

DSHS may use or disclose PHI about you for activities necessary for oversight of the health care system, government benefit programs, or to enforce civil rights laws. This may include:

- Audits or inspections;
- Investigations of possible fraud; or
- Investigations of whether someone licensed by DSHS is providing good care.

## ***Government benefit programs***

We may use or disclose your PHI as needed to comply with a government benefit program, such as Medicaid.

## ***Research***

We may use or disclose your PHI if a research board says it can be used for a research project, or if information identifying you is removed from the PHI. Your PHI may also be used to allow a researcher to prepare for research, as long as the researcher agrees to keep the PHI confidential. PHI about people who have died can also be used for research.

## ***To your legally authorized representative (LAR)***

We may share your PHI with a person the law allows to represent your interests, such as a guardian, unless DSHS thinks that it would harm you to do so.

## ***Family member, other relative or close personal friend***

Unless you are a patient in a state hospital, DSHS may disclose limited PHI about you to a family member, other relative, or close personal friend when the PHI is related to that person's involvement with your care or payment for your care and you have an opportunity to stop or limit the disclosure before it happens.

## ***Purposes relating to death***

If you die, we may disclose your PHI to your personal representative and to coroners or medical examiners to identify you or determine the cause of death. We may also disclose information about you for burial purposes, including grave marker inscription, unless you tell us not to.

## ***Other uses and disclosures***

We may disclose your PHI:

- In a criminal or civil proceeding if a court or administrative judge has issued an order or subpoena that requires us to disclose it;
- In commitment proceedings for involuntary commitment for court-ordered treatment or services;
- For court-ordered examinations for a mental or emotional condition or disorder;
- In proceedings regarding abuse or neglect of a resident of an institution;
- In license revocation proceedings against a doctor or other professional;
- To create health information that does not identify any specific individual;
- To the U.S. or a foreign military for military purposes;
- For national security purposes;
- To federal officials to protect the President and others;
- For security clearances and medical suitability determinations required by the U.S. government; and,
- To comply with workers' compensation or similar laws.

## ***Secretary of Health and Human Services***

We must disclose your PHI to the United States Department of Health and Human Services when requested in order to enforce the privacy laws.

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**DSHS may only disclose information about your treatment for alcohol or drug abuse without your permission in the following circumstances:**

- Pursuant to a special court order that complies with 42 Code of Federal Regulations Part 2, Subpart E;
- To medical personnel in a medical emergency;
- To qualified personnel for research, audit, or program evaluation;
- To report suspected child abuse or neglect;
- In relation to a crime on the premises of the program or against personnel of the program, committed by you; or
- To Advocacy, Inc. and/or the Texas Department of Family and Protective Services, as allowed by law, to investigate a report that you have been abused or have been denied your rights.

**Records about treatment for alcohol or drug abuse are protected by federal law and regulations found in the Code of Federal Regulations at Title 42, Part 2. Violation of the laws that protect these records is a crime, and suspected violations may be reported to appropriate authorities in accordance with federal regulations. Federal and state laws prohibit re-disclosure of information about alcohol or drug abuse treatment without your permission. Federal rules restrict any use of information about alcohol or drug abuse treatment to criminally investigate or prosecute any alcohol or drug abuse patient.**

## HOW TO FILE A COMPLAINT:

If you believe that DSHS has violated your privacy rights, you have the right to file a complaint with the:

**DSHS HIPAA Privacy Officer** by mail at Mail Code 1915 P.O. Box 149347, Austin, TX 78714-9347; or by telephone at 512--963-7111 or 888-963-7111 (toll free); or by e-mail at: [privacy.hipaa@dshs.state.tx.us](mailto:privacy.hipaa@dshs.state.tx.us)

If you are receiving care from a DSHS state-operated hospital, then you may also contact:

**DSHS Consumer Services and Rights Protection/Ombudsman Office** by mail at Mail Code 2019, P.O. Box 149347 Austin, TX 78714-9347; or by telephone at (512) 206-5760 or (800) 252-8154 (toll free);

You may also contact the:

**U.S. Secretary of Health and Human Services, Office for Civil Rights, Region VI** – Dallas by mail at 1301 Young Street, Suite 1169, Dallas, TX 75202; or by telephone at (214) 767-4056 or (214) 767-8940 (TDD) or (800) 368-1019 (toll free OCR Hotline); by fax at (214) 767-0432;

**For complaints regarding the violation of your right to confidentiality by an alcohol or drug abuse treatment program, contact the United States Attorney's Office for the judicial district in which the violation occurred.**

**There will be no retaliation for filing a complaint.**

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## **Appendix F**

### **Ordering Hepatitis B Biologicals & DSHS Specimen Submission**

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

### Ordering HBIG and Hepatitis B Vaccine from DSHS

To order emergency HBIG and/or hepatitis B vaccine for newborns, Texas Department of State Health Services (DSHS) Public Health Region (PHR) and Local Health Department (LHD) offices must email the Texas Perinatal Hepatitis B Prevention Program (PHBPP) at [TxPeriHepB@dshs.texas.gov](mailto:TxPeriHepB@dshs.texas.gov) with the following information:

- **The Provider Identification Number (PIN)**
- **Clinic Days and Hours:** List the hours the clinic will be open to accept vaccine shipments for each day of the week and note any lunch periods when no one is available to receive the vaccine. Be sure to note any holidays or clinic closings.
- **Contact Person:** Name of person who is physically present at the clinic to accept the shipment.
- **Phone:** Phone number of the contact person.
- **Clinic Address:** Provide complete name and address of clinic.
- **Pick from List:** Provide the vaccine needed and the vaccine formulation requested and the request for HBIG.
- **Order Amount:** Indicate number of doses needed.
- **Date of Order:** Date the order was completed.

Upon receiving a vaccine request, the DSHS PHBPP will forward the request to the Vaccine Management Group to submit the order in the Inventory Tracking Electronic Assets Management System (ITEAMS).

The order will be shipped via the DSHS Pharmacy Unit. The DSHS Pharmacy Unit ships orders on Monday, Tuesday, and Wednesday of each week. To meet shipping deadlines, orders must be received before 2:00 p.m. on these days. In the event of an emergency, please call the DSHS Immunization Section at 800-252-9152. For after hour emergencies, call the DSHS emergency telephone number (512) 776-4911 and ask for the physician on-call then give the physician the information concerning your emergency.

## Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

### Submitting Specimens to DSHS-Austin Laboratory

If your agency does not already have a submitter identification (ID), one must be created with the DSHS Laboratory **prior to** submitting specimens for testing. To request a submitter ID, the *Submitter Identification (ID) Number Request Form* should be completed. It is available at the DSHS laboratory website at [www.dshs.state.tx.us/WorkArea/DownloadAsset.aspx?id=8589956433](http://www.dshs.state.tx.us/WorkArea/DownloadAsset.aspx?id=8589956433). Once completed, the form should be faxed to (512) 776-7533. Once the lab has received the completed form, a submitter ID will be created. Specimens cannot be shipped until a submitter ID has been acquired and given to your facility. For questions, please call (512) 776-7578.

**Note:** Do not collect a specimen until you have a submitter ID, as this process may take several days to complete.

To submit a specimen for testing at the DSHS Laboratory after a submitter ID is obtained:

1. Complete the DSHS Specimen Submission Form (G-2A) for the corresponding sample. The information below is required for all specimens submitted to the DSHS Laboratory. **Submissions missing any of the information below will not be processed.** For additional guidance, a current sample of the G-2A submission form and detailed instructions is available at [http://www.dshs.state.tx.us/lab/MRS\\_forms.shtm](http://www.dshs.state.tx.us/lab/MRS_forms.shtm).

- **Section 1**

- Submitter
  - Name
  - Submitter ID
  - National Provider Identifier (NPI) number
  - Address and contact information

- **Section 2**

- Patient identifiers
  - **Name**
  - **Date of Birth**



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- Medical records number
  - Address and contact information
  - Collection
    - Date and Time (must match the specimen)
  - **Section 3**
    - Specimen source (serum, plasma, etc.)
  - **Section 7**
    - Requested test(s): (*check all boxes that apply*)
      - Hepatitis B surface antibody (anti-HBs)
      - Hepatitis B surface antigen (HBsAg)
      - Hepatitis B core antibody (anti-HBc)
      - Hepatitis B core IgM antibody (IgM anti-HBc)
  - **Section 8**
    - Ordering Physician Information (including NPI Number)
  - **Section 9**
    - Payor Source
      - Immunizations
2. Retain a copy of the G2-A for your records.
- Tip:** *Keep a copy of the submission form in the patient's case management chart.*
3. Clearly label the red top or tiger top tube and paperwork with:
- Patient's full name and DOB
  - Date **and** time of collection
  - Initials of person collecting specimen
- NOTE:** All information (name, date, time) on the submission form **must** match the information on the specimen tube. If any information does not match, the specimen will be rejected, and no testing will be performed.
4. Obtain 6-8 mL of venous blood (minimum of 2 mL) in a red top tube

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(serum tube) or tiger top tube (Serum Separator Tube [SST]).

5. Single or Separated Serum may be submitted; **whole blood is not accepted.**
6. The tiger top SST tubes cannot be frozen. If specimen needs to be frozen, remove the separated serum and place in a red top tube. If frozen, the date and time removed from the freezer must be noted in the section at the bottom right corner of the G-2A form.
7. Do not send specimens to be delivered on Saturday, as staff will not be available to receive deliveries.
8. Do not ship on Fridays or the day before state holidays. State holidays/closures can be found at <http://www.hr.sao.texas.gov/Holidays>.

**Table F.1. DSHS Lab Criteria for Hepatitis B Specimen Testing**

Test	Specimen Type	Time allowed from collection to laboratory arrival	Temperature	Shipping Requirement
<b>Anti-HBs</b> <b>HBsAg</b> <b>Anti-HBc</b> <b>IgM</b>	Serum separated from the clot (red top or tiger top)	Up to 48 hours	Cold 2°C to 8°C	Ship on cold packs
	Serum separated from the clot (red top only)	Greater than 48 hours	Frozen -20°C or colder	Ship on dry ice

For additional information on protocols for shipping biological specimens, visit [www.dshs.state.tx.us/lab/mrs\\_shipping.shtm](http://www.dshs.state.tx.us/lab/mrs_shipping.shtm).

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For any other questions regarding laboratory submission, visit [www.dshs.state.tx.us/lab](http://www.dshs.state.tx.us/lab) or call (512) 776-7578.

For frequently asked questions (FAQs) about the laboratory, visit: [www.dshs.state.tx.us/lab/ab\\_faqs.shtm](http://www.dshs.state.tx.us/lab/ab_faqs.shtm).

To obtain laboratory results, status on laboratory tests, or to have a duplicate report sent, please call (512) 776-7578.

Specimens and their G-2A form should be shipped by overnight carrier to:

**Attn: Walter Douglass**  
**Texas Department of State Health Services**  
**Laboratory Services Section**  
**1100 West 49<sup>th</sup> Street**  
**Austin, Texas 78756-3194**

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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## **Appendix G**

### **Immunization Action Coalition Hepatitis B Birth Dose Honor Roll**

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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# Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual

FROM THE IMMUNIZATION ACTION COALITION

## Do you qualify for the Hepatitis B Birth Dose Honor Roll? If so, apply today.

The Immunization Action Coalition (IAC) is recognizing hospitals and birthing centers that have attained 90% or greater coverage rates for administering hepatitis B vaccine at birth and have met specific additional criteria. These criteria define the important elements of written birth dose policies aimed at protecting newborns, including when medical errors occur.

### Criteria for Inclusion into the Honor Roll

To be included in IAC's Hepatitis B Birth Dose Honor Roll, a birthing institution must have:

- ☒ Achieved, over a 12-month period, a coverage rate of 90% or greater for administering hepatitis B vaccine before hospital discharge to all newborns (regardless of weight), including those whose parents refuse vaccination, and
- ☒ Implemented certain written policies, procedures, and protocols to protect all newborns from hepatitis B virus infection prior to hospital discharge.

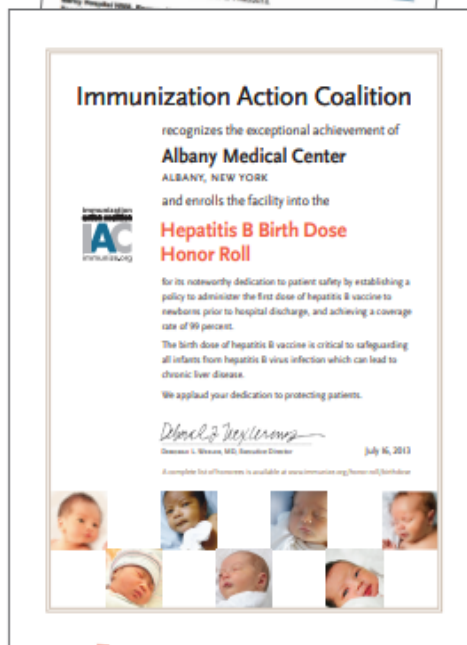
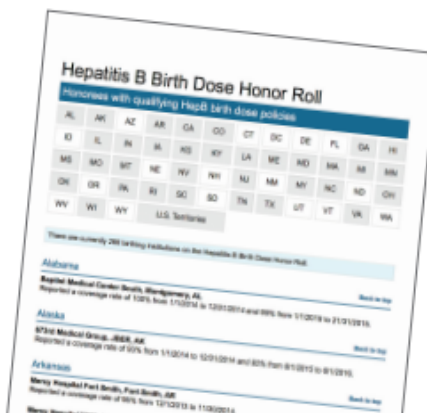
To apply for the Birth Dose Honor Roll, visit

[www.immunize.org/honor-roll/birthdose](http://www.immunize.org/honor-roll/birthdose)

### Benefits

- Inclusion in online Honor Roll
- Announcement of achievement in nation's largest immunization e-newsletter, *IAC Express*, sent to approximately 50,000 subscribers
- Receipt of beautiful 8.5" x 11" color award certificate suitable for framing
- Peer recognition in the immunization community

**IMMUNIZATION ACTION COALITION** Saint Paul, Minnesota • 651-647-9009 • [www.immunize.org](http://www.immunize.org) • [www.vaccineinformation.org](http://www.vaccineinformation.org)  
[www.immunize.org/catg.d/p2205.pdf](http://www.immunize.org/catg.d/p2205.pdf) • Item #P2205 (7/16)



The universal hepatitis B vaccine birth dose is supported by leading health organizations

- American Academy of Family Physicians (AAFP)
- American Academy of Pediatrics (AAP)
- American College of Obstetricians and Gynecologists (ACOG)
- Centers for Disease Control and Prevention (CDC)

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### Texas Hospitals Enrolled in the Immunization Action Coalition (IAC) Hepatitis B Birth Dose Honor Roll

Facility	City	Years Qualified
Ben Taub Hospital	Houston	2
Baylor, Scott & White Medical Center-Brenham	Brenham	2
Baylor, Scott & White Medical Center-College Station	College Station	3
Baylor, Scott & White Medical Center-Lakepointe	Rowlett	1
Baylor, Scott & White Medical Center-Marble Falls	Marble Falls	1
Baylor, Scott & White Medical Center-Round Rock	Round Rock	1
Baylor, Scott & White Medical Center-Waxahachie	Waxahachie	3
Big Bend Medical Center	Alpine	2
Brownfield Regional Medical Center	Brownfield	2
BSA Health System	Amarillo	2
CHI St. Joseph Health Bryan	Bryan	2
CHI St. Luke's Health Memorial	Lufkin	1
Childress Regional Medical Center	Childress	1
CHRISTUS Mother Frances Hospital - Sulphur Springs	Sulphur Springs	3
CHRISTUS Spohn Hospital Kleberg	Kingsville	1
CHRISTUS St. Michael Health System	Texarkana	1
Cogdell Memorial Hospital	Snyder	4



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<b>Facility</b>	<b>City</b>	<b>Years Qualified</b>
Coleman County Medical Center	Coleman	1
Columbus Community Hospital	Columbus	2
Coon Memorial Hospital	Dalhart	1
Covenant Children's Hospital	Lubbock	1
Covenant Hospital Levelland	Levelland	1
Covenant Hospital Plainview	Plainview	3
Del Sol Medical Center	El Paso	1
Doctors Hospital of Laredo	Laredo	1
East Texas Medical Center Jacksonville	Jacksonville	2
Golden Plains Community Hospital	Borger	2
Good Shepherd Medical Center Marshall	Marshall	1
Goodall-Witcher Healthcare Foundation	Clifton	1
HCA The Women's Hospital of Texas	Houston	2
Hendrick Medical Center	Abilene	1
Hereford Regional Medical Center	Hereford	1
Hill Regional Hospital	Hillsboro	2
The Hospitals of Providence-East Campus	El Paso	1
The Hospitals of Providence-Memorial Campus	El Paso	1
The Hospitals of Providence-Sierra Campus	El Paso	1
The Hospitals of Providence Transmountain Campus	El Paso	1

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Facility	City	Years Qualified
Houston Methodist Hospital	Houston	2
Houston Methodist ST. John Hospital	Nassau Bay	2
Houston Methodist Sugarland Hospital	Sugarland	1
Houston Northwest Medical Center	Houston	1
Hunt Regional Medical Center Greenville	Greenville	1
Lake Granbury Medical Center	Granbury	1
Lamb Healthcare Center	Littlefield	1
Las Palmas Medical Center	El Paso	1
Lyndon B. Johnson General Hospital	Houston	4
Medical Arts Hospital	Lamesa	1
Medical Center Hospital Odessa	Odessa	1
Memorial Hermann Pearland Hospital	Pearland	2
Memorial Hermann Southeast Hospital	Houston	4
Memorial Hermann Southwest Hospital	Houston	2
Methodist Dallas Medical Center	Dallas	2
Methodist San Jacinto Hospital	Baytown	2
Midland Memorial Hospital	Midland	1
Moore County Hospital	Dumas	1
Nacogdoches Medical Center	Nacogdoches	1
North Texas Medical Center	Gainesville	1
Ochiltree General Hospital	Perryton	2
Odessa Regional Medical Center	Odessa	2

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Facility	City	Years Qualified
Olney Hamilton Hospital	Olney	3
Palo Pinto General Hospital	Mineral Wells	5
Pampa Regional Medical Center	Pampa	1
Pecos County Memorial Hospital	Fort Stockton	1
Reeves County Hospital District	Pecos	1
Rio Grande Regional Hospital	McAllen	1
Rolling Plains Memorial Hospital	Sweetwater	1
Scenic Mountain Medical Center	Big Spring	2
Seminole Memorial Hospital	Seminole	3
Seton Medical Center Williamson	Round Rock	1
Seymour Hospital	Seymour	1
Shannon Medical Center	San Angelo	4
St David's Georgetown Hospital	Georgetown	2
St. David's Round Rock Medical Center	Round Rock	4
St. David's South Austin Medical Center	Austin	2
Starr County Memorial Hospital	Rio Grande City	2
Texas Children's Hospital	Houston	1
Texas Health Harris Methodist Hospital	Stephenville	1
Texas Health Huguley-Fort Worth South	Fort Worth	3
Texas Health Rockwall	Rockwall	2
Texoma Medical Center	Denison	1
Tomball Regional Medical Center	Tomball	1

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Facility	City	Years Qualified
United Regional	Wichita Falls	1
UTMB Health Angleton-Danbury Campus	Angleton	1
Valley Baptist Medical Center Brownsville	Brownsville	3
Wadley Regional Medical Center	Texarkana	1
Weatherford Regional Medical Center	Weatherford	1
William Beaumont Army Medical Center	El Paso	1
Wilson N. Jones Regional Medical Center	Sherman	2
Yoakum County Memorial Hospital	Denver City	4

# Appendix H

## Frequently Asked Questions

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

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## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

### **1. What should we do when we get discrepant lab results for cases? (i.e., when a prenatal HbsAg lab is positive and the delivery HbsAg lab is negative?)**

Women who have had ANY confirmed positive HBsAg lab result should be case managed and their infants should receive Post-Exposure Prophylaxis (PEP) at birth. They should be case managed until HBsAg status is confirmed. To determine chronic hepatitis B, the client needs to have two (2) positive HBsAg results at least six (6) months apart. Clients with discrepant labs should be tested for HBsAg, Anti-HBs & Anti-HBc. This will help differentiate between acute and chronic hepatitis B cases. In addition, getting the vaccine history can help determine if they had a false positive HbsAg result.

### **2. When should I close out an index case as “referred for medical follow up” and how do I do that?**

Referred for medical follow-up means that the case manager has instructed the index case to follow-up with their PCP or specialist for management of hepatitis B. Case managers do not need to get an actual referral for the client. Any index case with chronic hepatitis B can be closed as “referred to medical follow up,” as long as they have been educated about the need for regular hepatitis B monitoring and advised to see their specialist/PCP.

### **3. What should we do if postvaccine serology testing (PVST) for an infant is done before the infant is 9 months of age?**

Completing PVST prior to 9 months of age is not recommended, as it can lead to inaccurate results due to the detection of passive anti-HBs from the HBIG administered at birth. Also, testing after 9 months of age will increase the chance of detecting a late hepatitis B infection. If an infant completes testing early, they should be re-tested again after 9 months of age to ensure accurate results. Education should be given to the provider about the need to wait until the infant is over 9 months of age to perform PVST.

### **4. I have pediatric providers who want to wait to do PVST at 1 year of age. How should I respond to this?**

Case managers should educate providers on why completing PVST at 9 months of age is optimal for the child’s health and safety. Infants who

## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

complete the hepatitis B vaccine series on time should have PVST done at 9 months of age to capture any late-occurring hepatitis B infections, while avoiding inaccurately sensing passive anti-HBs still circulating from the HBIG given at birth. PVST at 9 months of age is also convenient because the infant is due for a well-child check-up.

Waiting to perform PVST until the child is older can result in false-negative Anti-HBs results and more vaccines for the infant. In addition, infants who do not respond to the first series of vaccines are still susceptible to hepatitis B and are at high risk of exposure in their household. It is imperative that the susceptible infants are re-vaccinated immediately to prevent hepatitis B transmission. Also, there are occasional cases of perinatal hepatitis B infection, despite PEP, and these infants need to be evaluated and reported as soon as possible.

### **5. What should we do when we have cases that are not responding to calls/letters?**

Utilize all available resources to check for updated contact information, including providers, NEDSS, ImmTrac2, and Medicaid/WIC, as applicable. Ask the provider if they have received a record request from another provider or know of any plans to move out of the country or out of the state. Follow the instructions listed in Chapter 9: Case Management to establish contact with the client. Do not close out as “never located” or “lost to follow-up” without following the steps listed in the manual. If unable to establish contact after following the steps listed in the manual, contact your coordinator for advice on how to close the case.

### **6. What are some strategies to educate providers?**

Provider education and training is a vital component of the Texas Department of State Health Services (DSHS) Perinatal Hepatitis B Prevention Program (PHBPP). It is the responsibility of the case managers to provide training to prenatal providers, labor & delivery staff, and pediatricians. These providers all need to be aware of the state laws and statutes related to HbsAg testing and reporting, serology interpretation, recommended post-exposure prophylactics (PEP), how to handle mothers with an unknown status, and the hepatitis B vaccine series and PVST.



## **Texas Perinatal Hepatitis B Prevention Program (PHBPP) Manual**

There are various ways to provide training. An in-person training is best for new providers or new labor and delivery staff. See the training checklist for details of topics and materials for each type of training. In-person training may also be needed after there is a missed HBsAg screen, PEP, etc., to review the facility's policies and procedures.

### **7. Can you explain what is different for infants who weigh less than 2,000 grams (4.4 lbs.) at birth?**

Infants who weigh less than 2,000 g at birth (<4.4 lbs.) are considered low birthweight infants (LBW). LBW infants born to HbsAg-positive mothers should receive HBIG and the birth dose of HBV within 12 hours of birth, however, the HBV birth dose does not count toward the vaccine series because LBW infants may have decreased immunogenicity. These infants should complete the three (3) additional doses according to ACIP's vaccine recommendation schedule and will need to receive at least four (4) total doses of the hepatitis B vaccine. Ensure LBW infants are flagged/noted in the case management tracking system to confirm the infants receive the appropriate number of hepatitis B vaccine doses.

**NOTE:** LBW infants born to women of unknown HBsAg status should receive HBIG and the hepatitis B vaccine within 12 hours of birth as well.

LBW infants born to HbsAg-negative mothers can have their first hepatitis B vaccine deferred by the provider until 1 month of age or hospital discharge.

### **8. What should we do if we have a HbsAg positive mother who refuses post-exposure prophylaxis for her infant?**

It is important to provide education to the mother prior to the infant's birth about the potential consequences of perinatal hepatitis B infection and how to prevent transmission. Use real-life personal stories about hepatitis B to illustrate the importance of prevention. The Hepatitis B Foundation ([hepb.org](http://hepb.org)) has short videos of people sharing their experiences with hepatitis B. If a mother still refuses PEP after delivery, the hospital should require the mother to sign a refusal to vaccinate/against medical advice form. Obtain a copy of the refusal documentation for the case management file. Obtain information for

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the infant's pediatrician and follow up at their 2-month visit to see if the mother consented to the hepatitis B vaccine. If not, close out the case as "noncompliant/refused."

Generally, involving child protective services or another authoritative figure has not been successful in convincing these mothers to consent to PEP. Providing real-life examples and stories may help convince a hesitant mother to allow PEP.

### **9. I have an index case who has moved out of my jurisdiction, what should I do?**

First, review the Case Management Report (CMR) for completion prior to transferring. Close out the case appropriately, for example as "transferred to another jurisdiction", "transferred to San Antonio/Houston", or "moved out of state". There does not need to be any transfer form completed if the client moves out of the country. Make sure to document the case's new address and contact information in the comment section. Complete the *Case Management Transfer Form* (Stock no. F11-11015) and send that form along with the CMR(s) to your PHR coordinator. Central Office (CO) is responsible for sending the case to the appropriate jurisdiction.

If you discover the client has moved out of the state but are unable to obtain the new address, contact CO for assistance. CO can contact the other state to see if they are able to find the case. If the other state cannot find an address, the case will have to be closed as "lost to follow-up" instead of "transferred out of state". Remember that all transfers out of state need to be done by CO.

### **10. I just received PVST results for one of my cases, but the provider only performed one lab test instead of both. What should I do?**

First, check the date of when the lab was performed. Most commercial labs keep specimens for four or five (4-5) days and may be able to add labs to an existing specimen. If the lab was recent, immediately call the provider and ask them to call the lab and add the other test to the specimen.

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If it has been more than a week, notify the provider and explain why both labs need to be completed. The provider should notify the guardian to return with the infant for additional testing.

Some providers may not feel it is necessary to repeat a lab draw for one missing lab. Reiterate the need for both labs to ensure the infant is not infected and that vaccination was successful.

### **11. I have an anti-HBs result for an infant that is <10 IU/mL or non- reactive. What should we do?**

First, make sure the HbsAg lab was drawn along with the anti-HBs to rule out an HB infection. If the HbsAg is also negative, this infant is considered "susceptible". The infant should receive a booster dose of hepatitis B vaccine immediately. The infant can then repeat PVST (HBsAg and Anti-HBs) one to two (1-2) months after the booster dose. If the anti-HBs remains non-reactive after the booster dose, the infant should repeat an entire second hepatitis B vaccine series and needs two (2) more doses of hepatitis B vaccine. The infant should then repeat PVST 1-2 months after the last vaccine. The CDC recently recommended this "booster dose" option based on studies that found that children showed an adequate immune response (anti-HBs  $\geq 10$  mIU/mL) after just one (1) hepatitis B vaccine.

The guardian and provider can also choose to immediately repeat the entire three-dose hepatitis B vaccine series and repeat PVST one to two (1-2) months after the last vaccine.

### **12. I have an infant who has received three (3) doses of hepatitis B vaccine, but the last dose was given at 4 months of age. Is this infant considered complete?**

No, this infant needs another dose of hepatitis B vaccine, on or after 6 months of age.

### **13. Any tips for finding infants in ImmTrac?**

ImmTrac2 has a "smart search" function. You do not need to know the name of the infant to use this function. Instead, you can put in "baby" and "girl" for the first and last name section. Then, put in the appropriate birthday, sex, and street address. This can help find infants when their first and last names are unknown. ImmTrac2 also

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has instructional videos and webinars online at [www.dshs.texas.gov/immunize/immtrac/User-Training/](http://www.dshs.texas.gov/immunize/immtrac/User-Training/).

### **14. I received a delivery report with no known mother information. The hospital says the infant was safely surrendered. What should I do and how can I case manage without the mother's information?**

The CDC recommends that all infants born to women whose hepatitis B status remains unknown indefinitely (e.g., safely surrendered after birth) be enrolled in PHBPP. These infants will need to receive HBIG and the hepatitis B birth dose, complete the Hepatitis B vaccine series, and complete PVST.

If you receive a delivery report for an infant that was safely surrendered, contact the hospital, and ask to speak with the infant's social worker. The social worker should have information about the child's placement (e.g., with a foster family, with relatives etc.) and their contact information. Once the contact information is received, reach out to the responsible guardians, and tell them about PHBPP and the need for case management. The "mother's case management report" can be completed without knowing the mother's information. For example, use "Jane Doe" for the mother's name and leave all other information blank. Write a note in the comment section that this was a safe surrender infant. Open the infant CMR and use the guardian's demographic information for the "phone number" and "address" fields. Make a note that this is a safe surrender infant.

### **15. Should HBsAg positive pregnant also have HBV DNA testing?**

Yes, the CDC recommends that HBsAg positive pregnant women also be tested for HBV DNA. The test is used to guide antiviral therapy that might be indicated for women with very high HBV DNA viral loads.

### **16. How can I help my hospitals enroll in IAC's *Hepatitis B Honor Roll*?**

The *Hepatitis B Birth Dose Honor Roll* recognizes U.S. birthing institutions with a birth dose coverage rate of 90% or greater and who have also met additional criteria to ensure newborns do not fall through the cracks in the event of a medical error. Application for

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Honor Roll inclusion is available at [www.immunize.org/honor-roll/birthdose/apply.aspx](http://www.immunize.org/honor-roll/birthdose/apply.aspx).

### **17. What types of support are available for these mothers?**

The DSHS Immunization Section PHBPP has developed educational materials for HBsAg-positive women and their healthcare providers. These materials can be found at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

The CDC and the organization Hep B Moms have information about hepatitis B and perinatal hepatitis B available to order for free or to download in many different languages from: [www.cdc.gov/hepatitis/hbv/perinatalxmtm.htm#eduTools](http://www.cdc.gov/hepatitis/hbv/perinatalxmtm.htm#eduTools) and [www.hepbmoms.org/brochures](http://www.hepbmoms.org/brochures).

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