



HEP B

PERINATAL HEPATITIS B PREVENTION PROGRAM MANUAL

Revised 05/2016

Texas Perinatal Hepatitis B Prevention Program Manual

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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

(≤): less than or equal to / younger than or equal to

(≥): 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

EMR: Electronic Medical Record

FDA: Federal Drug Administration

FIPS: Federal Information Processing Standard

FQHC: Federally Qualified Health Clinic

GSK: Glaxo Smith Kline

HB: Hepatitis B

HBIG: Hepatitis B Immune Globulin
HBV: Hepatitis B Virus
HIPAA: Health Insurance Portability and Accountability Act
HIV: Human Immunodeficiency Virus
HSR: Health Service Region
IIS: Immunization Information System
IM: Intramuscular
ImmTrac: Texas Immunization Registry
IOM: Institute of Medicine
IT: Information Technology
ITEAMS: Inventory Tracking Electronic Assets Management System
IV: Intravenous
LHD: Local Health Department
MSM: Men who have sex with men
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: Postexposure prophylaxis
PHBPP: Perinatal Hepatitis B Prevention Program
PIN: Provider Identification Number
PVST: Postvaccination Serologic Testing
RHC: Rural Health Clinic
SST: Serum Separator Tube
TAC: Texas Administrative Code
TVFC: Texas Vaccines for Children
WHO: World Health Organization

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 (US) or US 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) through the National Electronic Disease Surveillance System (NEDSS). It is the responsibility of the DSHS Health Service Region (HSR) and Local Health Department (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 Branch Perinatal Hepatitis B Prevention Program (PHBPP) Coordinator **within one working day** of notification.

Case Management Forms

All current copies of the case management forms discussed in this manual, along with detailed instructions, can be found at www.texasperinatalhepb.org. For additional guidance please contact your DSHS HSR PHBPP Coordinator.

Contact Information

For a complete list of names and email addresses, please visit the DSHS Immunization Branch PHBPP website at www.texasperinatalhepb.org. A regional map of Texas is located on the next page.

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DSHS Immunization Branch PHBPP Database Manager:

Ph.: (512) 776 – 6813
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DSHS HSR PHBPP Coordinators:

– Regions 1 / 9 / 10

Ph.: (432) 571 – 4146
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Fax: (817) 264 – 4895

– Regions 4 / 5 / 6

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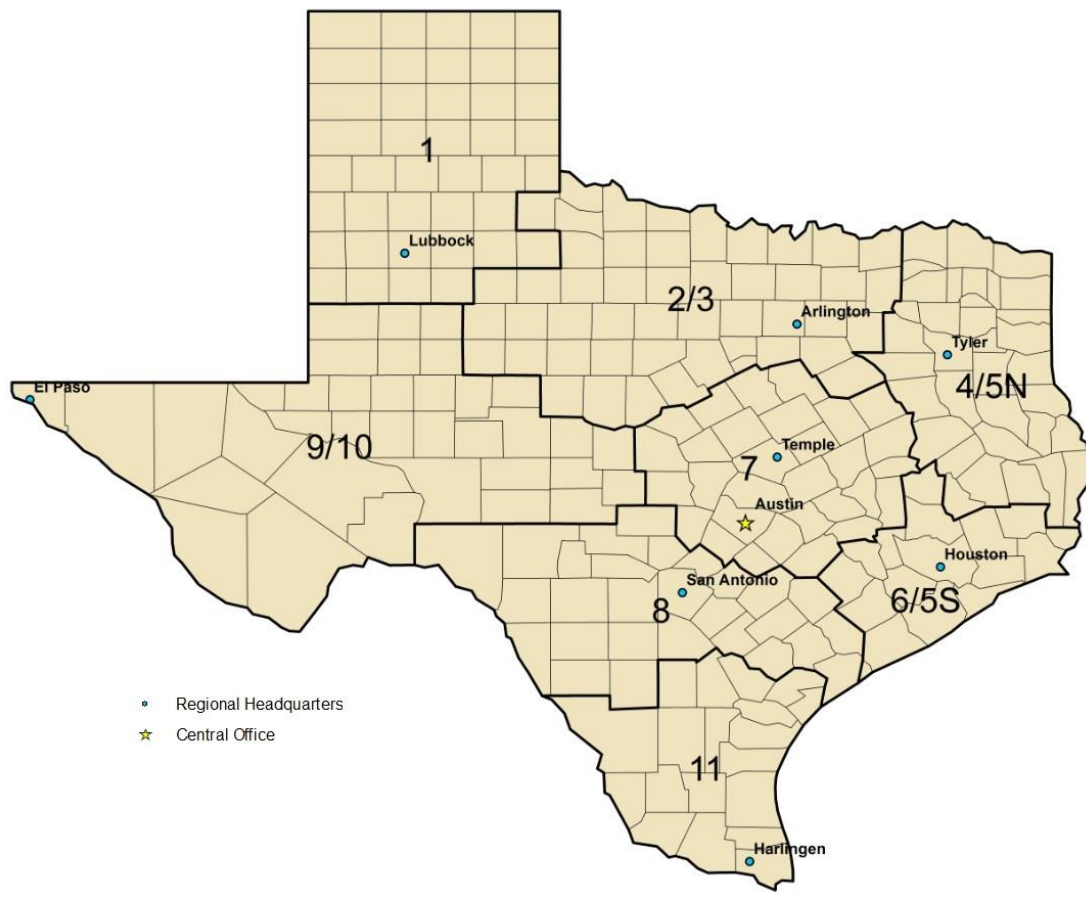
– Region 8

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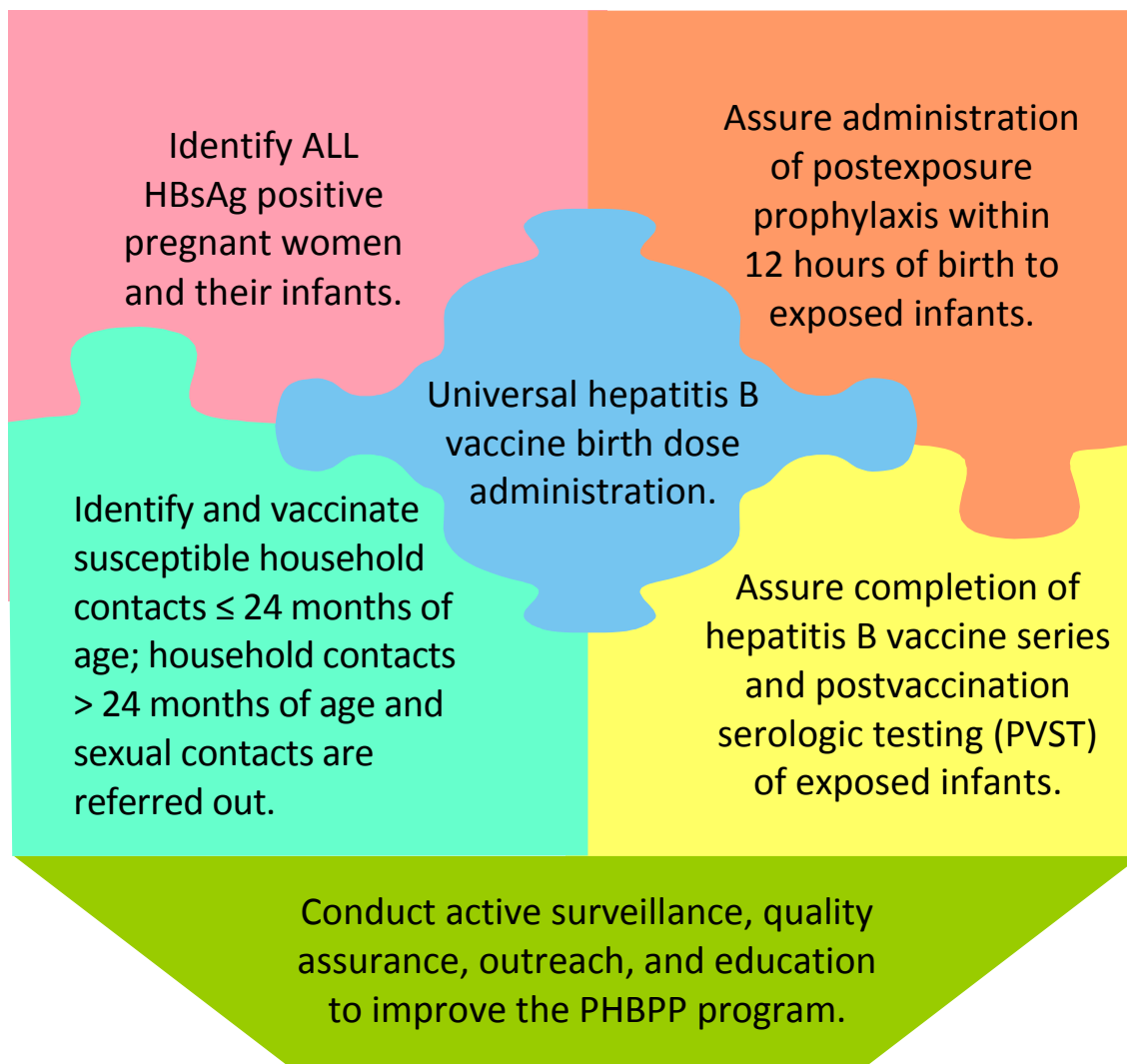
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Six Responsibilities of the Perinatal Hepatitis B Prevention Program



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Perinatal Hepatitis B Prevention at a Glance

Maternal hepatitis B surface antigen (HBsAg) testing
<ul style="list-style-type: none"> All pregnant women must be screened for hepatitis B infection once during gestation and again upon admittance for delivery for each pregnancy.
Reporting and tracking
<ul style="list-style-type: none"> All HBsAg-positive pregnant women must be reported within one week to the DSHS HSR or LHD or the DSHS Immunization Branch PHBPP. Infants born to HBsAg-positive pregnant women and household contacts ≤ 24 months of age should be identified, reported to the DSHS HSR or LHD within one work day, and case managed by program staff.
Vaccination of infants at birth born to:
<u>Mother who is HBsAg-positive</u> <ul style="list-style-type: none"> Hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth (regardless of birthweight). For preterm, or low birthweight infants $< 2,000$ g (< 4.4 lbs.), the hepatitis B vaccine series should be re-initiated at one month of age.
<u>Mother whose HBsAg status is unknown</u> <ul style="list-style-type: none"> Hepatitis B vaccine within 12 hours of birth. Mother should be tested immediately to determine HBsAg status. If mother is determined to be HBsAg-positive, immediately administer HBIG to the infant before hospital discharge. <i>Note: HBIG should not be administered more than seven days after birth.</i> Infants weighing $< 2,000$ g (< 4.4 lbs.) should receive HBIG and hepatitis B vaccine within 12 hours of birth due to decreased immunogenicity. The hepatitis B vaccine series should be re-initiated at one month of age.
<u>Mother who is HBsAg-negative</u> <ul style="list-style-type: none"> All medically-stable infants $> 2,000$ g (> 4.4 lbs.) should receive hepatitis B vaccine before hospital discharge. Pre-term, or low-birthweight infants $< 2,000$ g (< 4.4 lbs.) born to HBsAg-negative mothers can delay vaccination until one month of age.
Hepatitis B vaccine series
<ul style="list-style-type: none"> All infants should complete a three-dose vaccine series with either a single-antigen or combination vaccine, according to the recommended hepatitis B vaccination schedule.
Hepatitis B postvaccination serologic testing (PVST)
<ul style="list-style-type: none"> All infants born to HBsAg-positive pregnant women 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, PVST testing should be done at 9 months of age.

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Chapter 1

Program Background and Introduction



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Background

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.

Although vaccine prevention and awareness has steadily increased since the start of the program, it was estimated in 2013 by the National Health and Nutrition Examination Survey (NHANES) that 1,038 to 1,483* infants were born to HBsAg-positive women in Texas. However, only 562* infants were identified as being born to HBsAg-positive women.

In 2013, a total of 3,050 cases of acute hepatitis B were reported nationwide to the Centers for Disease Control and Prevention (CDC); the highest rate was amongst 30 - 39 year olds. From 2003 - 2011, rates of acute hepatitis B declined among all age groups. From 2011 - 2013 rates of acute hepatitis B increased among both the 30 - 39 year old and 40 - 49 year old age groups but remain steady amongst the other age groups.

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 less than two percent of perinatal infections in most studies. Every year, more than 24,000 infants are born to women chronically infected with hepatitis B. Without timely post-exposure prophylaxis (PEP) at birth, approximately 10,000 of these infants would become chronically infected themselves, while 2,500 would die of liver failure or liver cancer as early as age 10.

Transmission to these high-risk babies could be prevented 85 - 95 percent 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, reported cases have not been reliable for monitoring purposes.

Less than five percent 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 complications arise. Infants infected during their first year of life have an 80 - 90 percent chance of developing a chronic HBV infection compared to only 30 -50 percent of children infected after the first year of life, but before age six. Alternatively, less than five percent of otherwise healthy adults 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 2014 National Immunization Survey (NIS), 86.5 percent of Texas children aged 19 - 35 months, have three or more doses of hepatitis B vaccine. The 2014 NIS results also show that 77.4 percent of children in Texas received the first dose of hepatitis B vaccine between birth and three days of age.

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

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.

Under Texas law, both acute and chronic cases 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.

Key Elements of the Perinatal Hepatitis B Prevention Program (PHBPP)

The DSHS Immunization Branch PHBPP has several important features including, but not limited to: surveillance, case management, promotion of the universal birth dose and collaboration between DSHS HSR offices, LHDs, medical providers, and laboratories. The ten objectives of the program are listed below. All case management and reporting forms can be found online at www.texasperinatalhepb.org.

1) Ensure that all pregnant women are tested for hepatitis B surface antigen.

- 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.
- 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) and reason for testing (pregnancy) be specified when submitting these specimens to the laboratory.
- 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 unborn child and what measures can be taken in an effort to protect the child from transmission (HBIG, hepatitis B vaccine series, PVST). The patient should also be informed that the DSHS HSR or LHD will be contacting them for case management.
- Delivery hospitals should determine if a pregnant woman presenting to their hospital was screened for HBsAg prenatally and document those results in both the mother and infant's medical records.
- Delivery hospitals must draw blood to screen for HBV infection upon delivery, regardless of the result obtained at the prenatal examination.

- Delivery 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.
 - Ordering admission lab tests that specify to draw “HBsAg” – this will help 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 tracking of HBsAg-positive women.

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

3) Ensure that delivery facilities / hospitals receive all prenatal HBsAg lab reports prior to delivery.

- 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 that the baby receives all necessary care upon delivery, using the above methods.

4) Ensure identification and management of infants born to HBsAg-positive mothers. (Please refer to Chapter 4 on PEP guidelines.)

- Delivery facilities / hospitals should implement policies and procedures to ensure proper identification of HBsAg-positive pregnant women and their infants. Please 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 should document all required information. Please refer to number 5 under Key Elements for reporting information.
- Document proper health information on infant’s birth certificate (hepatitis B infection during pregnancy).
- If an HBsAg-positive mother 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 of her infant(s) and all education provided regarding hepatitis B and the potential consequences to her newborn.

5) Ensure reporting of infants born to HBsAg-positive mothers.

- Infants born to HBsAg-positive mothers must be reported within one day by completing the Hospital / Provider Report form and sending it to either their DSHS HSR or LHD.
- Delivery facilities / hospitals must report all of the information mentioned above in number 4 - Key Elements regarding birth, HBIG, and hepatitis B vaccine on the appropriate forms.
- Delivery facilities / hospitals should document the following information on the Hospital / Provider Report form:
 - maternal HBsAg status (and other serology) at time of delivery
 - provider (doctor/clinic)
 - date and time of birth
 - birth weight
 - 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.)

* A chart with formulations and manufacturers of HBIG can be found in Chapter 4, postexposure prophylaxis (PEP).

6) Ensure identification and management of infants born to mothers of unknown HBsAg status. (Please refer to Chapter 4 on PEP guidelines.)

- 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 proper health information on infant's birth certificate (i.e., hepatitis B during pregnancy).

7) Ensure timely completion of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers. (Please refer to Chapter 4 for use of combination vaccines.)

- Dose one should be given within 12 hours of birth, but ideally no later than hospital discharge.
- Dose two should be given at one month of age, but no later than two months of age.
- Dose three should be given at six months of age:
 - Must be at least eight weeks after dose two
 - 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 / manufacturer for each dose of the hepatitis B vaccine administered to the infant.
- If the child was not already registered for the Texas Immunization Registry (ImmTrac), at birth, parental consent should be obtained and the vaccination history of infants should be entered into ImmTrac as soon as possible after each visit.

8) Ensure timely completion of PVST for all infants born to HBsAg-positive women.

- To determine infant outcomes after appropriate PEP, PVST should be performed on all infants born to HBsAg-positive women once:
 - the infant has completed a full hepatitis B vaccine series;
 - the infant is at least nine months of age; and
 - at least one month has passed since the infant received the final dose of a hepatitis B containing vaccine.
- Providers should order:
 - HBsAg; and
 - Anti-HBs
- Providers should document the infant's PVST and report results (positive or negative) to their DSHS HSR or LHD.

9) Ensure vaccination of household contacts ≤ 24 months of age. (Please refer to Chapter 9 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. Please refer to Chapter 9 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, and sexual partners to the HBsAg-positive mother, should be referred to a health care provider for health care evaluation.

10) Ensure program quality, monitoring, and evaluation.

- Within the quarterly report time frames, each DSHS HSR and LHD should report the following to the DSHS Immunization Branch PHBPP as part of their grant activity report:
 - number of HBsAg-positive pregnant women identified;
 - number of HBsAg-positive pregnant women referred for medical follow up;

- number of infants born to HBsAg-positive women; and
- number of susceptible household contacts that are ≤ 24 months of age.

Note: For comprehensive information regarding grant activities, please visit <http://www.dshs.state.tx.us/immunize/providers.shtm>.

- 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; or
 - 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 HSR or LHD in an attempt to correct any identified error(s).

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 days at room temperature. It is a small, round, enveloped virus with partially double-stranded circular Deoxyribonucleic Acid (DNA) and is highly infectious; the CDC has stated that it is 50 to 100 times more infectious than the Human Immunodeficiency Virus (HIV). There are nine serotypes and eight genotypes of HBV recognized worldwide.

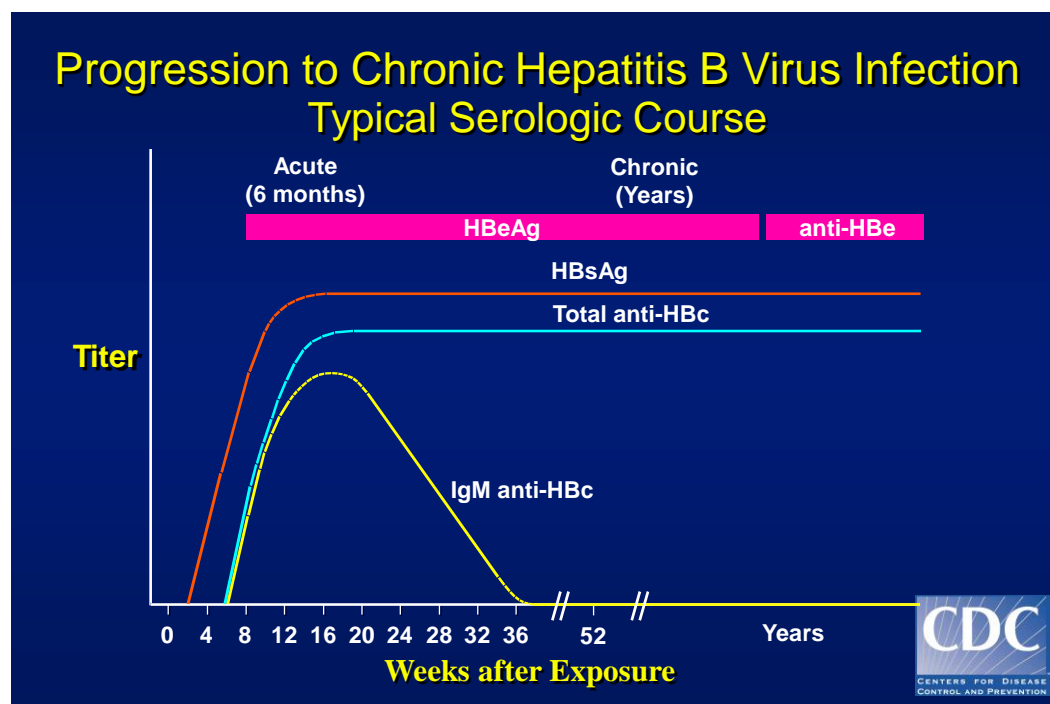
HBV Infection

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 US. The World Health Organization (WHO) estimates that two billion people have been infected worldwide with the hepatitis B virus. Two hundred and forty million of those remain chronically infected while more than 780,000 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; most of whom become infected during childhood. Five to ten percent of the adult population in these areas are chronically infected. 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 US, an estimated 700,000 – 1.4 million people are living with chronic hepatitis B infection.

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 is able to eliminate the virus from the blood and provide lasting immunity against reinfection in about 95 percent of cases. The remainder of adults whose immune system does not eliminate the virus, develops 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 (Figure 1). These “chronic carriers” are capable of transmitting the virus to other individuals who are unprotected.

Figure 1. Progression to Chronic Hepatitis B Virus Infection Typical Serologic Course



HBV Lab Tests

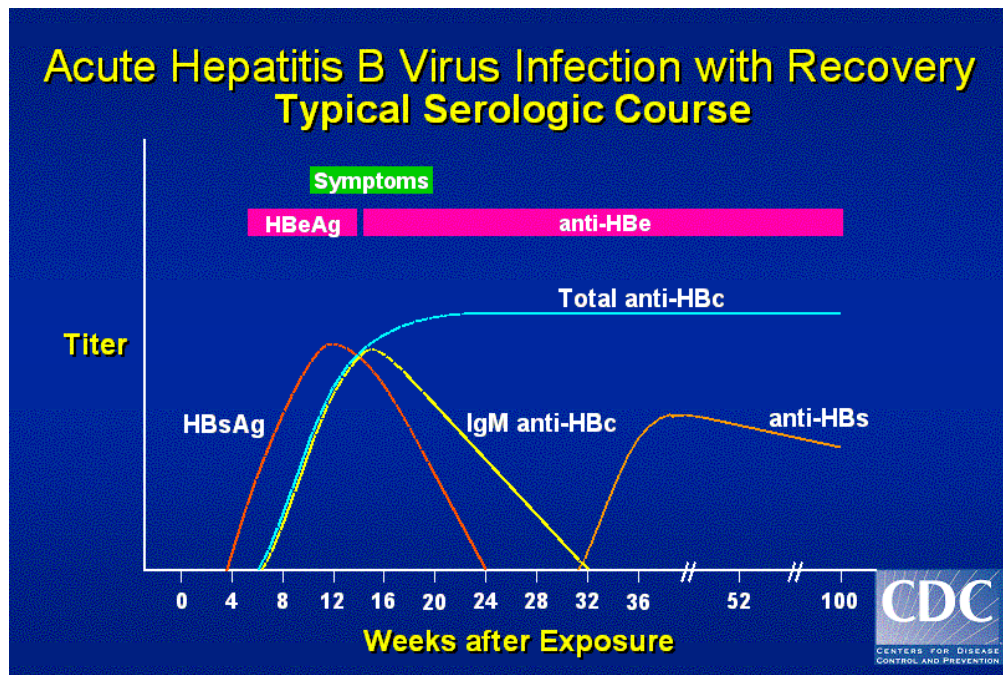
There are several approved laboratory tests available for hepatitis B. The main uses for these tests would be to determine whether a patient's signs and symptoms are due to HBV infection, to diagnose and monitor chronic infection, and to detect previous exposure to the virus. Testing can also be done to:

- screen for infection in at-risk populations or blood donors;
- to determine carrier status; and
- screen for immunity due to vaccination or prior infection.

There are several antigenic components of the virus that can result in a variety of positive laboratory tests (Figure 2).

The HBsAg is found on the surface of the virus and can be identified in serum samples 30 to 60 days after exposure to the virus. This component of the virus is not infectious; however, when present in the blood, it does indicate that the complete virus is present, and the person infected may transmit the virus to others. Once the immune system detects the HBsAg component of the virus due to natural infection or vaccination, it begins to develop antibodies (anti-HBs). The presence of anti-HBs in the serum indicates immunity to the virus. Anti-HBs is also referred to as hepatitis B surface antibody (HBsAb) which can easily be confused with the HBsAg.

Figure 2. Acute Hepatitis B Virus Infection with Recovery Typical Serologic Course



Communicability

Persons with either acute or chronic HBV infection should be considered potentially infectious. When symptoms are present in persons with acute HBV infection, HBsAg can be found in blood and body fluids for one to two months before and after onset of symptoms.

Clinical Manifestations

The clinical manifestations of acute HBV infection are age dependent. Infants, children younger than ten years of age, and immunosuppressed adults with newly acquired HBV infection are usually asymptomatic (no symptoms); about 30 - 50 percent of adults show symptoms of infection. Because infected persons are often asymptomatic, they are generally unaware that they are infected, resulting in inadvertent transmission to others. 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
- headache
- myalgia
- skin rashes
- arthralgia
- arthritis
- dark urine starting one to two days before the onset of jaundice
- right upper quadrant abdominal pain

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.

For more information on acute and chronic HBV infections, please consult The Red Book: Report of the Committee on Infectious Diseases (30th 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 percent 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 US. HBV infection is estimated to be the cause of 80 percent of hepatocellular carcinoma worldwide.

Generally speaking, 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 one to two percent of acutely infected persons with mortality rates of 0.5 – 1 percent; although it is suspected to be higher in acutely infected infants. About 200 to 300 Americans die each year of fulminant disease.

Epidemiology

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

Mucosal exposure can occur:

- during birth;
- sexual contact;
- accidental blood splash to the eyes or mouth;
- shared household products (i.e., toothbrush); and
- other routes when 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. (Table 1)

Table 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

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 the healthcare setting, long term care facilities, and in the home health setting due to breaches in infection control practices are well described.

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

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 thus a lower likelihood of transmission to the infant. However, approximately 20 - 30 percent of the chronic infections in the US are due to a variant of HBV call a “pre-core mutant.” This variant of the virus does not produce e-antigen while replicating yet may have a viral load somewhere in between the e-antigen positive and e-antigen negative cases. Using molecular technology, the HBV viral load can be directly measured and quantified.

For a newborn infant whose mother is positive for both HBsAg and HBeAg, the risk for chronic HBV infection is 70 - 90 percent by age six months in the absence of PEP (HBIG and hepatitis B vaccine). On the contrary, if the mother is HBsAg-positive but HBeAg-negative, the risk for chronic infection is less than 10 percent 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 fewer than two percent 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 and in cord blood of their neonates. Postpartum transmission through exposure to infectious maternal saliva, stool, or urine is quite rare.

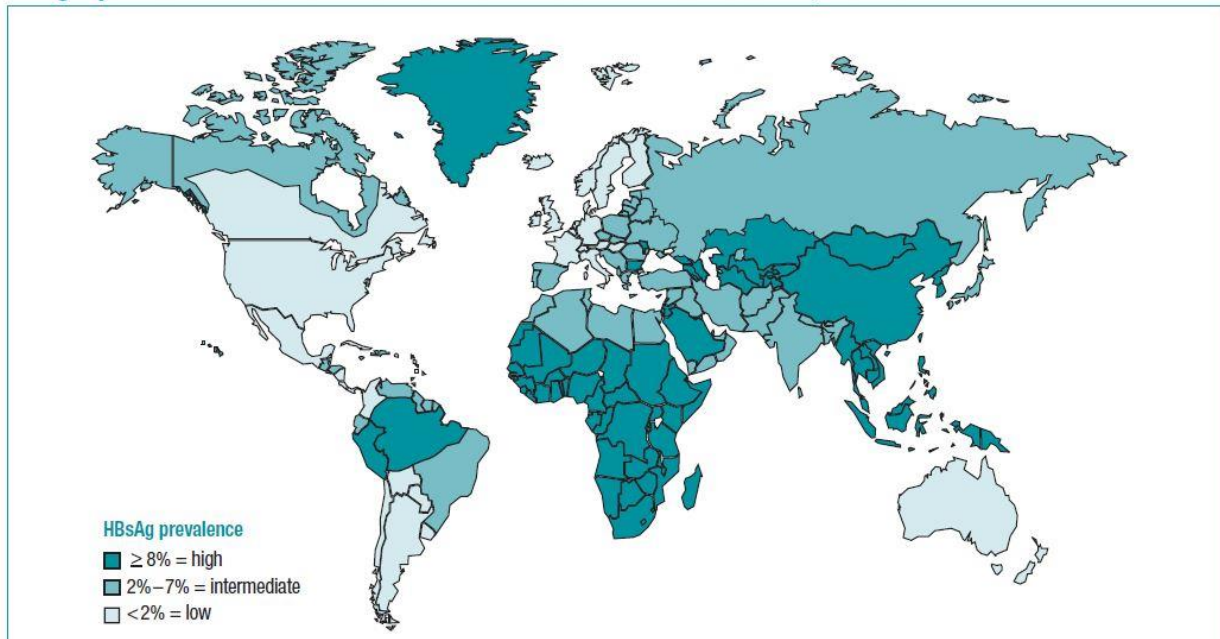
It has been thought that breastfeeding serves as an additional mechanism by which infants may acquire HBV infection. Although trace amounts of HBsAg have been found in breast milk, research strongly suggests that any risk of transmission associated with breast milk is negligible compared to the high 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 state that it is safe for an infected woman to breastfeed her child because the benefits outweigh the risks. All mothers who breastfeed should take good care of their nipples to avoid 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 (Figure 3)
- 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 3. 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://www.cdc.gov/travel/yellowbookch4-HepB.aspx>.

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Chapter 3

Statutes and Rules



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TEXAS STATUTES AND RULES

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 diseases. This chapter addresses statutes and rules that require providers to screen pregnant women for hepatitis B, administer PEP to at-risk infants, and report infected mothers and infants to the DSHS Immunization Branch PHBPP. The test currently recommended by the CDC for evaluation of hepatitis B infection during pregnancy is the HBsAg. The DSHS Immunization Branch PHBPP website, 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 DSHS State Health Services Council 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 board shall prescribe the form and method of reporting which may be in writing, by telephone, by electronic data transmission, or by other means. The council may require reports to contain any information pertaining to a case that is necessary including, but not limited to, the information below. 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.

- Patient's name, address, age, sex, race, and occupation;
- Date of onset of disease or condition;
- Probable source of infection; and
- Name of the attending physician.

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 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. 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 in compliance 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 the DSHS State Health Services Council.

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
- administering needed vaccination 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 and immunization required by this section if:

- 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 health care 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 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.

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 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 and perinatal hepatitis B infections 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 and ethnicity, preferred language, and 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; and
- 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:

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

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

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

Hepatitis B (acute and chronic) identified prenatally or at delivery shall be made no later than one 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 person permitted by law to attend a pregnant woman during gestation or delivery shall report to the 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 HSR.

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 of Health (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.

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.

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 health care providers at the time of the newborn screening tests.

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 has been age-appropriately immunized or that the newborn has been referred to another health care provider for immunizations. Please 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:

<http://www.gpoaccess.gov/cfr/>

Chapter 4

Postexposure Prophylaxis (PEP)



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Prevention

The CDC has released two comprehensive documents pertaining to the elimination of HBV infection in the US. These documents provide 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 HBsAg;
- PEP of infants born to HBsAg-positive women or to women with unknown HBsAg status; and
- Routine vaccination of previously unvaccinated children and adolescents.

In these documents, 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.

Part one of the document (Recommendations for Infants, Children, and Adolescents) can be accessed electronically at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm>. Part two of the document (Immunization of Adults) can be accessed electronically at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a1.htm>.

The Institute of Medicine (IOM) also released a report on preventing and controlling viral hepatitis infections in the US. After reviewing evidence on the prevention and control of hepatitis B and hepatitis C, the committee identified the underlying factors 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>.

Postexposure 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 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. In the case of perinatal hepatitis B, HBIG is intended to give the infant short-term protection against the hepatitis B virus which they might have been exposed to during birth. HBIG that is commercially available in the US does not contain thimerosal, a common mercury-containing preservative found in some immunizations.

HBIG is used as passive immunization 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. For infants exposed during labor and delivery, they should receive HBIG and the birth dose of hepatitis B vaccine within 12 hours of birth. After the immune globulin is no longer effective, the infant's immune system should already be producing its' own antibodies (anti-HBs) to the hepatitis B virus in response to the vaccine. It is important that the infant complete the vaccine series on time, in order to give the infant the best chance of developing immunity against the virus.

HBIG Product Information for Perinatal Exposure			
Product Name	Manufacturer	Perinatal Dosing	Presentation*
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	1mL single dose <i>vial</i>

*as relevant only to perinatal administration

Hepatitis B Vaccine

The hepatitis B vaccine is the best protection against the hepatitis B virus. 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 US in 1989. This was the first vaccine licensed in the US 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.

As of March 2000, all hepatitis B vaccines produced for distribution in the US are thimerosal-free.

The hepatitis B vaccine is available as a single-antigen formulation (monovalent vaccine) as well as in fixed combination with other vaccines (combination vaccine).

Postexposure Prophylaxis (PEP) for Infants at Birth

Born to HBsAg-positive mother	
HBIG	Administer within 12 hours.
Hepatitis B birth dose	Administer within 12 hours.
Born to HBsAg-unknown mother	
HBIG	If positive results are received, administer immediately .
	If discharge is planned before day seven and results are still unknown, HBIG should be administered before the infant is discharged from the delivery facility.
	If negative results are received before discharge, no HBIG needed.
Hepatitis B birth dose	Administer within 12 hours.

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. In 2002, ACIP indicated a preference for the first dose to be administered to newborns before hospital discharge. In December 2005, ACIP issued revised recommendations specifying that all medically stable newborns who weigh > 2,000 g (4.4 lbs.) receive their first dose of hepatitis B vaccine before hospital discharge.

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 < 2,000 g (4.4 lbs.) at birth and who received the birth dose of hepatitis B vaccine should have the series reinitiated at ≥ 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 and five 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 health care 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 percent of infants who were not infected perinatally became infected by the age of five years. Guidelines for standing orders in labor and delivery and nursery units to prevent hepatitis B virus transmission to newborns can be found in Appendix D of this manual or on the DSHS Immunization Branch PHBPP website at www.texasperinatalhepb.org.

Vaccination Schedule and Use

Infants and Children

Hepatitis B vaccination is recommended for all infants soon after birth and before hospital discharge, regardless of birthweight.

- Engerix-B® (GSK)
 - 0.5 mL (10 mcg) / dose
 - Approved: 0 - 19 years of age
 - three doses – administered Intramuscular (IM)
 - Schedule: Birth, 1 - 2 months, 6 months
- Recombivax HB® (Merck)
 - 0.5 mL (5 mcg) / dose
 - Approved: 0 - 19 years of age
 - three doses – administered IM
 - Schedule: Birth, 1 - 2 months, 6 months
- Pediarix® (GSK): DTaP+Hep B+IPV
 - 0.5 mL (10mcg) / dose
 - Approved: 6 weeks – 6 years of age
 - three doses* – administered IM
 - Schedule: 2 months, 4 months, 6 months

* 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 hepatitis B vaccine, including the birth dose; this is safe and will not harm the child.

It is preferred that the same vaccine / manufacturer 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 that the child previously received is not immediately available, or is unknown, vaccination should not be delayed; the child should receive available age appropriate vaccine.

Infants should not receive the final dose of hepatitis B vaccine prior to six 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 doses of vaccine are spaced at least four 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 in which it is difficult to ensure that infants will be brought back for all of 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 weeks after the first dose.
- The third dose should be administered at least eight 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 (six 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 administered too soon should be calculated from the incorrectly administered dose. For example, children who incorrectly received their third dose of hepatitis B at age five 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 seven months.

Preterm Infants

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

Preterm infants with low birth weight < 2,000 g (4.4 lbs.) have a decreased response to hepatitis B vaccine administered before one month of age. However, by one month of age, preterm infants, regardless of initial birth weight or gestational age, are as likely to respond as adequately as full-term infants. Furthermore, preterm infants, or those weighing < 2,000 g (4.4 lbs.), should restart the hepatitis B vaccine series, at one month of age. Although the birth dose is not considered a valid dose in the series for these infants, it is **imperative** that the infants born to HBsAg-positive and unknown status mothers receive the birth dose in addition to HBIG for the best protection.

If ordered by the physician, preterm infants of low birth weight whose mothers are HBsAg-negative, during this pregnancy and at delivery, can receive the first dose of the hepatitis B vaccine series at one month of age, so long as the mother's lab report is documented in the infant's chart by the ordering physician. Preterm infants discharged from the hospital before one 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.

Vaccine Administration and Contraindications

Hepatitis B vaccine can be given concurrently with other vaccines. Pregnancy and lactation are not contraindications to receiving hepatitis B vaccine. The vaccine is to be administered intramuscular (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 three 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 three 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 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 hepatitis B vaccine and sudden infant death syndrome (SIDS), multiple sclerosis (MS), autoimmune diseases, chronic fatigue syndrome, or autism.

Postvaccination Serologic Testing (PVST)

Postvaccination seroprotection is achieved in 98 percent of healthy full-term infants who received a three dose or four dose hepatitis B vaccine series; infants of low birthweight < 2,000 g (4.4 lbs.) 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 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. The CDC recently published an update regarding a shortened interval for PVST in infants born to mothers infected with hepatitis B. This update, titled [Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers](#) can be found in MMWR 64(39); 1118 - 20. The guidance on timing of PVST provided by the CDC indicates that the optimal time to collect PVST in infants who completed the vaccine series on time is between nine and 12 months of age. For infants whose series was delayed, the PVST should be collected 1 - 2 months after completion of the series. Please note, testing is not recommended before age nine 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 six months of age, should have PVST performed three months after the final dose of the hepatitis B vaccine series has been administered; ideally at the next well-child visit at nine months of age to determine the success of PEP.

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 nine months of age. For example, an infant who did not receive their final dose of hepatitis B vaccine until eight months of age, can still complete the PVST on time at nine months of age, so long as one month (28 days or four weeks) has passed. Please 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 DSHS HSRs and LHDs must ensure in 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 from the DSHS Immunization Branch on an emergency basis, see below for Ordering Instructions. The LHDs must order HBIG and hepatitis B vaccine through their DSHS HSR. Both biologics must be shipped to a DSHS HSR or LHD.

HBIG and Hepatitis B Vaccine Ordering Instructions from DSHS:

To order HBIG and hepatitis B vaccine for newborns, DSHS HSRs and LHDs must email the DSHS Immunization Branch Vaccine Call Center at vaccallcenter@dshs.state.tx.us 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 Immunization Branch Vaccine Call Center 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 Branch. The DSHS Pharmacy Branch ships orders on Monday, Tuesday, and Wednesday of each week. In order 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 Branch 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.

Handling and Storage

Careful handling of hepatitis B vaccine and HBIG is extremely important (see package insert for detailed storage and handling procedures). 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 (TVFC) Program and are due to expire within 90 days, please contact your DSHS HSR or LHD for assistance in transferring the product.

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.

Chapter 5

Serology Testing



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Diagnostic Tests for Hepatitis B Virus (HBV)

Diagnosis of HBV infection (acute vs. chronic) is based on clinical, laboratory, and epidemiologic findings. HBV infection cannot be differentiated on the basis of 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 or chronic. Commercial serological antigen tests are available to detect HBsAg and HBeAg.

For comprehensive information on interpretation of hepatitis B serology and assays not routinely required for the PHBPP, please refer to Appendix D.

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 as early as 1 - 2 weeks and as late as 11 or 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 (**acute infection**), HBsAg disappears in most patients within a few weeks to several months after infection. People with **chronic HBV infection** 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.

Hepatitis B 'little e' Antigen (HBeAg) is a marker associated with HBV infection and, when positive, indicates active viral replication within the liver and high infectivity. The presence HBeAg in serum correlates with higher concentrations of HBV and greater infectivity. Testing for HBeAg is useful in the selection of candidates to receive antiviral therapy and to monitor the response to therapy.

Please refer to Appendix C for additional CDC resources on interpreting hepatitis B serology.

Diagnostic Tests for Hepatitis B Virus (HBV) Antigens and Antibodies

Factor To Be Tested	HBV Antigen or Antibody	Purpose
HBsAg	Hepatitis B surface antigen	Detection of acutely or chronically infected persons.
Anti-HBs	Antibody to HBsAg	Identification of persons who have resolved infections with HBV; determination of immunity after immunization.
HBeAg	Hepatitis B e antigen	Identification of infected persons at increased risk for transmitting HBV.

Maternal Screening

The DSHS Immunization Branch PHBPP requires maternal HBsAg serology to be case managed. In addition, HBeAg gives the DSHS Immunization Branch PHBPP additional information regarding infectivity; although this serologic test is not required for a case to be managed by the DSHS Immunization Branch PHBPP, it is desired.

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.

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;
- determining HBV carrier status at the time of delivery;
- ensuring that the infant receives appropriate and timely PEP immediately after birth;
- providing appropriate counseling to families before delivery;
- obtaining the name of contacts ≤ 24 months of age for case management; and
- 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 week of identification. All pregnant women identified as being HBsAg-positive at the time of delivery must be reported to the DSHS HSR or LHD.

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 provided to the provider / delivery hospital by the DSHS HSR PHBPP Coordinator and / or the LHD.

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 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 HSR and LHD each time the hospital is notified of an HBsAg-positive mother's plans to deliver at that hospital. 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 within 12 hours of birth, or, before hospital discharge 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
- Report all HBsAg-positive mothers to the DSHS HSR or LHD within one 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. *Please see below guidelines and recommendations 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 at-risk infants who are born to HBsAg-positive women. For these infants, (PVST), for HBsAg and its corresponding antibody (anti-HBs), should be performed. The CDC recently updated their recommendations and general guidance for PVST, which can be found in the October 9, 2015 MMWR titled, "Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B - Infected Mothers" accessible at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm>. In summation, the updated MMWR states that PVST should be done one to two months after completion of the vaccine series. However, testing is not recommended before age nine 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 six months of age must wait three months for PVST to be done; ideally at the next well-child visit at nine months to determine the success of PEP. It is important to test for HBsAg and anti-HBs to determine the success or failure of vaccination, as up to five percent of infants may not respond adequately to vaccination. Please note, testing delays after series completion can lead to false negative anti-HBs results.

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.

For contacts ≤ 24 months of age, the same serologic testing (HBsAg and anti-HBs) should be done at the appropriate age, at least one month after the final dose of the hepatitis B vaccine series was given, so long as the child is at least nine months of age.

Postvaccination Serologic Testing Interpretation

Test Results	Interpretation	Action
HBsAg (-) Anti-HBs (+)	Immune due to vaccination	Notify the DSHS HSR or LHD, no further action needed.
HBsAg (-) Anti-HBs (-)	Susceptible / Non-responder	See guidance below and notify the DSHS HSR or LHD.
HBsAg (+) Anti-HBs (-)	Infant infected with hepatitis B virus	Notify the DSHS HSR or LHD, provide education / counseling and refer for evaluation.

Susceptible / Non-responder

Children that fail to respond to the first complete hepatitis B vaccine series should complete a second three-dose series on the usual 0, 1, and 6 month schedule. They should then receive PVST again 1 - 2 months after completion of the second hepatitis B vaccine series. Although fewer than five percent of individuals who receive six doses of hepatitis B vaccine will not respond, immunity should not be assumed and PVST should still be repeated after completion of the second series.

Children that fail to respond to two complete series of 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. Documentation of the referral should be made on the mother's case management form.

Serologic Testing of the Mother with unknown HBsAg status

Prenatal HBsAg Status	Delivery HBsAg Status	Action
Unknown	Unknown	Test for HBsAg immediately.
Positive	Unknown	
Unknown	Positive	In six 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.

If the mother's HBsAg status is unknown at delivery, the mother, her infant, and contacts ≤ 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 health care provider for testing and vaccination if susceptible.

Discrepant HBsAg Results

Discrepant results occur when the mother's HBsAg test during the current pregnancy yields conflicting results.

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

All infants born to mothers with discrepant HBsAg test results should receive appropriate PEP. 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 HSR or LHD. Please refer to Chapter 4 for further guidelines on PEP.

The Role of the DSHS Health Service Region (HSR) 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 15 days** of notification.
- The *Mother Case Management Report* form must contain the following information:
 - Name
 - Date of birth (DOB)
 - the types of tests
 - the laboratories that performed the tests
 - the hepatitis B vaccination dates (if applicable)
 - the types of vaccines (if applicable)
 - other pertinent health information

Case Management of Discrepant Hepatitis B Serology Results

- Case managers should ensure that six months have passed between HBsAg-positive results to determine the mother's status.
- Please note that all cases should remain open and follow-up of the infant and contacts ≤ 24 months of age should be continued until the mother's status can be determined.

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Chapter 6

Laboratory and Reporting



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Laboratory Parameters

A positive anti-HBs of ≥ 10 mIU / mL indicates adequate immunity to hepatitis B; this immunity can be from either a past hepatitis B infection or hepatitis B vaccination. After receiving a primary hepatitis B vaccine series, individuals with anti-HBs levels of ≥ 10 mIU/mL are considered protected and immune to the HBV, in accordance with the 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 with a second three-dose series. The ACIP does not recommend more than two hepatitis B vaccine series for non-responders.

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

Please refer to Appendix C for Interpretation of PVST.

Inconclusive Laboratory Results

Contact the Reporting Laboratory for information clarifying reports of inconclusive laboratory results such as equivocal anti-HBs and appropriate follow-up instructions for re-testing.

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 main reporting sources are laboratories, prenatal care providers, and delivery hospitals. Additional sources for reporting may include:

1. Midwife centers / home births;
2. Pediatricians / Family Practices;
3. Planned Parenthood;
4. Federally Qualified Health Clinics (FQHCs); and
5. Rural Health Clinics (RHCs).

Laboratory Reports

A primary reporting source for the PHBPP is the laboratory. Nationwide, there are 244,000 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.

The following are a few examples of problems encountered using laboratory reporting as a source of perinatal cases:

- Provider information, including contact information, may be omitted

- Appropriate serology tests markers may not have been ordered
- 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 provided education pertaining to the information that is required by law for reporting of certain conditions. Please refer to Chapter 3 for additional information pertaining to statutes and rules of reporting.

Labor and Delivery Hospital Reports

The PHBPP also uses hospital reports to identify infants born to HBsAg-positive women. In order for the labor and delivery hospital to be an effective reporting source, it is necessary to educate individuals responsible for determining a pregnant woman's HBsAg status and administering HBIG and the hepatitis B vaccine to the newborn. In order 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 D.

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 (i.e., should reporting 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 mail / 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.

The DSHS HSR 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 www.texasperinatalhepb.org.

Flow charts located in Appendix B document the flow of information on serology testing and case management of HBsAg-positive women that must occur for a PHBPP to succeed.

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 and is available at the DSHS laboratory website 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.

Tip: Do not collect a specimen until you have a submitter ID. This process may take several days to complete.

To submit a specimen for testing at the DSHS Laboratory, please do the following:

- 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, please see visit http://www.dshs.state.tx.us/lab/MRS_forms.shtm for a current sample of the G-2A submission form and detailed instructions.
 - **Section 1**
 - Submitter
 - ✧ Name
 - ✧ Submitter ID
 - ✧ National Provider Identifier (NPI) Number
 - ✧ Address and Contact Information
 - **Section 2**
 - Patient
 - ✧ Name and Date of Birth (DOB)
 - ✧ 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)
 - **Section 8**
 - Ordering Physician Information (including NPI Number)
 - **Section 9**
 - Payor Source
 - ✧ Immunizations
 - 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;*
 - Clearly label the red top or tiger top tube and paperwork with:
 - Patient's full name and DOB;
 - Date and time of collection; and
 - Initials of person collecting specimen.
- Note:** All information (name, date, and 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.

- Obtain 6 - 8 mL of venous blood (minimum of 2 mL) in a red top tube (serum tube) or tiger top tube (Serum Separator Tube [SST]).
- Single or Separated serum may be submitted; whole blood is not accepted.
- 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.
- Do not send specimens to be delivered on Saturday as staff will not be available to receive deliveries.
- Do not ship on Fridays or day before state holidays. State holidays / closures can be found at www.dshs.state.tx.us/Layouts/ContentPage.aspx?PageID=34563&id=34296&terms=holiday.

For additional guidance, please visit http://www.dshs.state.tx.us/lab/MRS_forms.shtm for a current sample of the G-2A submission form and detailed instructions.

DSHS Lab Criteria for Hepatitis B Specimen Testing

Test	Specimen Type	Time from collection to arrival at the laboratory	Temperature	Shipping Requirement
Anti-HBs HBsAg Anti-HBc IgM	Serum separated from the clot (red top or tiger top)	Up to 48 hours	Cold 2° to 8°C	Ship on cold packs
	Serum separated from the clot (red top only)	More than 48 hours	Frozen - 20°C or colder	Ship on dry ice

For additional information on protocols for shipping biological specimens, please visit www.dshs.state.tx.us/lab/mrs_shipping.shtm.

For any other questions regarding laboratory submission, please visit www.dshs.state.tx.us/lab, or call (512) 776 – 7578.

For frequently asked questions (FAQs) about the laboratory, please visit: 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:

Walter Douglas
Texas Department of State Health Services
Laboratory Services Section
MC – 1947
1100 West 49th Street
Austin, Texas 78756 – 3194

CPT Codes for Hepatitis B Serology Testing

SEROLOGY TEST	CPT CODE
HBsAg	87340
HBsAg – confirmatory test	87341
Anti-HBs (Qualitative)	86706
Anti-HBs (Quantitative) - <i>preferred</i>	86317
HBeAg	87350
Anti-HBe	86707
HBcAb	86704
Prenatal Profile with HBsAg	80055
Hepatitis B IgM antibody	86705
HBV DNA (Quantitative)	87517

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Chapter 7

Counseling and Education



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Interviewing / Counseling Format

The client interview is crucial to the case management process. It includes educating the client patient on her condition and reassuring her that competent health care workers will coordinate case management services for her, her infant(s), and her contacts ≤ 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 allowable by law. When a case manager initially contacts the client and she makes it known that that is an inconvenient time for her, the case manager should inquire about a more convenient day or 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 (DSHS HSR or LHD) that will be managing her case;
- Discussion with the client that her case managers are trained public health care professionals and have experience assisting persons with hepatitis B in understanding and managing their disease;
- Review the PHBPP and case management services provided by the program; and
- Discuss with the client that part of your job is to ensure that her medical information remains confidential, as permitted by law.

Patient Education, Assessment, and Counseling

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 so that they do not interfere with the rest of the process, gathering information that can be used in later sessions, and giving the client sufficient 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. Additionally, during the interview, clients may reveal perceived barriers which can be used as motivation or benchmarks against inconsistencies identified later on in the interview / counseling session. To conduct the assessment, the following should be done:

- 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
 - Avoid or limit alcohol consumption
 - Consult health care provider before beginning any medicine, including herbal remedies and over-the-counter (OTC) medications
 - Obtain vaccination against hepatitis A
 - Transmission*
 - Work and school exclusions not necessary
 - Testing and treatment

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

- Ask the client about problems or questions regarding hepatitis B and offer clarification on misconceptions.
- Discuss the meaning of the client's test result(s), and the possible need for additional testing. Give her 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 ≤ 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 series of vaccine).
- All contacts > 24 months of age should be referred to providers for medical evaluation.

Program Compliance

It is important that the client understands the importance of the hepatitis B vaccine series and PVST in order to prevent infection of her infant(s). The case manager should reinforce messages expressed by the health care 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 hepatitis B vaccine at birth.
- Educate the client regarding the importance for the newborn(s) and other children in the household ≤ 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 when with any changes to contact information or care providers (infant or mother).

Patient Education

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

Concluding the Interview

- Ask the client what questions or problems remain.
- Briefly review and reinforce all components of the PHBPP.
- Reinforce the need to communicate her HBsAg status to her contacts > 24 months of age and the need for a medical evaluation.

- Make arrangements for the next communication, if indicated.
- 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: *In order 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 8

Tracking Systems



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Tracking System

There are a variety of systems that can be created to assist program personnel to track clients. It is essential to build a system that is both efficient and reliable. Various methods may be used to maintain information in a tracking system. Tracking should be done at the DSHS HSR or LHD level, and to some degree, at the state level.

The key elements to an effective tracking system should include:

- Mother's:
 - Case management form
 - Lab reports
 - Hospital / provider form
- Case management notes
- Infant's:
 - Case management form
 - Immunization Record
 - Hospital/provider form (HBIG and the hepatitis B birth dose)
 - Mechanism to track upcoming appointments and due dates of vaccine and serology
- Contacts ≤ 24 months of age
 - Case management form(s)
 - Immunization record(s)
 - Mechanism to track upcoming appointments and due dates of vaccine and serology

Computer Tracking Systems

An electronic database makes it much easier to organize case information as well as create effective reminder / recall systems. A feature that any electronic tracking system needs is the ability to sort/filter files according to a unique identifier and link the index case to the infant(s) and associated contact(s). Information within the computer tracking system needs to be made accessible to all case managers and updated on a timely basis in order to enhance tracking system efficiency.

Computer programs that can be used to organize your tracking system are:

- Microsoft Excel®
- Microsoft Access®*
- Electronic Medical Records (EMR) systems

* Although your Information Technology (IT) department may be able to provide you with the software, not all IT departments provide support for Microsoft Access®. Please ensure that your case management team has sufficient training to create and maintain a database within this program.

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Chapter 9

Case Management



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What is Case Management?

Case management is an organized and coordinated service delivery approach, tailoring individualized and specific services to the needs of the client in order to facilitate continued support.

The DSHS HSR PHBPP Coordinators and LHD case managers should conduct case management on HBsAg-positive mothers, their infant(s), and household contacts ≤ 24 months of age according to the PHBPP guidelines.

Case management in the PHBPP involves:

- 1) Interviewing HBsAg-positive mothers and performing tasks such as providing information (brochures).
- 2) Educating HBsAg-positive women and their families.
- 3) Making recommendations for referral.
- 4) 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 the DSHS HSR and / or LHD staff. If the mother decides to follow-up with her private physician, this is acceptable and should be encouraged. However, the DSHS HSR and LHD staff still have 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 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 the case manager's 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.

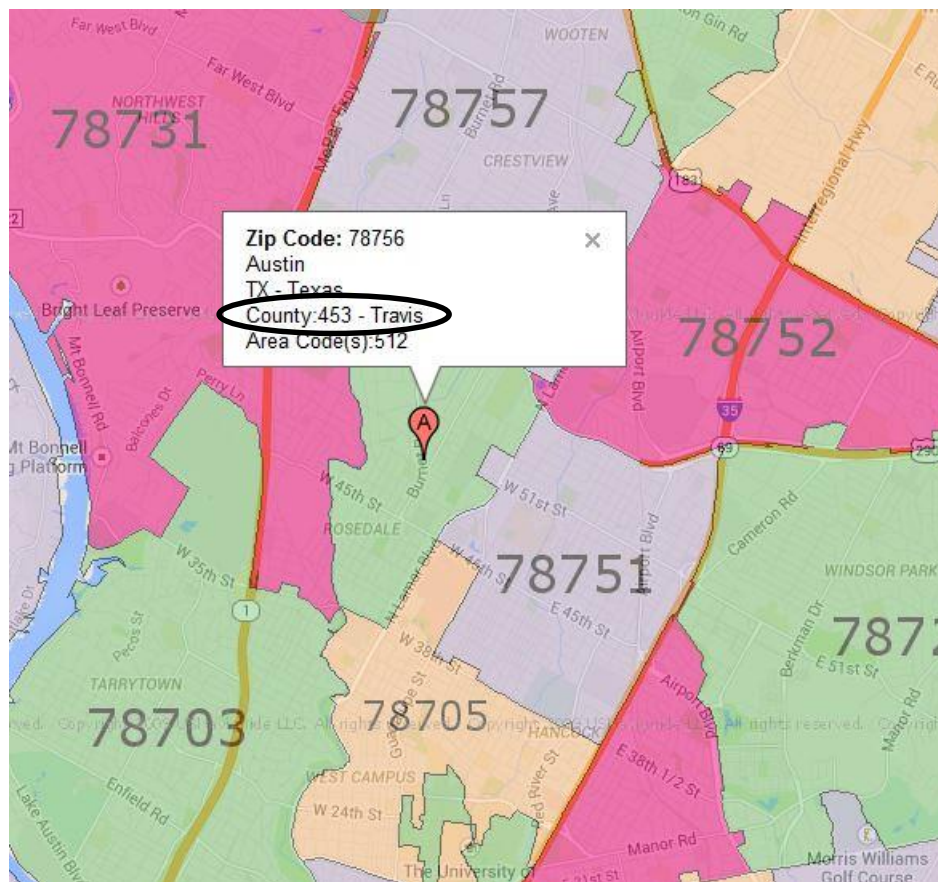
The DSHS HSR PHBPP Coordinators should review all case reports for completion prior to submission to the DSHS Immunization Branch PHBPP. Reporting forms are available at www.texasperinatalhepb.org.

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

The appropriate method to determine case jurisdiction is by using the Federal Information Processing Standard (FIPS) codes. FIPS codes can be found using the zip code or the patient's street address (with city) at the following website: <http://www.zipmap.net/Texas.htm>.

- Enter the zip code or street address with city and click "Find Zipcode".
- Once you click "Find Zipcode," a red balloon will be located on a map within a colored zip code.
- Click on the red balloon to display additional information.
- The FIPS code is displayed as: County: *Number - County Name*.

Please see example below. For more information on FIPS code(s) for your jurisdiction, please contact the DSHS Immunization Branch PHBPP Coordinator at (800) 252 – 9152.



As you can see on this map, the Zip Code of DSHS Immunization Branch was entered as 78756.

The information displayed and highlighted within the black oval is the information needed for assigning a case to the appropriate jurisdiction. The FIPS code displayed for Zip Code 78756 is **453**.

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 HSR or LHD level. This information should be documented in the top right corner of all case management forms.

The format for the ID # is: *yr/county/mother/hh###*

An ID number is assigned by using the following:

- **yr:** year client identified in the PHBPP (i.e., 2013, 2014, etc.)
- **county:** three-digit FIPS* county code
- **mother:** three-digit individual code as assigned by the case manager (this is a chronological number unique to each individual).
- **hh##:** 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 ≤ 24 months of age only: ≥ 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 ≤ 24 months of age
- 2014/000/001/11 – second contact ≤ 24 months of age

The Initial Record

Upon opening a case, mother's case management form should be filled out with available information and submitted to the DSHS HSR PHBPP Coordinator **within 15 days**. All forms can be found online at 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
- Demographics, including address
- Provider information (name and contact info)
- Estimated Date of Delivery / Estimated Due Date (EDD) or infant DOB and pregnancy outcome
- HBsAg + lab report (with confirmation)

Preferred information, but not required for initial submission of form within 15 days, is:

- Phone number
- Country of birth
- Mother's maternal grandmother's country of birth
- Planned delivery hospital
- Race
- Preferred language
- Insurance information

Contacting the HBsAg-Positive Pregnant Woman

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

Tip: *Contact the provider first to find out whether or not they have notified the client of the positive HBsAg result and provided any counseling or education. If they have not, request that they contact the client with her results and let her know that the DSHS HSR or LHD will be contacting her. Call the provider again to verify that they have notified the client.*

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

Once the client has been contacted, please see further guidance in this chapter on case management of HBsAg-positive pregnant women. If you are having difficulty when attempting to contact the client for case management services, please utilize the chart on the following page for help and actions to take.

Filing System

A filing or "tickler" system should not be your main source for your case management tracking. Rather, it should complement your electronic database and reminder / recall system(s) in order to create an effective PHBPP. One file should be created for each index case (mother) and her associated infant(s) and contact(s) within the program for each of her pregnancies. It is recommended that cases be filed according to their unique case identification number (*yr/county/mother/hh#*) so that any case manager can easily access a case when necessary.

Reminders / Recalls

Due to the critical need to complete the hepatitis B vaccine series and PVST on time, reminders are required to inform parents as to when vaccinations and serology testing for their infant(s) is due. It should never be assumed that all parents use effective methods of reminders for themselves nor can you rely on the physician's office for repeated notification of appointments. In order to be effective, the system should be set up in a way that makes it easy to remind the coordinators, who can then notify clients when an immunization or test is due. A good tracking system should notify parents and providers at least one week prior to hepatitis B vaccine and / or PVST due date(s).

Systems that work best:

- Notification(s) may be in the form of:
 - Phone call(s) with messages if no answer – *preferred method*;
 - Letter(s) sent to parent(s); or
 - Computer / phone system that automatically calls patients.
- Remind / notify parents and provider one week before immunization visit(s).
- Contact provider within one day of scheduled appointment to ensure that patient received necessary vaccine(s) / PVST.
- If appointment was missed, contact parent(s) immediately to make arrangements for follow-up visit or a home visit.

Problems Contacting the HBsAg-positive mother	
Problem	Action
No answer	Make at least five attempts to call on different days of the week at different times of the day.
Phone is disconnected	<p>Contact the physician to verify patient's contact information. Inquire as to how they are contacting her for remind / recall. Is there a cell phone number? If new number obtained, please follow steps above "No Answer."</p> <p>If no new number has been obtained, a first class letter should be sent to the client's home address including your contact information. Your letter should request that the client contact you directly regarding a recent health issue (do not discuss HBsAg results in letter).</p>
No response to first class United States Postal Service (USPS) letter	Certified letter requiring a signature should be sent to the client's home address including your contact information. Your letter should request that the client contact you directly regarding a recent health issue (do not discuss HBsAg results in letter).
Certified letter returned with "Forwarding Address Requested" stamp	Certified letter requiring a signature should be sent to the client's forwarding address including your contact information. Your letter should request that the client contact you directly regarding a recent health issue (do not discuss HBsAg results in letter).
No response after certified letter sent to forwarding address	Try visiting the residence or the home to conduct a home visit and provide education. Know the patient's preferred language.
Unsuccessful home visit / no one home	Work directly with the physician's office to manage the case. Request that the physician educate the patient regarding the importance of the DSHS HSR or LHD 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 a planned delivery hospital, attempts must still be made to locate the infant around the time of delivery.
Client moved to another jurisdiction / state	Obtain accurate location information, complete the appropriate Transfer form and fax to the DSHS Immunization Branch PHBPP at (512) 776 - 7544. The PHBPP will forward the transfer information to the new jurisdiction.

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

- Contact the post office to see if there is a forwarding request for the client;
- Make a home visit to the address you've obtained, if no response to certified letters;

Tip: Find out from the physician what the patient's preferred language is to avoid any barriers when first contacting the patient.

- Contact the laboratory providing the test results for contact information on the patient; or
- Access Accurint, which is an online searchable database available to law enforcement, and government agencies. Accurint includes the postal addresses, driver's licenses, property ownership, and criminal records. To use this database you must request the assistance of the DSHS HSR or LHD Sexually Transmitted Disease (STD) program person.

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

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 & hepatitis B vaccine) administered to their infants, and the necessity of PVST after completing the vaccine series. The DSHS Immunization Branch PHBPP has developed educational materials for HBsAg-positive women and their health care providers. Materials can be found at www.texasperinatalhepb.org.

Case Management of HBsAg-Positive Pregnant Women

Each DSHS HSR 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 2 years of age) will be handled confidentially by the PHBPP staff. Complete the *Mother Case Management Report* (Stock # EF11-10932). The report form can be accessed at www.texasperinatalhepb.org. It should be completed and submitted within **15 days** to the DSHS HSR PHBPP Coordinators for review who will submit the completed forms by mail or fax to:

**Texas Department of State Health Services
Perinatal Hepatitis B Prevention Program
MC – 1946
P.O. Box 149347
Austin, Texas 78714 – 9347
Telephone: (800) 252 – 9152
Fax: (512) 776 – 7544**

Every time the form is updated, it should be **immediately submitted** to the DSHS HSR PHBPP Coordinator who will send to the DSHS Immunization Branch PHBPP Database Manager. The procedures outlined below should be followed when a pregnant woman is identified as HBsAg-positive. You may receive the report from the provider, the laboratory, or through National Electronic Disease Surveillance System (NEDSS). Occasionally, positive lab results will be submitted to the health department without contact information for the client. In that case, you will have to contact the provider first to obtain that information.

- 1) Contact the provider first to obtain the following information:
 - OB-GYN medical records
 - HBsAg lab result(s) with positive confirmatory test
 - 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
 - Face sheet showing patient's contact and insurance information
- 2) 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. A family member that is ≥ 18 years can provide translation.
- 3) 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; you should document the reason for not obtaining the insurance status.

Tip: *You can usually obtain insurance information from the provider by requesting a "face sheet."*
- 4) Educate client about HBV, communicability of the virus, and the importance of protecting her infant from HBV transmission through the use of HBIG and 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.*
- 5) Services that will be provided by the DSHS HSR 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 HSR or LHD, the PHBPP staff should conduct home visits to provide these services, only if absolutely necessary.
- 6) Provide patient educational brochure to the client (*Stock # E11-11444*) which is available through the DSHS Immunization Branch PHBPP at <https://secure.immunizetexasorderform.com/default.asp>. Ensure that all educational materials are provided in a culturally sensitive manner.
- 7) Information about the woman's alcohol and drug (illegal / non-prescription) use should be acquired in a non-intimidating manner.
 - If the patient answers yes to the use of alcohol and / or drugs, ask if she would like a referral to the nearest Substance Abuse Program.
 - DSHS funded Substance Abuse Services can be found by a County search at www.dshs.state.tx.us/treatment/ or by calling 1-877-9-NO-DRUG (1-877-966-3784).
 - If so, give a brief overview on the role of the Substance Abuse Program and the address to the nearest location in her area.

- Provide her with the brochure that describes the program and ensure that she has the needed contact information; allow the patient to make the decision on her own to call and request help from the Substance Abuse Center, unless she requests your assistance in doing so.
 - Substance abuse brochures can be obtained from your nearest Substance Abuse Program clinical site.
- 8) Refer the HBsAg-positive pregnant woman to her health care provider for further medical evaluation and appropriate health care management. Document her provider's name, telephone number, address and specialty. See further guidance under the Provider Education Section of this chapter.
- Note:** *The health care provider or the OB-GYN might refer the HBsAg-positive pregnant woman to a gastroenterologist, hepatologist, or an infectious disease specialist. Her case should still be managed regardless of which specialty is following her.*
- When the HBsAg-positive pregnant woman is being monitored for hepatitis B by a physician, information regarding supportive care and treatment must be noted in the patient's medical chart. The information must include:
 - the type of supportive care
 - treatment or antiviral agents (brand and dose)
 - date antivirals were initiated
- 9) After the initial interview with the pregnant woman, program involvement 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.
- 10) Notify the client's health care provider (or other specialty) of the role of the DSHS HSR and / or LHD, including the case management services that will be provided to the newborn and household contacts ≤ 24 months of age.
- 11) Complete and submit the *Mother Case Management Report* to the DSHS HSR PHBPP Coordinator **within 15 days**. This form is available at www.texasperinatalhepb.org.
- 12) Identify all household contacts who are ≤ 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 ≤ 24 months of age.
 - All sexual partners and contacts > 24 months of age should be referred to a health care 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. Please contact your DSHS HSR or LHD for additional information.
- 13) Notify the delivery hospital where the client plans to deliver her infant(s) **at least two months prior** to her estimated date of delivery.
- 14) Ensure that the hospital has HBIG and hepatitis B vaccine available in advance no less than seven days before her estimated date of delivery.

- 15) Review with the Newborn Nursery their standing orders and written policies pertaining to the administration of HBIG and hepatitis B vaccine birth dose in addition to testing the infected mother for HBsAg upon delivery.
- 16) Periodically contact the hospital (delivery unit or newborn nursery) to inquire as to whether or not the mother has delivered yet.
- 17) Once the infant has been born, complete and submit the initial *Infant Case Management Report* within **15 days after the birth of infant** to the DSHS HSR PHBPP Coordinator. This form is available at www.texasperinatalhepb.org.

Note: Case management on HBsAg-positive women with a stillbirth or miscarriage will be eligible for the program; however, they should be referred to a health care provider for health care to delay further injury to the liver. The case management report is coded as referred to medical follow-up and status code is noted as infected.

Provider Education

Patients who have acute and chronic HBV infection 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. If not already familiar in doing so, the provider should be educated as to:

- interpretation of serology results (refer to Appendix C);
- monitoring patients for disease progression and prevention; and
- 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 that the medical providers are trained on risk-factors for HBV infection in pregnant women, their infants, sexual partners, and household contacts; if needed, staff should train 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 health care provider.

Case Management of Infant(s) Born to HBsAg-Positive Pregnant Women

Case management of infants born to HBsAg-positive women is labor intensive. Adequate case management should require no more than nine months to complete perinatal hepatitis B prevention case management services once the infant has been born (Refer to Guideline 3 in Appendix B). For children who do not adequately respond to the vaccine series and who are also not infected with HBV, case management services could take up to 17 months to complete.

- 1) It is imperative that the case manager informs labor and delivery staff (at planned delivery hospital) of the woman's HBsAg-positive status at least two 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 (within 12 hours).

- Hospitals may order HBIG and hepatitis B vaccine directly from the manufacturer.
 - HBIG can be ordered through the DSHS Immunization Branch only in emergency situations. Please see guidelines later in this chapter.
- 2) Within 12 hours of delivery, appropriate PEP treatment should be administered. Infants born to HBsAg-positive women should not be placed in special isolation. For additional guidance on PEP and vaccine schedules, please refer to Appendix A. HBsAg-positive mothers can breastfeed their infant without delay unless there is significant breast pathology. For additional information, please refer to 'Perinatal Transmission' in Chapter 2.
- 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 status unknown woman:
 - Administer first dose (birth dose) of hepatitis B vaccine within 12 hours
 - If unknown at discharge, administer HBIG before discharging infant
 - If HBIG was not given before discharge and the HBsAg result later comes back as positive:
 - Administer HBIG, no later than seven days
 - If the infant has already been discharged, it is the delivery facility's responsibility to recall infant and administer
 - 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
- 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. The form must be completed and submitted **within 15 days** of infant birth to the DSHS HSR PHBPP Coordinator for review who must submit the *Infant Case Management Report* by mail or fax to:

**Texas Department of State Health Services
 Perinatal Hepatitis B Prevention Program
 MC – 1946
 P.O. Box 149347
 Austin, Texas 78714 – 9347
 Telephone: (800) 252 – 9152
 Fax: (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 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 health care provider to notify them when vaccines and PVST are due. For additional information, please refer to the *Reminders / Recalls* section of this chapter as discussed previously.
- 7) Infant should complete the hepatitis B vaccine series on time
 - Dose # 2: one month of age (no later than two months of age)
 - Dose # 3: six months of age

Please refer to Appendix A 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 work with the DSHS HSR PHBPP Coordinator and / or the DSHS Immunization Branch to obtain the vaccine. Infants born to HBsAg-positive mothers can receive DSHS Immunization Branch-supplied vaccine even if they receive health care in the private sector.

- 8) The immunization information should be obtained from the infant's health care provider and be documented on the *Infant Case Management Report form*. If the parents consented to ImmTrac, vaccine information can also be obtained from this system. Every time the form is updated, it should be **immediately submitted** to the DSHS HSR PHBPP Coordinator who will send to the DSHS Immunization Branch PHBPP Database Manager. Below is the information to be documented:
 - date administered
 - dose administered
 - formulation (i.e., Pediarix®, Engerix-B®, Recombivax HB®, etc.)
 - manufacturer
 - lot number
 - provider / clinic that administered the dose
- 9) Contact the parent or guardian by phone or mail to remind him / her about PVST at the child's nine month wellness visit.
- 10) The PVST should be performed to determine the success of PEP.
 - **No earlier than nine months of age**
 - **At least one to two months after completion of hepatitis B vaccine series**
 - HBsAg
 - anti-HBs
 - Test at the next well-child visit at nine months

Tip: Request that the pediatrician and / or nurse make a note and flag the child's medical record indicating 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 been scheduled, follow-up with the parent or guardian to schedule an appointment with the provider.

A release of information is not needed from the parent(s) / guardian(s) to request that the pediatrician 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 release this information to the infant's care provider. Ideally, the hospital and / or DSHS HSR or LHD should notify the infant's care provider immediately after birth.

A PVST is not recommended before the age of nine 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 anti-HBc might be detected up to age 24 months in infants born to HBV infected mothers.

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 Branch PHBPP along with a copy of the infant's results.

Perinatal Hepatitis B Virus Infection Case Definition

The case definition for perinatal hepatitis B virus infection is HBsAg positivity in an infant aged 1 - 24 months born in the US or US 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 DSHS through NEDSS. It is the responsibility of the DSHS HSR 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 Branch PHBPP Coordinator **within one working day** of notification.

Case Management of Contact(s) ≤ 24 months of age to HBsAg-Positive Pregnant Women

Household contacts are defined as persons ≤ 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 health care provider. The *Contact ≤ 24 Months Case Management Report form* should be completed for all contacts identified who are ≤ 24 months of age and case management should be completed.

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

- 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 # EF11-1093) for each contact ≤ 24 months of age identified **within 15 days** of identification. This form, along with instructions is available at 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 of the following chart. HBsAg-positive results must have confirmatory testing performed.

* The contact's HBV status may be provided by phone only after confirmation of the contact's identity with multiple identifiers, if permissible by your agency's policies and procedures. Serology results should not be mailed due to possible breach in confidentiality.

Actions after 1 st PVST Results			
HBsAg	Anti-HBs	Status	Action
Negative	Negative	Susceptible	Proceed to Step # 4 below.
Negative	Positive	Immune	Submit form and documentation to DSHS HSR PHBPP Coordinator.
Positive	Negative	Infected	Refer to physician for follow-up and evaluation.

- 4) If needed, ensure initiation and completion of hepatitis B vaccine series.
- 5) All updates to the *Contacts ≤ 24 months of age Case Management* form should be **submitted immediately**. DSHS HSR PHBPP Coordinators must submit reports to the DSHS Immunization Branch PHBPP Coordinator.
- 6) Perform PVST one to two months after completing the vaccine series to determine if adequate protection has been achieved with one complete series of vaccine. Please keep in mind that PVST should not be done before nine months of age.
- 7) If adequate protection was not demonstrated on the PVST, repeat the hepatitis B vaccine series and repeat PVST one to two months after completion of the second series. Be sure that HBsAg-positive results are being interpreted from confirmatory testing.

Actions after 2nd PVST Results			
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 HSR PHBPP Coordinator.
Positive	Negative	Infected	Refer to physician for follow-up and evaluation.

- 8) Record all information on the Contact Case Management Report form. Any updates should be submitted immediately to the DSHS HSR 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 off is < 10 for reporting inadequate anti-HBs, and ≥ 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 HSR PHBPP Coordinator.

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

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

Chapter 10

Resources



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DSHS Resources

Home page: www.dshs.state.tx.us

Infectious Disease Control Unit: www.texasdisease.org

Immunization Branch: www.ImmunizeTexas.com

Perinatal Hepatitis B: www.texasperinatalhepb.org

Adult Safety Net Program: www.dshs.state.tx.us/immunize/ASN/Public.shtm

DSHS HSR Adult and Adolescent Immunization (AAI) Coordinators
www.dshs.state.tx.us/asn/
www.dshs.state.tx.us/HSR-AAI-Coordinators.aspx

Centers for Disease Control and Prevention Resources

Home page: www.cdc.gov

National Immunization Program: www.cdc.gov/vaccines

CDC National Center for Infectious Diseases: Viral Hepatitis B
www.cdc.gov/ncidod/diseases/hepatitis/b/index.htm

Division of Viral Hepatitis: www.cdc.gov/hepatitis

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

National Health and Examination Survey: www.cdc.gov/nchs/nhanes.htm

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

Center for Disease Control and Prevention, 2015. Epidemiology and Prevention of Vaccine-Preventable Diseases The Pink Book: Course Textbook - 13th Ed. (2015). Taken from (www.cdc.gov/vaccines/pubs/pinkbook/hepb.html).

2010 Statistics and Surveillance:
www.cdc.gov/hepatitis/Statistics/2010Surveillance/PDFs/2010HepSurveillanceRpt.pdf

Morbidity and Mortality Weekly Report (MMWR). December 2006. 55(RR16); 32 - 33
www.cdc.gov/mmwr/preview/mmwrhtml/rr5516a4.htm

Morbidity and Mortality Weekly Report (MMWR). October 2015. 64(39); 1118 - 20
www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm

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

Other Resources

Immunization Action Coalition: www.immunize.org/askexperts/experts_hepb.asp

World Health Organization (WHO): www.who.int/mediacentre/factsheets/fs204/en/

American Academy of Pediatrics (AAP): www.aap.org

American College of Obstetrician and Gynecologist (ACOG): www.acog.org

American Liver Foundation: www.liverfoundation.org

Asian Liver Center at Stanford University: www.liver.stanford.edu

Every Child By Two: www.ecbt.org

GlaxoSmithKline: www.gskvaccines.com

Healthfinder: www.healthfinder.gov

Hepatitis B Foundation: www.hepb.org

Hepatitis B Moms: www.hepbmoms.org

Hepatitis Foundation International: www.hepfi.org

HepNet (Hepatitis Information Network): www.hepnet.com

Immunization Action Coalition: www.immunize.org

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

Medline, PubMed: www.nlm.nih.gov

Medscape: www.medscape.com

Merck & Co., Inc.: www.merck.com

Parents of Kids With Infectious Diseases (PKIDS): www.pkids.org

The Vaccine Page (UniSci): www.vaccines.com

Viral Hepatitis Prevention Board: www.vhpb.org

Hepatitis B Key Facts: www.who.int/mediacentre/factsheets/fs204/en/

Publications and Newsletters

The following immunization and hepatitis resources may be ordered directly from the organizations listed:

Pink Book-Epidemiology and Prevention of Vaccine-Preventable Diseases:

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Red Book-Report of the Committee on Infectious Diseases: www.aap.org/bookstorepubs.html

NEEDLETIPS and the Hepatitis B Coalition News: www.immunize.org

Morbidity and Mortality Weekly Report (MMWR): www.cdc.gov/mmwr

Morbidity and Mortality Weekly Report (MMWR):

www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s_cid=rr5416a1_e

Morbidity and Mortality Weekly Report (MMWR). October 2015. 64(39); 1118 - 20

www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm

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APPENDICES

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Appendix A

Vaccine Schedule



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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.



- 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.

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- 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)

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), 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.

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 third and final dose of the hepatitis B vaccine series at six months of age, as long as all minimum intervals (below) are met.

Infant Hepatitis B Vaccine Schedule Using Combination Vaccines

Pediarix® Vaccine Schedule		
Biologic	Dose	Age of Infant
Hepatitis B vaccine - dose 1	0.5 mL	Birth (Monovalent vaccine ONLY)
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**

* Not approved for use in infants < 6 weeks of age.

** Final dose of hepatitis B vaccine cannot be administered < 6 months (24 weeks) of age.

Minimum Intervals	
Dose 1 to 2	4 weeks
Dose 2 to 3	8 weeks
Dose 3*	16 weeks after 1 st dose

*Dose three should not be administered before six months (24 weeks) of age.

Postexposure Prophylaxis (PEP) Treatment of Infants

Born to HBsAg – Positive 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*,±
Hepatitis B vaccine - dose 2	0.5 mL	1 month
Hepatitis B vaccine - dose 3	0.5 mL	6 months**

* Administer at separate anatomical sites. Preferred site: anterolateral thighs.

** Infant should not receive third dose of hepatitis B vaccine before 6 months (24 weeks) of age.

± Regardless of infant's birth weight.

Born to HBsAg – Unknown Status mother		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	< 2,000 g (4.4 lbs.) – within 12 hours of birth*
		> 2,000 g (4.4 lbs.) – 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**

* Administer at separate anatomical sites. Preferred site: anterolateral thighs.

** Infant should not receive third dose of hepatitis B vaccine before 6 months (24 weeks) of age.

If the mother's HBsAg delivery result comes back negative, the infant does not need to receive HBIG. However, it will not harm the child if HBIG has already been administered.

Vaccination and PEP of Preterm Infants Weighing < 2,000 grams (4.4 pounds)

Born to HBsAg – Positive <u>OR</u> HBsAg - Unknown 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* (Do not count birth dose as part of series)
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**

* Administer at separate anatomical sites. Preferred site: anterolateral thighs.

** Infant should not receive third dose of hepatitis B vaccine before 6 months (24 weeks) of age.

± All preterm infants weighing < 2,000 g (4.4 lbs.) at birth should reinitiate the series beginning at 1 month of age.

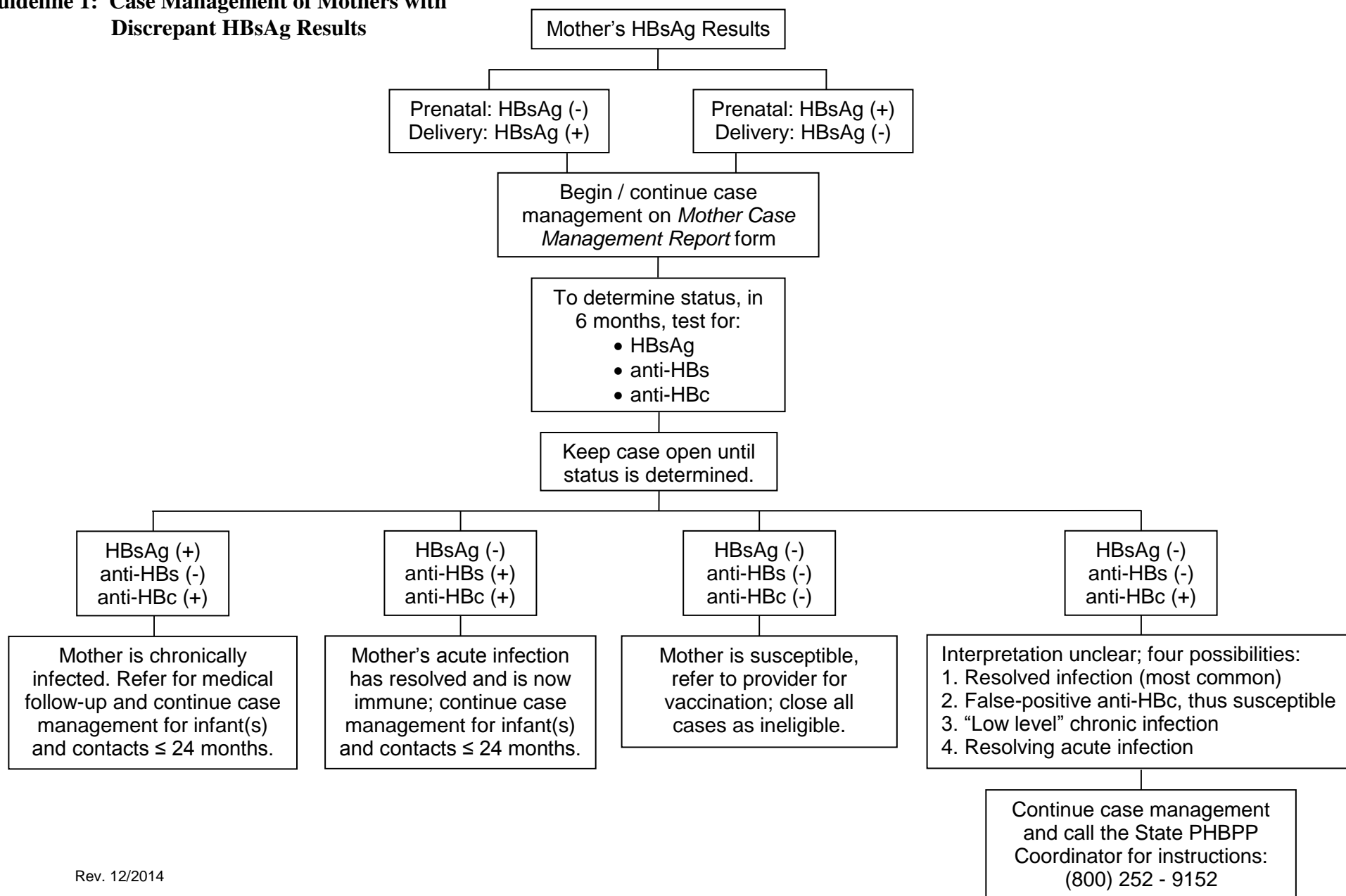
Appendix B

Flowcharts and Diagrams



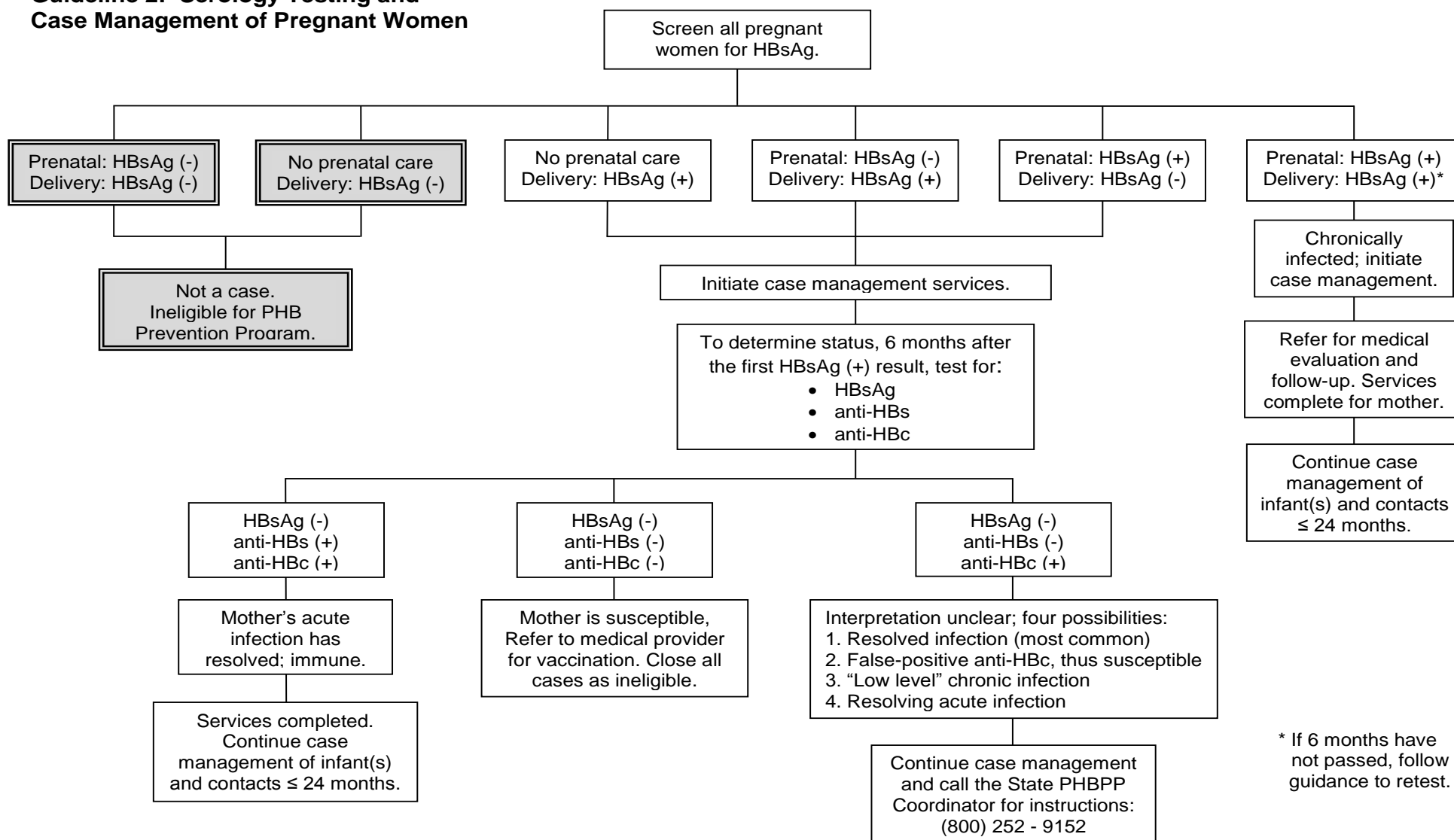
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Guideline 1: Case Management of Mothers with Discrepant HBsAg Results



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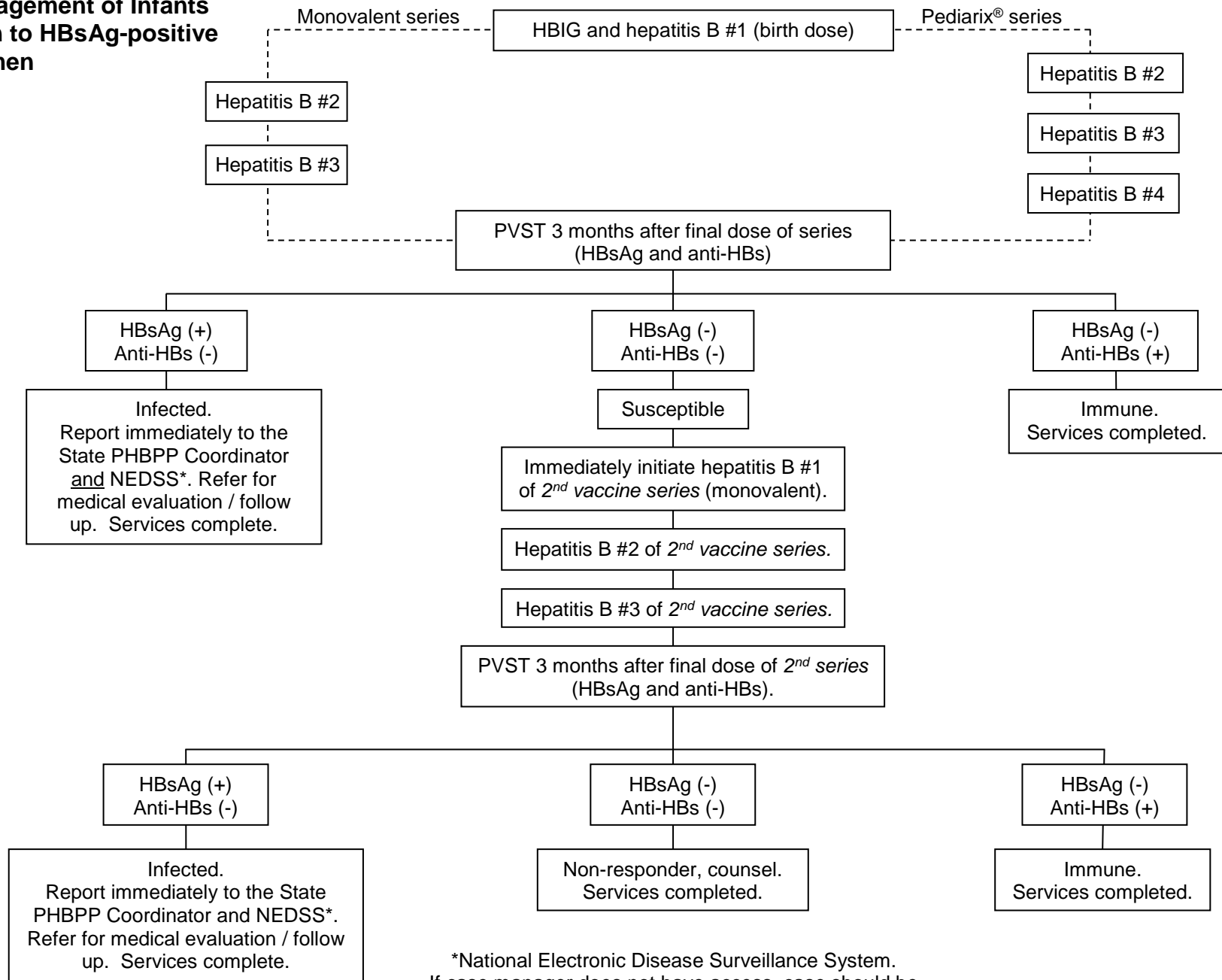
Guideline 2: Serology Testing and Case Management of Pregnant Women



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

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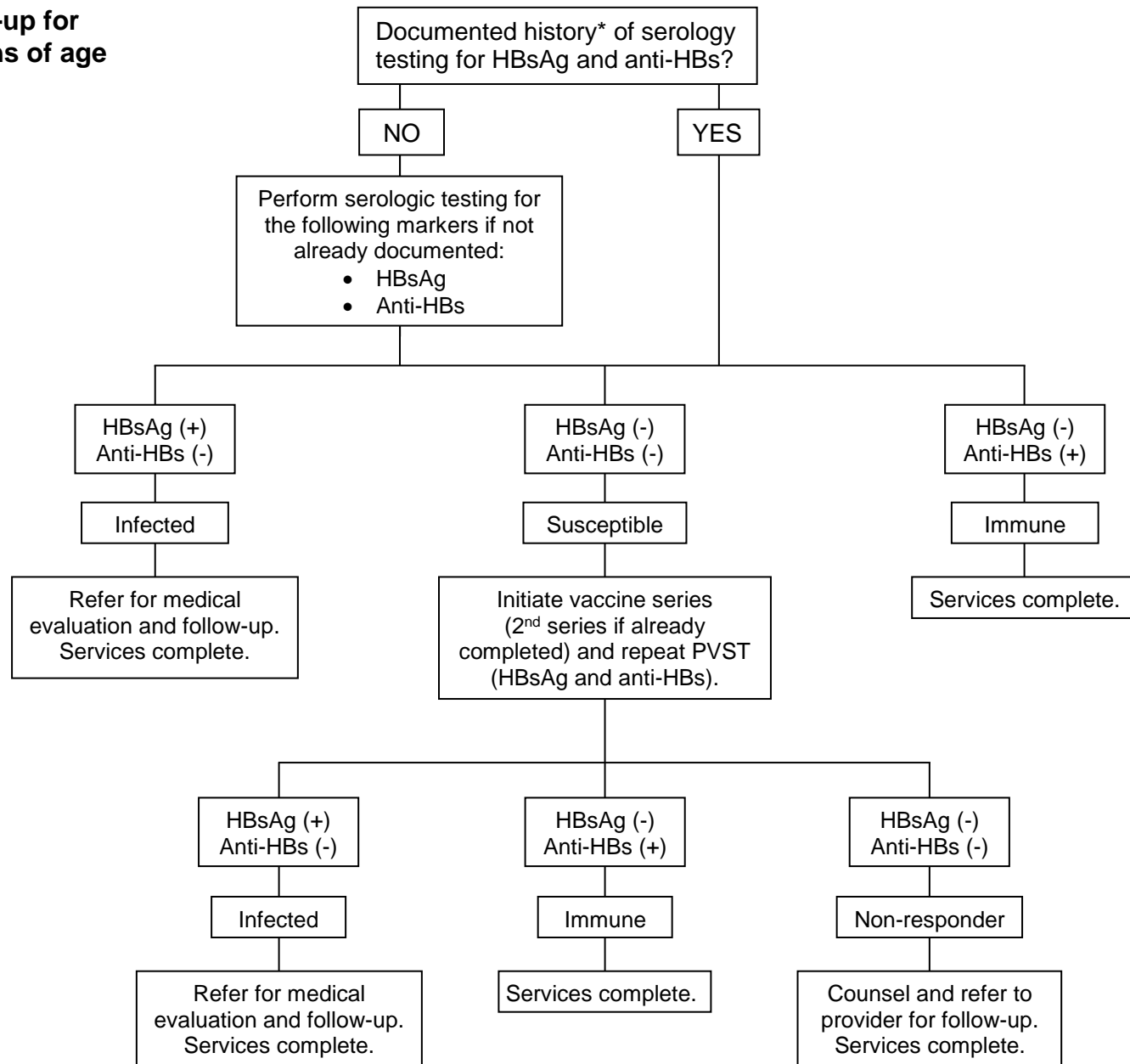
Guideline 3: Case Management of Infants Born to HBsAg-positive Women



*National Electronic Disease Surveillance System.
If case manager does not have access, case should be submitted to overseeing Epidemiology Team for reporting.

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



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

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Appendix C

Serology Interpretation



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Hepatitis B Antigens and Markers

1) 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 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. Tests for HBV DNA are not performed as a standard test and are generally only used as indicators of disease progression, suitability for therapy, and research purposes.

2) 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.

3) Hepatitis B Surface Antigen (HBsAg)

HBsAg is found on the surface of the virus and can be identified about 30 - 60 days after exposure to the virus. The surface antigen component of the virus is not infectious, however, it does indicate that the virus is present and can be transmitted to others. HBsAg testing is the current standard to indicate current infection with hepatitis B. If HBsAg is present for more than six months this generally indicates a chronic infection.

4) 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.

There are mutant strains of HBV exist that replicate without producing HBeAg. In many cases, infection with these mutant strains is more aggressive than HBe producing strains.

5) Hepatitis B 'little e' Antibody (anti-HBe)

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

6) 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 the 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.

7) 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 that infection occurred. Any individual that has been infected with the virus will test positive for anti-HBc; it will remain positive for life.

8) Hepatitis B Immunoglobulin M (IgM anti-HBc)

IgM anti-HBc is detectable around 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.

9) 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 hepatitis B vaccine indicating that the individual adequately responded to the vaccine and is protected from infection.

Figure 1. Acute Hepatitis B Virus Infection with Recovery

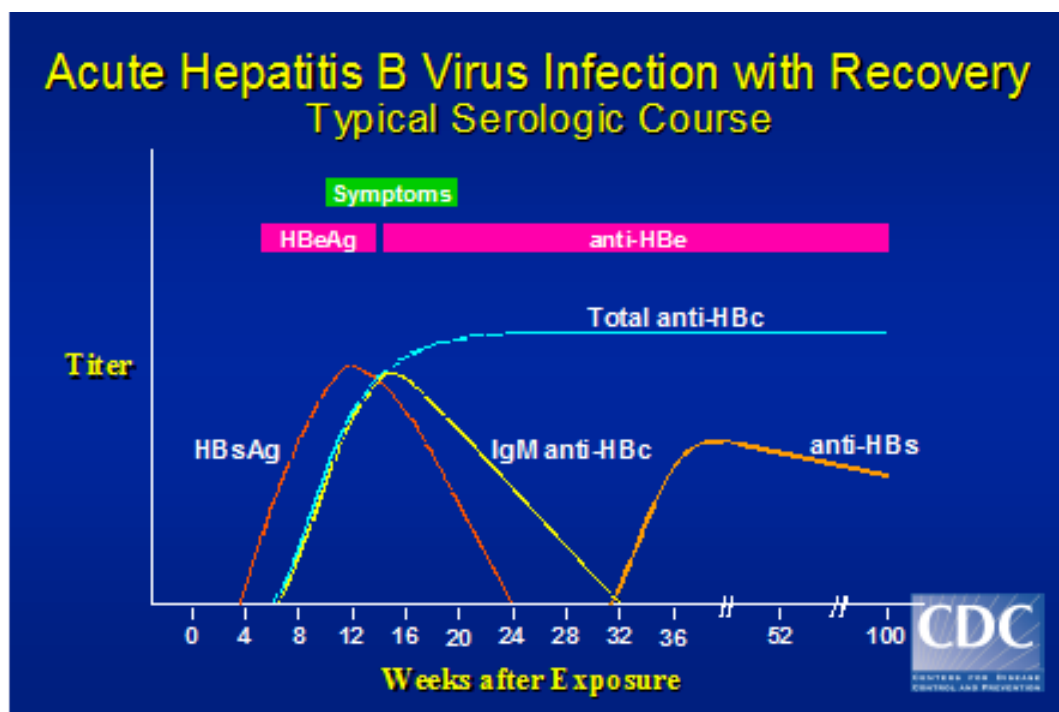
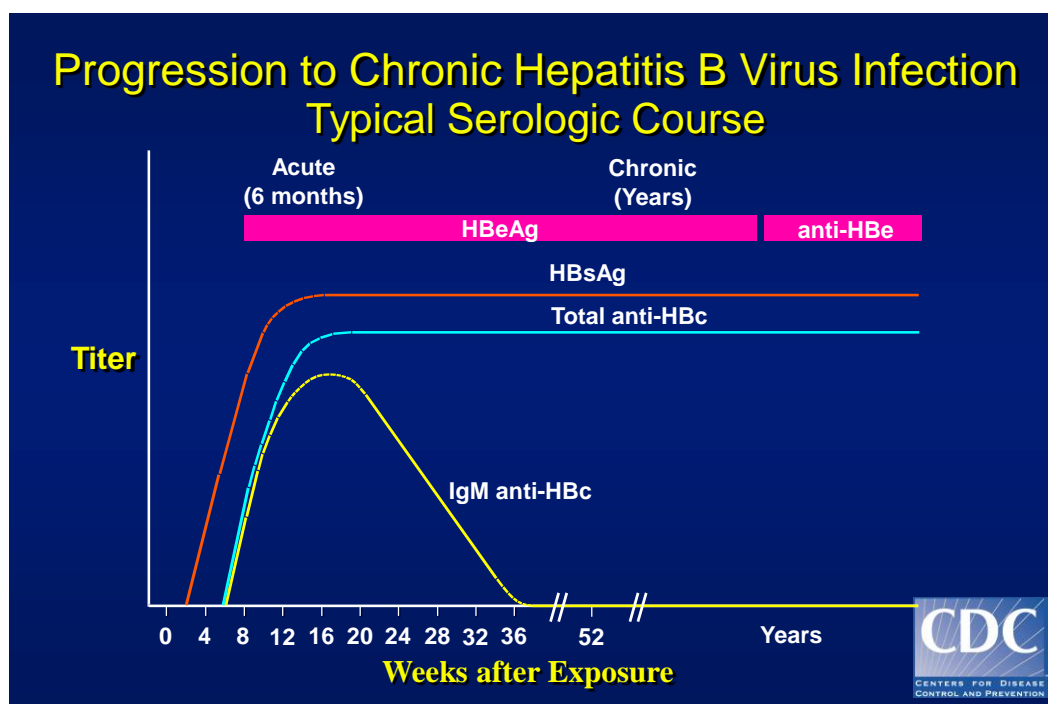


Figure 2. Progression to Chronic Hepatitis B Virus Infection



Interpretation of Post-Vaccination Serologic Testing and Action for Infants

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 series of hepatitis B vaccine. The first dose of the second series should be given as soon as post-vaccination serology results are known and follow the 0, 1, and 6 month schedule. The infant should be tested again for HBsAg and anti-HBs (PVST), 1 - 2 months after completion of the second series. These infants will receive a total of at least six doses of hepatitis B vaccine.
+	-	<p>The vaccination effort failed. The infant is infected with HBV (perinatal hepatitis B infection) and is likely to become a chronic carrier. All confirmed cases of perinatal hepatitis B virus infection should be reported to the state through the 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>Note: The surveillance case definition for perinatal hepatitis B virus infection is HBsAg positivity in any infant aged 1 - 24 months who was born in the US or in US territories to an HBsAg-positive mother.</p>

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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.

Tests	Results	Interpretation
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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Centers for Disease Control and Prevention
Division of Viral Hepatitis



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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 (≤ 6 mos). Its presence indicates acute infection.

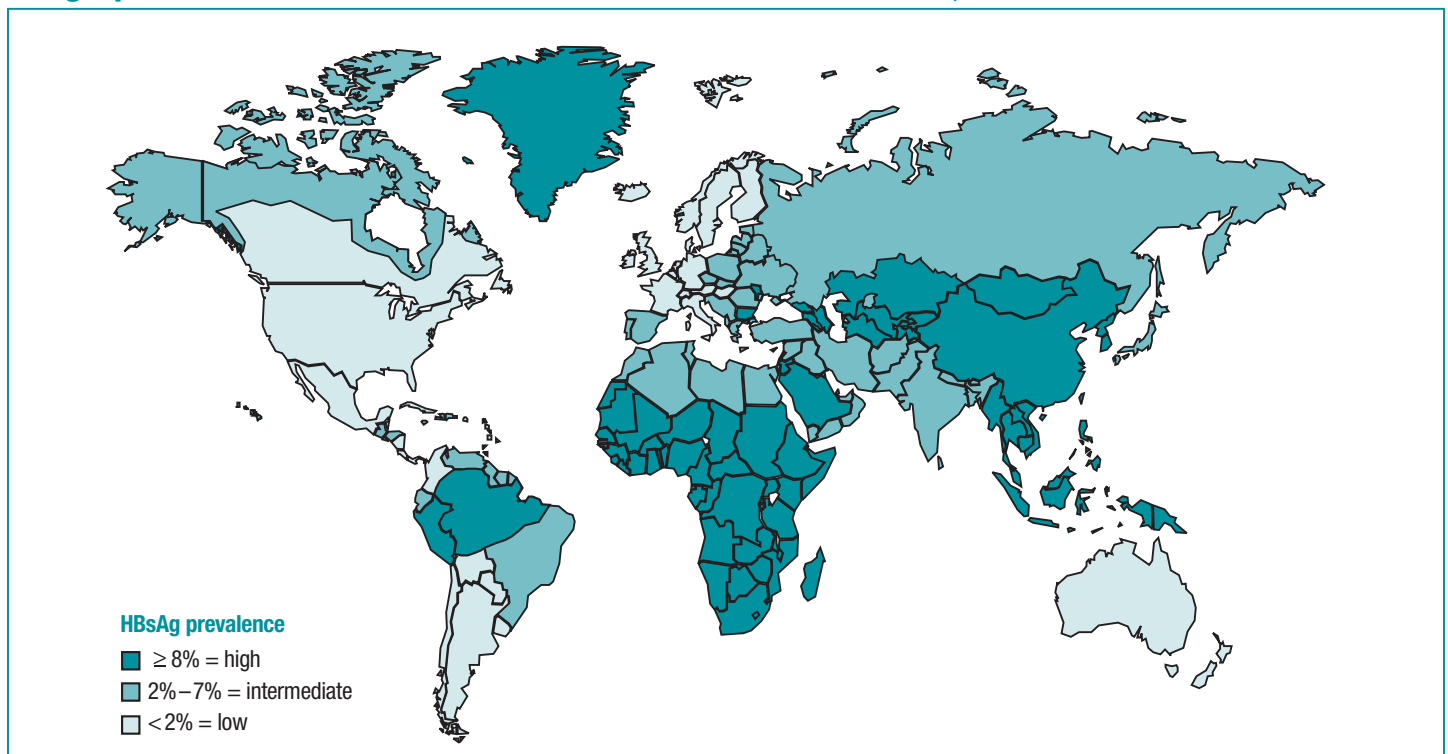
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Recommendations for Routine Testing and Follow-up for Chronic Hepatitis B Virus (HBV) Infection

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"> – immigrants – refugees – asylum seekers – internationally adopted children 	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://www.cdc.gov/travel/yellowbookch4-HepB.aspx>.

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).



Appendix D

Policies, Standing Orders, and HIPAA



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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.*

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 HBsAg¹ 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 (or have a link to the mother's HBsAg test result).
- 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 HBsAg¹ if the pregnant woman was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-

drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing

- 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 HBsAg¹ 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* HBsAg¹ 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 (available at www.immunize.org/vis).

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.^{2, 3, 4}
- 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.^{3, 5} 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.

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- 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 HBsAg¹ test.
- 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 HBsAg¹ 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^{3,6} (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 as well as postvaccination testing of the infant for both HBsAg and antibody to HBsAg (anti-HBs) after completion of the hepatitis B vaccine series to assess the hepatitis B status of the infant following vaccination.
- 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 critically important for the protection of her baby's health that the baby receives the full hepatitis B vaccine series on the recommended schedule;
 - c That blood tests (HBsAg and antibody to hepatitis B surface antigen [anti-HBs]) need to be drawn from the baby 1–2 months after completion of the 3- or 4-dose hepatitis B vaccine series and also no earlier than 9–12 months of age to determine if the child developed a protective immune response to vaccination or needs additional management⁷;
 - 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.
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.
7. The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection (see "Update: Shortened interval for postvaccination serologic testing of infants born to hepatitis B-infected mothers," *MMWR*, 2015;64: 1118–20).

For "Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Birth Dose," visit www.immunize.org/catg.d/p2131.pdf.

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

Routine 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., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing.
- 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) 1–2 months after completion of the hepatitis B vaccine series and no earlier than when the infant is 9–12 months of age.

NOTE: The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection.

- 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;

CONTINUED ON THE NEXT PAGE ►



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www.immunize.org/catg.d/p2131.pdf • Item #P2131 (2/16)

- c Blood tests (HBsAg and anti-HBs) will need to be obtained from the infant 1–2 months after completion of the hepatitis B vaccine series (at 9–12 months of age) 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.
- 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 the previous section (see “For highest-risk infants: the mother is HBsAg positive”).

REFERENCES

1. 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.
2. CDC. Update: Shortened interval for postvaccination serologic testing of infants born to hepatitis B-infected mothers, *MMWR*, 2015;64:1118–20 at www.cdc.gov/mmwr/pdf/wk/mm6439.pdf.

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.

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.

(1) Does the entity (in whole or in part) perform any of the following covered functions...?

- provide [for] or pay the cost of medical care;
- provide [direct] medical or health services (or furnish, bill, or receive payment for health care in the normal course of business); or
- receive, process, or facilitate the processing of health information received from another entity into standard or nonstandard formats.

(2) Does the entity receive or transmit individually identifiable health information pertaining to...?

- | | |
|--|---|
| <ul style="list-style-type: none"> • health plan enrollment (or disenrollment); • health plan eligibility determinations; • health plan premium payments; • referral certification, authorization; | <ul style="list-style-type: none"> • claim submissions (encounter info); • health plan benefit coordination; • claim status inquiries; • payment and remittance advices; • first report of injury; and/or • health claim attachments. |
|--|---|

(3) Does the entity conduct any or all of these standard transactions electronically...?

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.

§ 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.

§ 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.

§ 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, 104th Congress, 2nd Session (21 August 1996), *Health Insurance Portability and Accountability Act*.

§ 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.

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.

DEFINITIONS

Business associate^{*}:

- (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^{*} 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[†] 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[†] means a treatment relationship between an individual and a health care provider that is not an indirect treatment relationship.

Disclosure[†] 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^{*} 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.

Health care component[†] 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^{*} 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^{*} 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[†] 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^{*} 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)).

* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504

(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[†] 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[†] 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^{*} 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[†] 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[†] 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.

* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504

Public health authority[†] 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[‡] means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

Required by law[‡] 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^{*} 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[†] 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[†] 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.

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.

* 45 CFR § 160.103

† 45 CFR § 164.501

‡ 45 CFR § 164.504

Department of State Health Services

Notice of Privacy Practices

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.

Si quiere este aviso en español, llame gratis al 2-1-1 o al 1-877-541-7905.

About this Notice:

Effective date: This Notice takes effect on July 20, 2015 and stays in effect until replaced by another notice.

This Notice is required by HIPAA (the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. §1320d, et seq., and regulations adopted under that act).

In this Notice, “agency,” refers to the Texas Department of State Health Services.

This Notice tells you about: (1) your privacy rights, (2) the agency’s duty to protect health information that identifies you, and (3) how the agency can use or share health information that identifies you without your written permission. This Notice doesn’t apply to health information that does not identify you or your legally authorized representative.

In this Notice, “You” or “your” means you, the individual to whom this Notice is addressed or your legally authorized representative.

In this Notice, “health information” means:

- Medical information or legally protected health information about you whether in oral, paper or electronic form that relates to:
 - Your past, present, or future physical or mental health or condition;
 - Health care provided to you; or
 - The past, present, or future payment for providing your health care.
- Genetic information about you, and
- Health Information created or received by a health-care service provider, health plan, public health authority, employer, life insurer, school or university, or health-care clearinghouse.

The agency reserves the right to change the terms of this Notice. The new Notice will be sent to your most recent address that the agency has on file. It is your duty to promptly tell the agency if you have had a change of address. The practices in the new Notice will apply to all the health information the agency has about you, regardless of when the agency received or created the information.

The agency is considered a “hybrid covered entity,” which means that only certain parts of the agency have health care components and others are not. This Notice applies to the parts of the agency that are health care components, or are serving as a health care provider (for example, agency state mental health hospitals and the agency Laboratory), health plan services known as “Texas Health Steps” and the agency’s Centralizing Billing Services health care clearinghouse.

Your privacy rights:

The law gives you the right to:

- Receive adequate notice of: (1) the uses and disclosures of protected health information that can be made by the agency or your health-care service provider, (2) your rights related to your health information, and (3) the agency's and health-care service provider's legal duties to protected health information, with some legal exceptions. The agency provides you this notice via this Notice of Privacy Practices, which is also available online on the agency's website: www.dshs.state.tx.us.
- Ask the agency or your health-care service provider to restrict certain uses or disclosures of health information about you. The agency is not required to agree to these requests, except in some cases when you request that we not disclose information to your health plan about services for which you paid with your own money in full. The agency may require your request to be in writing.
- Request confidential communications about your health information and make reasonable requests to get information in a different way or location. The agency or health-care service provider may require the request to be in writing with a statement or explanation for the request. For example, you might explain that sending information to your usual address might put you in danger. You must be specific about where and how the agency can contact you.
- In some situations, look at or get a copy of certain health information, including laboratory test results that the agency or your health-care service provider has about you.
- Ask the agency or your health-care service provider's privacy office to correct certain information about you if you believe the information is wrong or incomplete. Most of the time, the agency can't change or delete information, even if it is incorrect. If the agency or health-care service provider decides it should make a correction, it will add the correct information to the record and note that the new information takes the place of the old information. The old information will remain in the record. If the agency or health-care service provider denies your request to change the information, you can have your written disagreement reviewed by the agency's privacy officer and placed in your record.
- Ask for a list of disclosures the agency or health-care service provider has made of certain health information.
- Ask for and get a paper copy of this Notice from the agency or its privacy office.
- Cancel permission you have given the agency or your health-care service provider to use or share health information that identifies you in some cases, unless the agency or health-care service provider has already taken action based on your permission. You must cancel your permission in writing and deliver it to the agency's privacy office.
- In some situations, be notified by letter from the agency's privacy officer if your health information has been used or shared in an unauthorized manner.
- Be notified of material changes to the way the agency uses or shares health information about you. All changes to the Notice will be posted on the agency's web site and the revised Notice will be available to you at your health provider's office.
- For all notices to, or requests for copies of information from, the agency or health-care service provider's privacy office, please see the "Complaints and Questions" section for contact information.

The agency's duty to protect health information that identifies you:

The law requires the agency to take reasonable steps to protect the privacy and security of your health information. It also requires the agency to give you this Notice, which describes the agency's legal duties and privacy practices. In most situations, the agency can't use or share health information that identifies you without your written authorization, except to carry out treatment, payment for your health care or the agency's health-care operations, or as required by law, as described below. This Notice explains under

what circumstances the agency can use or share health information that identifies you without your permission. The agency is required to abide by the terms of the notice currently in effect.

Agency workforce (employees, trainees, volunteers and staff augmentation contractors) are trained and required to protect your health information. The agency does not give employees access to health information unless they need it for a business reason. Business reasons for needing access to health information include but are not limited to making benefit decisions, paying bills and planning for the care you need. The agency will punish employees who do not protect the privacy of health information that identifies you, according to law and agency policy.

The agency will notify you if your unsecured protected health information is breached, as required by law. The agency is required to notify you even if there is no reason to suspect any misuse of the protected health information. You will be notified by mail or by phone as soon as reasonably possible. It is your duty, or the duty of your legally authorized individual, to promptly tell the agency if you have had a change of address.

Uses and disclosures that might require your written authorization:

Agency uses or disclosures that might require your authorization include but are not limited to the following:

1. Psychotherapy notes. The agency must get your authorization, in some cases, to disclose your psychotherapy notes (certain notes that are taken by your mental health professional during the course of a counseling session) except:

- To carry out treatment, payment, health-care operations, or as required by law,
- For use by the originator of the psychotherapy notes for treatment,
- For use by the agency for its own training programs, or
- For use by the agency to defend itself in a legal action or other proceedings brought by you or your legally authorized representative.

2. Marketing. If applicable, the agency will not use or share your health information without your authorization for marketing communications about a product, such as a drug or medical device, or services that encourage you to buy or use a product or service, except if the communication is in the form of:

- A face-to-face communication made by the agency to you, or
- A promotional gift of little value provided by the agency.

If the marketing involves direct or indirect payment to the agency from a third party, the authorization must state that such payment is involved. The following activities are not considered marketing and don't require your authorization:

- Refill reminders or other communications about a drug or biologic that is currently being prescribed for you, as long as any payment received by the agency in exchange for the communication is reasonably related to the agency's cost of the communication.
- Certain treatment and health-care operation activities, except where the agency gets payment in exchange for making the communication:

3. Sale of Protected Health Information. The agency will not sell your protected health information to any other person in exchange for direct or indirect payment, except:

- To another health care provider, health plan or healthcare clearinghouse for treatment, payment, or health care operations; or
- To perform an insurance or health maintenance organization function authorized by law; or
- As otherwise authorized or required by state or federal law.

“Sell” or a “sale” means disclosures by the agency or its business associate where there is a direct or indirect payment from or on behalf of the third-party that gets the protected health information in exchange for payment.

- 4. Fundraising.** If applicable, the agency must get your written authorization if it shares your protected health information for fundraising purposes, except the agency may use or share the following health information with a business associate or to an institutionally related foundation:
- Demographic information relating to an individual, including name, address, other contact information, age, gender, and date of birth; and
 - Dates of health care provided to an individual;
 - Department of service information;
 - Treating physician;
 - Health outcome information; and
 - Health insurance information.

For example, the agency might participate in fundraising activities, organized by its state mental hospitals' volunteer services councils that are designed to improve the quality of patient care. These volunteer services council fundraising events are strictly voluntary and might include art shows, walks, runs, or bike rides. You must first provide the agency with your written authorization for any instance in which you choose to share your protected health information for such fundraising purposes.

- 5. Genetic information.** The agency will never use genetic information for underwriting purposes.

Uses and disclosures that do not require your written authorization:

- 1. Treatment.** The agency can use or share your health information with other health-care providers involved with your treatment. For example, the agency may provide your information to other providers so you can be seen by a specialist health-care provider for a consult. Or, if you are in a hospital, you may be treated by multiple health-care providers who have your information. By getting your information, health-care service providers will better understand your health history, which could help them provide your health care.
- 2. Payment.** The agency can use or disclose certain health information about you to pay or collect payment for your health care. For example, when your health-care service provider sends a bill to the agency or your health plan, it includes certain information about your condition and treatment. Another example would be when the agency uses or discloses your health information to determine either your eligibility for government benefits in a health plan, or whether the proposed treatment is covered by your insurance.
- 3. Health-care operations.** The agency can use or share health information about you for its health-care operations. The agency's health-care operations include but are not limited to:
- Conducting quality assessment and improvement activities,
 - Reviewing the competence, qualifications, and performance of health-care professionals or health plans,
 - Training health-care professionals and others,
 - Conducting accreditation, certification, licensing, or credentialing activities,
 - Carrying out activities related to the creation, renewal, or replacement of a contract for health insurance or health benefits,
 - Providing, receiving or arranging for medical review, legal services, or auditing functions, and
 - Engaging in business management or the general administrative activities of the agency.

The agency can also share health information about you with the agency's business associates (contractors) or business associate's subcontractors, if the business associate or the subcontractor:

- Needs the information to perform services on behalf of the agency, and
- Agrees to protect the privacy of the information according to agency standards.

Other examples of uses and disclosures for health-care operations by the agency include but are not limited to using or disclosing health information for case management; ensuring the agency's health-care service provider is qualified to treat individuals; or auditing a health-care service provider's bill to ensure the agency has been billed for only care you received. The agency also can contact you to tell you about treatment alternatives or additional benefits you might be interested in.

4. Government Health Benefits. If you apply for or enroll in government health benefits provided by the agency, such as Medicaid benefits, the agency can use or share health information about you in order to:

- Establish your eligibility for health benefits;
- Determine the amount of Medical Assistance to be provided to you;
- Provide health services to you; and
- Conduct or assist with an investigation, prosecution, or civil or criminal proceeding related to your health benefits.

5. Family members, other relatives, guardians, legally authorized representatives (LAR) or close personal friends. The agency can share your health information, with your agreement, or in an emergency if you are incapable of agreeing, or as otherwise authorized by law, with a family member, other relative, guardian, legal authorized representative, or close personal friend:

- When directly relevant to such person's involvement with your health care or payment related to your health care; or
- To notify the person of your location, general condition, or death.

Your "family" or "relative" means:

- (1) Your dependent, or
- (2) Any other person who is your first-degree, second-degree, third-degree, or fourth-degree relative, such as your:
 - Parents, spouses, siblings, and children.
 - Grandparents, grandchildren, aunts, uncles, nephews, and nieces.
 - Great-grandparents, great-grandchildren, great aunts, great uncles, and first cousins.
 - Great-great grandparents, great-great grandchildren, and children of first cousins.

The agency can make reasonable inferences of your best interest in allowing a person to act on your behalf such as to pick up prescriptions, medical supplies, X-rays, or other similar forms of protected health information, unless disclosure of the information is prohibited by law, such as substance use disorder information.

6. Substance Use Disorder Program Information. The agency is prohibited by law from sharing substance use disorder information about you or information that identifies you as seeking or getting substance use disorder treatment from a substance use disorder provider, program or facility to anyone, including family members, relatives, or friends without your written permission, unless permitted by law, for example in a medical emergency.

7. Mental Health Information. The agency will not share information about your mental health (information about your identity, diagnosis, evaluation, or treatment that are created or maintained by a professional for diagnosis, evaluation, or treatment of any mental or emotional condition or disorder, including alcoholism or drug addiction), unless expressly authorized by law.

8. "Required by law" uses or disclosures of PHI. The agency may use or disclose your 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, for example:

- A. To Government programs providing public benefits.** When administering a program providing public benefits, the agency may disclose protected health information relating to the program to another HIPAA-covered entity that is a government agency administering a government program providing public benefits if:
- The programs serve the same or similar types of people, and
 - The disclosure of protected health information is necessary to coordinate or improve how the programs are run.
- B. For Health oversight activities.** The agency might use or share health information about you to a health oversight agency for health oversight activities authorized by law. A health oversight agency must be a government agency or someone acting on behalf of a government agency.
- C. For Public health activities.** The agency can share health information about you as required by law for public health purposes, such as to:
- A public health authority for purposes of preventing or controlling disease, injury, or disability.
 - An official of a foreign government agency who is acting with the public health authority, and
 - A government agency allowed to get reports of child abuse or neglect.
- D. Victims of abuse, neglect or domestic violence.** The agency may disclose protected health information about you if the agency reasonably believes you to be a victim of abuse, neglect, or domestic violence to a government authority, including a social service or protective services agency authorized by law to receive reports of such abuse, neglect, or domestic violence, to the extent the disclosure is required by law and the disclosure complies with and is limited to what the law allows if:
- You agree to the disclosure;
 - A law authorizes disclosure; and
 - The agency, in the exercise of professional judgment, believes the disclosure is necessary to prevent serious harm to your or others, or
 - If you are unable to agree because you are incapacitated, a law enforcement or other public official authorized to receive the report represents that the protected health information for which disclosure is sought is not intended to be used against you and is needed for immediate action.

If the agency makes a report under this section, the agency will tell you or your legally authorized representative about the report unless:

- The agency in good faith believes that telling you would place you at risk of harm; or
 - The agency reasonably believes your legally authorized representative may be responsible for the abuse and telling that person would not be in your best interests.
- E. Serious threat to health or safety.** The agency can use or share health information about you if it believes the use or disclosure is needed:
- To prevent or lessen a serious and immediate threat to the health and safety of a person or the public and the disclosure is made to a person reasonably able to lessen or prevent such a threat;
 - For law enforcement authorities to identify or catch an individual who has admitted participating in a violent crime that resulted in serious physical harm to the victim, unless the information was learned while initiating or in the course of counseling or therapy; or
 - For law enforcement authorities to catch an individual who has escaped from lawful custody.
- F. For other law enforcement purposes.** The agency can share health information about you to a law enforcement official for the following law enforcement purposes:
- To comply with certain legal reporting requirements;

- To comply with a grand jury subpoena;
- To comply with an administrative request, such as a civil investigative demand that is specific and limited in scope, if the information is relevant to a legitimate law enforcement inquiry and de-identified information cannot reasonably be used;
- To identify and locate a suspect, fugitive, witness, or missing person, as long as the information provided to law enforcement is specifically authorized by law;
- In response to a request for information about an actual or suspected crime victim, if either:
 - The individual agrees to the disclosure; or
 - The requesting law enforcement official represents that the information is not intended to be used against the victim, is needed to determine whether a violation of law has occurred, and the agency determines that disclosure is in the best interests of the individual;
- To alert a law enforcement official of a death that the agency suspects is the result of criminal conduct; or
- To report evidence of a crime on the agency's property.

G. For judicial or administrative proceedings. The agency may share your health information in the course of any judicial or administrative proceeding with:

- A court order to share your health information from a regular or administrative court;
- A subpoena or request by a party to a lawsuit that the agency is also a party to, except a court order is required to disclose substance use disorder information, and the agency may ask the court for a protective court order.
- In some situations, you or your legally authorized representative will be notified of the request for your health information in the proceeding.

H. To the Secretary of U.S. Department of Health and Human Services. The agency must share health information about you to the Secretary of U.S. Department of Health and Human Services for legal compliance purposes.

I. Research. The agency can use or share health information about you for research:

- If certain information about you is removed so that it is de-identified,
- If you authorize the research,
- If the research is approved by an Institutional Review Board or Privacy Board, or
- As otherwise authorized by law

Your health information also can be used:

- To allow a researcher to prepare a research protocol, as long as the researcher
 - demonstrates that this information is necessary for the research
 - does not remove the information from the agency, or
 - agrees to keep the information confidential, or
- To allow a researcher to obtain information about people who have died, as long as the researcher
 - represents that the information is necessary for research that involves information about people who have died, and
 - provides, when requested, evidence of the death of the person whose information is sought

J. Correctional institutions and other law enforcement custodial situations. The agency may disclose an individual's health information to a correctional institution or law enforcement official that has lawful custody of that individual, as long as the institution or official tells the agency that the information is necessary:

- To provide that individual with health care;
- To protect the health or safety of that individual or others related to the activities of the correctional institution; or
- As otherwise required by law.

K. Other uses and disclosures. The agency can otherwise use or share health information about you:

- To create information that is de-identified and doesn't identify you.
- For military or veteran activities as required by law.
- For purposes of lawful national security activities.
- To federal officials to protect the president of the United States and others.
- To comply with workers' compensation laws or similar laws.
- To tell coroners or funeral directors about your death as required by law.
- As otherwise required or permitted by local, state or federal law.

Complaints and questions about the use or disclosure of your information:

If you believe your privacy rights have been violated, contact the agency. You may contact the agency if you: (1) have questions about this notice, (2) need more information about your privacy rights, (3) need a physical address for the agency, or (4) are requesting a copy of health information from the agency:

- **Texas Department of State Health Services (DSHS):** Call 1-512-776-7111 or 1-888-963-7111 (toll free) or email hipaa.privacy@dshs.state.tx.us.
- To request your results of lab tests performed by the DSHS Laboratory, please call (512) 776-7318 or visit <http://www.dshs.state.tx.us/lab/patientresults.aspx>.
- If you are receiving care from a DSHS state-operated hospital, contact the hospital's privacy office, or
- 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).

If you believe the agency has violated your privacy rights, you also can file a complaint with the:

Secretary
Office of Civil Rights
Region VI
U.S. Department of Health and Human Services
1301 Young St., Suite 1169
Dallas, Texas, 75202
Voice Phone (800) 368-1019
FAX (214) 767-0432
TDD (800) 537-7697

For complaints about a 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.

The agency prohibits retaliation against you for filing a complaint.

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Texas Department of State Health Services
Perinatal Hepatitis B Prevention Program
Immunization Branch
MC-1946
P.O. Box 149347
Austin, TX 78714-9347

Tel (800) 252-9152
Fax (512) 776-7544

www.TexasPerinatalHepB.org