

California Department of Public Health  
Perinatal Hepatitis B Prevention Program



COORDINATOR HANDBOOK

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## Perinatal Hepatitis B Prevention

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# INTRODUCTION

Hepatitis B is a serious liver disease caused by the hepatitis B virus (HBV) that occurs worldwide among people of all ages. It is highly infectious and can result in severe illness, liver damage, cirrhosis and increased risk for hepatocellular carcinoma. The disease can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness. Although many people recover and develop natural immunity to HBV after acute (initial) infection, others including infants infected at birth become chronic (lifelong) carriers. Chronic hepatitis B can lead to liver failure or liver cancer later in life. Worldwide it is estimated there are 350 million people with chronic HBV infection and about 620, 000 people die each year from hepatitis B associated acute and chronic liver disease.<sup>1</sup>

HBV can be spread through contact with blood and certain body fluids of people infected with HBV, such as blood products, semen, vaginal secretions, and saliva. Also, transmission of HBV can occur when the virus is passed from an infected mother to her infant during birth (perinatally). Perinatal hepatitis B virus transmission is a serious public health problem because approximately 70-95% of infants who are born to infected mothers become chronically infected if they don't receive prophylaxis.<sup>2</sup>

Fortunately, it is possible to prevent perinatal HBV infection. Once it is determined that a pregnant woman is infected with HBV, her exposed infant must receive immunoprophylaxis consisting of hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine within 12-24 hours after birth. When followed by completion of a three dose vaccine series it has been demonstrated that hepatitis b is prevented in 85-95% of infants of infected mothers.<sup>3</sup>

In 1989, infection with hepatitis B became a reportable condition under Title 17 of the California Code of Regulations (Appendix B).<sup>4</sup> Additionally, the California Health and Safety Code prenatal hepatitis B screening law became effective in 1991 and requires that all pregnant women be serologically screened for HBsAg (Appendix A).<sup>5</sup> This law, supported by the American College of Obstetricians and Gynecologists (ACOG) and the

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<sup>1</sup> Centers for Disease Control and Prevention, [National Center for HIV/AIDS, Viral Hepatitis, STD, and TB, Prevention Division of Viral Hepatitis](#).

<sup>2</sup> Wong, VC, Ip HM, Reesink HW, et al. Prevention of the HBsAg carrier state in newborn infants of mothers who are chronic carriers of HBsAg and HBeAg by administration of hepatitis-B vaccine and hepatitis-B immunoglobulin: double-blind randomized placebo-controlled study. *Lancet* 1984;1(8383):921-6.

<sup>3</sup> Centers for Disease Control and Prevention. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP); Part 1: Immunization of Infants, Children and Adolescents. *MMWR* 2005;54 (No. RR-16).

[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s\\_cid=rr5416a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s_cid=rr5416a1_e)

<sup>4</sup> California Code of Regulations (CCR), Title 17, § 2500, § 2593, §2641-2643, and §2800-2812.

<sup>5</sup> California Health and Safety (H&S) Code § 125050-125119.5.

American Academy of Pediatrics (AAP), was designed to identify pregnant women who are infected with hepatitis B.

A comprehensive strategy to eliminate hepatitis B virus transmission was first recommended by the Advisory Committee on Immunization Practices (ACIP) in 1991 and updated in 2005.<sup>6</sup> In California, an essential part of implementing this strategy was the establishment of the California Perinatal Hepatitis B Prevention Program (CA PHPP) by the California Department of Public Health (CDPH) in 1991. Currently, CA PHPP operates in 24 local health department (LHD) jurisdictions.

## **California Perinatal Hepatitis B Prevention Program**

Together with the screening and reporting laws and the recommendation for routine hepatitis B vaccination for all infants, the Perinatal Hepatitis B Prevention Program is designed to reduce the perinatal transmission of HBV to infants and prevent transmission of HBV to high risk household contacts.

The goals of the CA PHPP include:

- 1) Prenatal testing of pregnant women for HBsAg to identify infected mothers;
- 2) Appropriate immunoprophylaxis for infants born to these mothers and post vaccination serologic testing;
- 3) Outreach and education for infected women and their contacts, birth hospitals, prenatal care providers and pediatricians; and
- 4) Referrals for serologic tests and immunizations for susceptible household contacts.

In order to identify hepatitis B infected pregnant women and ensure that their infants and household contacts are appropriately immunized, a multi-system approach is employed. The Perinatal Hepatitis B Coordinator works together with clinical laboratories, private physicians, other health professionals and birth hospitals to ensure timely reporting of HBsAg-positive test results to facilitate follow-up for infected women and their families.

Once a case is identified and enrolled in the program, the Perinatal Hepatitis B Coordinator works together with parents, private providers and birth hospitals to ensure that all infants born to HBsAg-positive mothers receive timely immunoprophylaxis, appropriate immunizations and post vaccination serology testing to confirm immunity. The Perinatal Hepatitis B Coordinator also ensures that household contacts are being referred for serological screening and immunizations if they are susceptible to the disease. Outreach and culturally appropriate health education materials are used to reinforce the importance of preventing perinatal hepatitis B transmission.

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<sup>6</sup> Ibid

Perinatal Hepatitis B Coordinator submits a “Confidential HBsAg+ Case/Household Management Report (CDPH 8546)” or an electronic file equivalent to the State program (Appendix D). The State Perinatal Hepatitis B Prevention Program maintains and regularly updates a confidential database of HBsAg-infected mothers and their infants. Program analyses and reports are routinely generated to provide feedback to the individual local programs and CDC.

Approximately 3,000 pregnant women infected with hepatitis B are identified and enrolled in the CA PHPP each year. More detailed information on the demographics of these enrolled women, case management outcomes and number of women and infants enrolled by county are available on the CDPH Immunization Branch website at:

<http://www.cdph.ca.gov/programs/immunize/Pages/VaccinePreventableDisease.aspx>

The following materials are intended to be used by local perinatal hepatitis B prevention coordinators and other health department staff who provide follow up for HBV-infected pregnant women and their infants. The guidance provided in this manual is based on current recommendations of the CDC and the ACIP.

# CASE FINDING

## SCREENING

Perinatal hepatitis B prevention starts with screening all women for HBsAg during pregnancy. California Health and Safety Code<sup>7</sup> (§125080 and §125085) states:

“As early as possible during prenatal care the person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery shall obtain a blood specimen and submit it to a licensed or approved laboratory to determine the presence of hepatitis B surface antigen.”

California law does not require a prenatal care provider to retest a pregnant woman if the woman’s status is known to be positive, but her HBsAg status must be documented in her prenatal medical record (H&S Code §125090 (d)). The ACIP recommends that prenatal providers screen **all** women with **each** pregnancy, even if the provider knows she has been vaccinated or if she was previously identified as HBsAg positive. Testing with each pregnancy ensures that the LHD receives a laboratory report for an HBV-infected woman with each pregnancy.

If a woman’s HBsAg status is unknown at the time of labor and delivery, the provider attending the woman is legally required to order an HBsAg test “by a method that will ensure earliest possible results” (H & S Code § 125090 (d)). The ACIP guidelines also recommend that providers repeat the HBsAg test at the time of labor if the woman was at high-risk for acquiring hepatitis B infection in the last six months of the pregnancy (more than 1 sex partner, an HBsAg-positive sex partner, injection drug use, or recent evaluation or treatment for an STD).

## REPORTING CASES TO THE LHD.

The LHD may receive reports of HBV-infected pregnant women from laboratories, prenatal care providers, and birth hospitals. Coordinators should establish relationships with all of their reporting sources to ensure that they receive reports for ALL pregnant women who are infected with hepatitis B. The coordinator can facilitate reporting by hospitals and providers by providing them with reporting forms. (see Appendix D)

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<sup>7</sup> California Health and Safety (H&S) Code § 125050-125119.5.

Laboratories are required to report both acute and chronic hepatitis B cases within one working day to the health department where the ordering physician is located (Title 17 CCR § 2505)<sup>8</sup>. California H&S Code (§125085 (B), 125090) requires laboratories to report positive HBsAg results to the local health officer. Health care providers are required to report HBsAg positive pregnant women to the LHD where the case resides (Title 17, CCR § 2500 (b)).

### **Reviewing Laboratory Reports**

Most cases of HBsAg-positive pregnant women will be reported to the LHD by laboratories. Health department staff must review reports of HBV-infected individuals to identify women who are of childbearing age (i.e., 14 to 45 yrs.) and then contact the physician's office to determine if any of these women are pregnant. The health department may be able to obtain information from the provider's office more readily by sending a fax request for information (see Appendix B). The health department can also streamline the process of identifying which infected women are pregnant by prioritizing lab tests ordered by prenatal care providers. Coordinators should become familiar with the names of local medical providers who deliver infants, including those in family practice.

### **Birth Hospitals**

Since some pregnant women do not receive prenatal care before delivery, it is essential to work with birth hospitals to ensure that they test all pregnant women who have an unknown or undocumented HBsAg status. Hospital labs should report HBsAg positive results to the LHD. The birth hospital should notify the health department and the pediatric care provider of all infected women/exposed infants to ensure follow-up if a woman leaves the hospital before HBsAg results are known.

## **IMPROVING CASE IDENTIFICATION**

Despite screening and reporting laws and regulations, some HBV-infected women are not identified and some births to HBV-infected women are not reported to the health department. Perinatal hepatitis B prevention programs and LHDs can use the following mechanisms to improve case identification:

- Maintain a list of all laboratories that perform prenatal HBsAg testing (including birth hospital laboratories) and confirm that positive HBsAg test results are being reported to the health department.
- Periodically remind prenatal care providers and delivery hospitals to report all HBsAg-positive women to the health department. Provide them with a reporting form they can fax to the health department.

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<sup>8</sup> California Code of Regulations (CCR), Title 17, § 2500, § 2593, §2641-2643, and §2800-2812

- Establish clear health department protocols to review HBsAg-positive test results to identify women of childbearing age and to determine their pregnancy status.
- Work with birth hospitals to ensure that all pregnant or delivering women have been tested for HBsAg before hospital discharge.
- Work with birth hospitals to get them to report results for all women they test.

### **REPORTING CASES TO CDPH**

See the section “Reporting to CDPH”, for information on reporting HBV-infected pregnant women, their contacts, and their infants to the CDPH. All persons infected with hepatitis B, including infected pregnant women and infected infants, should be reported to CDPH using the AVSS system in addition to being reported to the Perinatal Hepatitis B Prevention Program.

### **HIPAA**

Public health authorities are legally authorized to collect protected health information for purposes of disease prevention and control. Under 45 CFR 164.512(b) (1) (i) of the HIPAA Privacy Rule<sup>9</sup>, providers, hospitals, and laboratories are permitted to report HBsAg positive women and disclose patient information for perinatal case management to state and LHDs without the authorization of the individual. HIPAA also permits local and state health department staff to review patient records for quality assurance purposes. (see Appendix B)

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<sup>9</sup> Health Insurance Portability and Accountability Act of 1996 (HIPAA), HIPAA Privacy Rule of 1999, 45 CFR §164.501-512

# CASE MANAGEMENT

Case management of HBsAg positive mothers and their infants is one of the core functions of a perinatal hepatitis B prevention program. This section outlines key steps for each phase of the process.

## CASE INITIATION

When an HBsAg-positive woman is identified during her pregnancy, LHD staff should do the following:

- **Contact the prenatal care provider** by phone or by fax (Appendix E) to obtain additional information. Confirm the woman's positive HBsAg status and request a copy of the HBsAg lab report. Inform the provider about the case management services the LHD will provide. Ask the doctor to place an alert in the patient's prenatal record so that the birth hospital is aware of her hepatitis B status.

*Obtain the following information:*

- ✓ Expected date of delivery,
  - ✓ Expected delivery hospital,
  - ✓ Contact information for the patient
  - ✓ Language spoken
  - ✓ Whether the patient is aware of her hepatitis B status
  - ✓ Risk factors for noncompliance or becoming lost to follow-up.
- **Contact the pregnant woman** to provide information about the Perinatal Hepatitis B Prevention Program. Begin providing education about hepatitis B and ask for information about close contacts.

*Provide the following information:*

- ✓ The importance of immunoprophylaxis for her infant
  - ✓ Ways to prevent hepatitis B transmission
  - ✓ Breastfeeding is safe
  - ✓ The need for evaluation and medical management for herself
  - ✓ The need for sexual, needle-sharing and household contacts to be screened and vaccinated if susceptible
  - ✓ Resources for free or low-cost services for uninsured contacts
- **Complete and submit the CA PHPP Confidential HBsAg Case/Household Report**

## PRIORITIZING CASES

Some women may require frequent reminders and repetition of information in order to get their infants vaccinated on schedule and to complete post-vaccination serologic testing. Other cases can be managed primarily by the medical care providers and will require minimal health department intervention.

A woman who was followed by the health department with a previous pregnancy may require case management with a subsequent pregnancy if she is at risk for poor follow through. Factors associated with under-immunization include poverty, minority status, immigration from a region where HBV infection is endemic, lack of prenatal care, family instability, or residence in a medically underserved area.

### **MANAGING CONTACTS**

All unvaccinated sexual, needle-sharing, and household contacts of persons with hepatitis B are at high risk of acquiring the disease. Investigation should be performed to identify these contacts and to provide information about recommended testing and appropriate follow-up. If the date of exposure is unknown, identify persons having contact during the prior six months.

Prevaccination testing should be done to determine susceptibility to hepatitis B infection. The first vaccine dose should generally be administered immediately after blood is collected for screening.

The Advisory Committee for Immunization Practices (ACIP) recommends determining susceptibility of unvaccinated close contacts by testing for core antibodies to hepatitis B (anti-HBc). If the result is positive, the same specimen can be used to test for HBsAg.

Persons who were vaccinated in other countries should be considered fully vaccinated if they have written documentation of  $\geq 3$  doses of vaccine administered at minimum intervals, including the third dose at  $\geq 24$  weeks after the first dose. However, persons born in Asia, the Pacific Islands, Africa, and other regions with high endemicity of HBV infection (prevalence  $\geq 8\%$ ) should be tested for HBsAg status, regardless of vaccination history. Persons who are susceptible should complete the age-appropriate vaccine series. Persons who are not fully vaccinated should complete the vaccine series.

Post-vaccination testing for serologic response is recommended for sexual partners of HBsAg positive persons and for contacts who are immunocompromised (*MMWR*, 54 (RR16), and should be completed 1-2 months after administration of the 3<sup>rd</sup> dose of vaccine. Persons found to have anti-HBs concentrations of  $<10$  mIU/mL should be revaccinated. Persons who do not respond to a second vaccine series should be tested for HBsAg.

*Additional measures to be taken:*

- ✓ Contacts should be given information regarding hepatitis B control measures (see Appendix C).
- ✓ Provide information on free or low fee services for serologic testing and hepatitis B vaccination to contacts who do not have access to health care.

- ✓ Contacts found to be infected with hepatitis B should be referred to a medical provider for disease management and should be reported to CDPH.
- ✓ Household, sexual, and needle-sharing contacts should be entered into a tracking system and should be followed by LHDs until completion of the hepatitis B vaccine series (see Perinatal Hepatitis B Household Contact Follow-up Form, Appendix D).
- ✓ Asymptomatic contacts should be instructed to immediately report any symptoms of hepatitis to their LHD and to seek care from a medical doctor.
- ✓ Symptomatic contacts should be considered cases and managed with the appropriate follow-up by a medical doctor.

### **ENSURE INFANT POST-EXPOSURE PROPHYLAXIS (PEP) AT TIME OF DELIVERY**

- Contact the hospital where delivery is planned. Inform the hospital of the infected woman's estimated date of delivery, her contact information, the provider's name and contact information, and the woman's HBsAg status. Fax a copy of the lab report to the hospital. Ask the hospital to report the delivery and the administration of hepatitis B vaccine and HBIG to the LHD (see Appendix E).
- Contact the mother to remind her of the importance of postexposure immunoprophylaxis for the infant at birth.
- Contact the pediatric care provider, if known, and ensure that she or he is aware of the guidelines for postexposure immunoprophylaxis and follow-up testing for the infant.
- Shortly after the estimated date of delivery, contact the hospital to obtain the date of delivery and information on the administration of HBIG and hepatitis B vaccine if the hospital has not already reported this information.
- If a woman is not identified as HBsAg positive until after delivery, the LHD should contact her as soon as possible to provide education about hepatitis B, about immunoprophylaxis for her infant, and to initiate contact follow up.

### **Failure to Provide Postexposure Prophylaxis**

Birth hospitals are responsible for administering hepatitis B postexposure immunoprophylaxis (PEP) to all infants born to mothers who are infected with hepatitis B. The failure of a hospital to provide PEP is reportable to the Joint Commission as a **sentinel event**. The Joint Commission defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof." Failure to provide PEP increases the infant's risk of acquiring hepatitis B infection which can lead to fulminant or chronic hepatitis, and

early death. A sentinel event may be reported by the hospital, the infant's physician, the health department, a parent, or the media, and must be reported within 12 months of the infant's birth.

If the coordinator learns of such an occurrence, he or she should contact the State Perinatal Hepatitis B Program coordinator immediately. The hospital nurse manager and infection control practitioner should be involved in investigating what occurred. The medical records of the mother and infant should be reviewed as well as the hospital's policies and standing orders related to prophylaxis of infants whose mothers are infected with hepatitis B so that corrective action can be taken to ensure that such an occurrence does not recur.

### **Parental Refusal of Post-exposure Prophylaxis**

Per California law, parents may refuse vaccination for school admission for a variety of reasons, including religious or philosophical reasons. Parents of an infant whose mother is hepatitis B-infected should be informed of the importance of PEP as a medical treatment to prevent hepatitis B infection and its consequences. If parents refuse PEP for their infant after receiving this information, parents should be informed that refusal of PEP may be considered medical neglect and will be reported to Child Protective Services under CA Welfare and Institutions Code, Section 300(b) and California Penal Code, Section 11165.2. If the infant is still hospitalized, the hospital or pediatrician should report the situation to Child Protective Services (CPS) and may be able to obtain an emergency court order to administer PEP. If the infant has been discharged, the pediatrician or coordinator may make a report to CPS.

The coordinator should provide birth hospitals with information on California laws pertaining to these situations and encourage them to develop a response plan. In addition, coordinators may need to work with county CPS departments to educate them about hepatitis B and the risk to infants who do not receive PEP. Coordinators who become aware of PEP refusals should report them immediately to the State Perinatal Hepatitis B Program coordinator.

### **COMPLETING THE VACCINE SERIES AND POST-VACCINATION TESTING**

The next phase of case management involves ensuring that the infant completes the hepatitis B vaccine series and post-vaccination serologic (PVS) testing within the recommended timeframes (see Appendix F).

- The coordinator should verify the date of administration of all doses of hepatitis B vaccine with the pediatric provider or the California Immunization Registry, [www.ca-sjis.org](http://www.ca-sjis.org). See "Hepatitis B Vaccination and Prophylaxis" for information on vaccine formulations, schedules, and dosing.
- The coordinator should provide reminders to the medical provider and parent/guardian as needed when an infant is due for hepatitis B vaccine and post-vaccination serologic testing. A reminder and recall system is important for all infants, but especially for those with risk factors associated with

under-immunization. Reminder and recall approaches work best if parents are notified before vaccination visits are due (reminder) and immediately after scheduled visits are missed (recall).

PVS testing should not be performed before 9 months of age to avoid detecting antibodies to HBsAg from HBIG. Testing too early may also miss the late appearance of HBsAg in an infected infant. If the infant is at least 9 months of age, the PVS test should be done approximately 1-2 months after the 3<sup>rd</sup> or final dose of vaccine. Anti-HBs levels decline rapidly in the first year after vaccination and may be undetectable by 5 years. Despite declines in detectable antibodies, most individuals who initially responded to a vaccine series remain protected against HBV infection.

Anti-HBs and HBsAg test results of infants should be verified with the pediatric provider. Necessary follow-up for the infant will depend on results.

- HBsAg negative infants with anti-HBs levels of  $\geq 10$  mIU/mL are protected and need no further medical management.
- HBsAg negative infants with anti-HBs levels of  $< 10$  mIU/mL should be revaccinated with a second 3-dose series using a 0, 1, and 6 month schedule and retested 1–2 months after the final dose. Alternatively, 1 to 3 additional doses of vaccine can be administered, followed by testing for anti-HBs 1 month after each dose to determine if subsequent doses are needed.
- Infants who are HBsAg positive should be reported to CDPH PHPP and referred for medical evaluation and management of chronic hepatitis B. Reporting forms for perinatal hepatitis B cases are found at :  
<http://www.cdph.ca.gov/pubsforms/forms/Pages/CD-Report-Forms.aspx>

If an infant is diagnosed with hepatitis B, contact the mother's primary care provider and request her HBeAg status. Report the mother's HBeAg status to the CA PHPP.

Infants who are susceptible after an initial vaccine series usually develop immunity after completing a second vaccine series. If the infant remains susceptible after a second vaccine series, he or she is unlikely to respond to additional doses of vaccine. The family should be counseled on precautions to prevent HBV infection and on medical follow up for the infant.

## **DATA TRACKING AND MANAGEMENT**

Successful case management requires effective data tracking and management. An effective system is one that allows the LHD to both manage cases and evaluate success of the program. If possible, health departments should integrate their case management data system with an immunization information system or disease reporting system.

A data management system should be able to index files according to the last name of either the mother or the infant. The following functions can simplify case management:

- ❖ Patient and provider reminder and recall
- ❖ Ability to generate letters
- ❖ Ability to run reports
- ❖ Ability to summarize data at the program level
- ❖ Case manager reminders (tickler file)

To optimize case management and enhance program evaluation, consider entering the following data elements in your data management system:

Mother

- ✓ Name
- ✓ Contact information
- ✓ Emergency contact
- ✓ Insurance status
- ✓ OB/GYN contact information
- ✓ GI/Liver disease specialist contact information
- ✓ Date of first appointment with liver disease specialist
- ✓ Date of birth
- ✓ Race/ethnicity
- ✓ Primary language spoken
- ✓ Country of birth
- ✓ Estimated due date
- ✓ Number of previous deliveries
- ✓ Prenatal care provider contact information
- ✓ HBV testing results (HBsAg, HBeAg, HBV DNA level) and dates specimens were obtained

Infant

- ✓ Name
- ✓ Date/time of birth
- ✓ Birth weight
- ✓ Gestational age
- ✓ Birth hospital
- ✓ Pediatrician contact information
- ✓ HBIG administration (date, time)
- ✓ 1<sup>st</sup> dose of hepatitis B vaccine (date, time)
- ✓ Dates of subsequent doses of hepatitis B vaccine
- ✓ Post-vaccination serologic testing results (HBsAg, anti-HBs level) and date specimen obtained
- ✓ Reason(s) for loss to follow-up (if applicable)

Sex partners, household contacts, and needle-sharing contacts of mother

- ✓ Pre-vaccination testing results (susceptible/not susceptible) and date specimen obtained
- ✓ Hepatitis B vaccine doses

## **Tracking**

For a tracking system to be effective, it should be organized in a way that makes it easy to remind the case manager when an immunization or laboratory test is due. The following are a few examples of case tracking systems.

### **1) Case-File System**

The case-file system for tracking the case/infant/contacts involves creating a file or card for each case which contains information about the index case, each contact, and the infant. Periodic review is required in order to generate reminder letters. The advantage to this system is that all information relating to the case is in one file. The disadvantage is that you must be sure to completely review each case every one to two weeks to ensure that all patients requiring intervention will be notified of the appropriate follow-up.

### **2) Tickler System**

The tickler system involves creating a card for each patient and filing the card according to the month and/or week the next intervention is due. Before the appropriate date, the patient's chart is pulled for follow-up. After each activity is completed, the card is refilled according to the next intervention date. When the patient has completed all appropriate follow-up, the card is "closed" and filed. The index case (HBsAg-positive mother) of the contacts should be documented on each contact's tickler card.

The disadvantage of the tickler system is that it is labor intensive. It takes time to write each card and it is easy to misfile cards. Cards must be carefully filed and organized.

### **3) Computer Tracking**

The computer is an easy tool with which to organize and link case information. A computer program should be able to index files according to the last name of either the mother or the baby. It should also be able to identify those patients who are overdue for their next intervention.

Many programs have software that generates reminder letters to mail to the patient, generate recall letters for those patients who are overdue, summarize data at the project level, and generate the reports. The usefulness of these programs varies according to county needs. Birth registries may be a useful source of computer tracking if they are available.

Tracking programs should generate a reminder letter two weeks before the next immunization or test is due. If the patient does not come in for treatment two weeks after the activity is due, another letter should be mailed. These letters may be mailed directly to the patient or to the health care provider. If the patient prefers to receive follow-up at their local health care provider, the LHD should continue to notify the provider and patient when the immunization or test is due.

### **Cases Lost to Follow-up**

Despite a good tracking system, some cases will be lost to follow-up. Completion rates decrease with each dose of missed vaccine. Families often move and lose contact with their health care provider. To find patients, coordinators may use the following sources:

- Updated demographic information on an infant might be available from an immunization information system.
- The individual health care provider and other larger health care providers in the county may have a current address.
- The post office may have a forwarding address. A justification form provided by the Postal Service must be completed and a department of health ID will probably be required.
- The social services department of the LHD may have up to date locating information for patients.
- Parole and probation offices may be contacted if the person is in the prison system.
- Whitepages.com or peoplesearch.com
- Your STD colleagues may have access to driver's license information or other methods of locating people

# REPORTING TO CDPH

## **Case Definition**

A case in the California Perinatal Hepatitis B Prevention Program is defined as an HBsAg-positive woman who is either pregnant or has just recently delivered an infant. When a LHD is notified of an HBsAg-positive woman, the health department should confirm that the case has been reported on a Confidential Morbidity Report (CMR) form. The CMR should read “HBsAg-positive Prenatal Screen.” Pregnant women who are HBsAg-positive typically meet the CDC case definition for chronic HBV infection. The CDC case definitions for hepatitis B are listed below.

### Chronic HBV Infection

Confirmed: a case that meets laboratory criteria for diagnosis of either

- 1) IgM antibodies to hepatitis B core antigen (anti-HBc) negative AND a positive result on one of the following tests: HBsAg, HBeAg or HBV DNA

OR

- 2) HBsAg positive or HBV DNA positive two times at least 6 months apart

Probable: a case with a single HBsAg positive or HBeAg positive lab result when no IgM anti-HBc results are available

### Acute HBV Infection

Confirmed: a case that meets the clinical case definition of acute illness with

- 1) Discrete onset of symptoms

AND

- 2) Jaundice or elevated serum aminotransferase levels

AND meets the laboratory confirmation for diagnosis of either

- 1) Immunoglobulin M (IgM) antibody to hepatitis B core antigen (anti-HBc) positive

OR

- 2) HBsAg positive IgM anti-HAV negative (if done)

### Perinatal HBV Infection

HBsAg positivity in any infant aged >1-24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother

## **Household Definition**

A household is defined as all persons residing at the primary residence of the HBsAg-positive woman for whom a case is opened, but may also include close or sexual contacts outside of this residence. The primary residence is that address where the woman spends the majority of her time. If a woman lives at or maintains two separate addresses, the LHD should follow individuals from both addresses. Data on all household and close contacts followed, regardless of their residence, should be included on the case/household management form.

## **Confidential Case/Household Management Report**

The Case/Household management report form is located in Appendix D. A fill-in electronic version is also available from the Division of Communicable Disease Control Forms website <http://www.cdph.ca.gov/pubsforms/forms/Pages/CD-Report-Forms.aspx> and upon request from the CA PHPP.

- **Page 1 (Data on the Mother):** This section includes descriptive questions regarding the mother's health status, race/ethnicity, source of payment for medical services, etc.
- **Page 2 (Data on the Infant):** This section includes questions pertaining primarily to the infant's hepatitis B immunization record.
- **Page 3 (Data on Household Contacts):** This section includes questions pertaining to the screening and immunization of household contacts.
- **Page 4 (Worksheet):** This page is provided for LHDs' use in following up with the case and household contacts. It is not necessary to submit the worksheet to the state.

### Confidentiality

Documentation and reporting of HBsAg-positive status is required under Section 2500 of the California Code of Regulations (California Health and Safety Code; see Appendix B). The reporting of all other information and data in the case/household management report form is voluntary. However, the CA PHPP requests this information for the purposes of monitoring perinatal hepatitis B prevention and to further document and describe the extent of the HBV burden in the state. Information provided may be transferred between LHDs for the purposes of case/household follow-up. The records maintained for this program are confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purposes of improving program effectiveness and to prevent further spread of hepatitis B. Any information published from these reports shall be restricted to statistical compilations relating to risk profiles, immunization histories or other epidemiologic data on hepatitis B which do not identify individual cases by name. Case/household management reports will be maintained in locked file cabinets. Access to computerized data files is restricted to only those individuals who have authorization from the State Perinatal Hepatitis B Prevention Program.

### **When to Report**

A photocopy (or electronic copy) of the case/household management report should be submitted to the State Perinatal Hepatitis B Prevention Program for each case/household on two separate occasions:

- (1) When the case is "opened" with the mother's information; and
- (2) When the case is "closed" with the infant and household contact information.

### Opening a Case

- A newly opened case should be submitted to the State Perinatal Hepatitis B Prevention Program as soon as possible (i.e., after a case/household identification number has been assigned to a confirmed case and the information on the "MOTHER" form has been completed).

- Send a copy of Page 1 (MOTHER) only of the case/household management report to:

Perinatal Hepatitis B Prevention Program  
California Department of Public Health  
Immunization Branch  
Building P, 2nd Floor  
850 Marina Bay Parkway  
Richmond, CA 94804

OR

Fax: (510) 620-3949  
Attention: Perinatal Hepatitis B Prevention Program

#### Closing a Case

- A case is closed after every effort has been made to follow up with an HBsAg-positive woman, her infant(s), and her household contacts. Examples of various scenarios in which a case might be closed are described below:
  - a) The infant has received HBIG, all three to four hepatitis B vaccine doses and post vaccination serologic testing and has been found to be immune. Every household contact has been screened and referred for appropriate follow-up.
  - b) The infant has received HBIG, all three hepatitis B vaccine doses and post vaccination serologic testing and has been found to be immune. Every effort has been made to screen the household contacts, but they have been lost to follow-up.
  - c) A case/household management report has been initiated for a pregnant woman known to be positive for HBsAg, but her pregnancy results in a miscarriage. Her household contacts have been screened and referred for appropriate follow-up.
  - d) A case/household management report has been initiated for a pregnant woman known to be positive for HBsAg, but she has moved and is lost to follow-up.
- If a county chooses, it may close a case after the infant receives HBIG and all 3 hepatitis B vaccine doses. Additional information about post-vaccine serology (PVS) testing and household contact follow-up should be sent to the State as an "Update" (see more information below).
- When a case is closed, regardless of the reason it is closed, a copy of the entire case/household management report (Pages 1-3: MOTHER, INFANT(S), and ALL HOUSEHOLD CONTACTS) should be sent to the State Perinatal Hepatitis B Prevention Program. The box "Close" should be marked on the top of Page 1 (MOTHER). Page 4, the optional worksheet, does not need to be submitted.

- Make sure the case identification numbers on each of the three pages are identical and that the closing date has been entered in Field 21 of the MOTHER form.

### New Closes

- Sometimes a case will be submitted for the first time to the State Perinatal Hepatitis B Prevention Program as a closed case. The following situations are two common examples of when this might occur:
  - a) A case has been identified, but the woman moves out of the country before the case has been submitted to the State Perinatal Hepatitis B Prevention Program.
  - b) A case was submitted but the State Perinatal Hepatitis B Prevention Program has no record of it, so the case is not “opened” in the state database.
- For new closes, send in the report forms as if closing the case, and mark both “New Report” and “Close” on the top of Page 1 (MOTHER).

### Updates/Revisions

- There are often changes to information originally obtained during the case/household follow-up period (e.g., demographic information, post vaccination serology test dates and results, etc.). These changes should be submitted to the State Perinatal Hepatitis B Prevention Program so that the state database may be updated accordingly.
- Make any changes by crossing out the old information and writing in the revised information. Mark any submitted revision as an “Update” at the top of Page 1 (MOTHER).

### **Transfers**

When a case/household moves, all of the information necessary for case management (e.g., forwarding address and phone number, immunization histories, etc.) should be forwarded to the new jurisdiction to ensure proper follow-up.

### Intrastate transfers – Between jurisdictions **with** Perinatal Hepatitis B Programs

- If a case transfers from one jurisdiction with a perinatal hepatitis B prevention program to another, the county to which the case has transferred is responsible for continuing case/household management, closing the case, and submitting the case/household management report to the State Perinatal Hepatitis B Prevention Program.
- The Perinatal Hepatitis B Prevention Program In-State Case Transfer Form (Appendix D) may be used during this transfer process.
- The case should retain its original identification number. However, the transfer county will assign the case a second “transfer county” identification number, using the prescribed 9-digit format.
- The county of origin should inform the State Perinatal Hepatitis B Prevention Program of the transfer and submit a copy of the form marked “In-State Transfer”

on the top of Page 1 (MOTHER), but should not submit the closing paperwork for the case.

- Should a case transfer more than twice during case follow-up, additional transfer county identification numbers should be written on the case/household management report under the first transfer number.

#### Intrastate transfers – To jurisdictions **without** a Perinatal Hepatitis B Program

- If a case transfers to a jurisdiction in California that does not have a perinatal hepatitis B prevention program, the county of origin should close the case and submit the appropriate paperwork to the State Perinatal Hepatitis B Prevention Program with the boxes “In-State Transfer” and “Close” marked on the top of Page 1 (MOTHER). Any known forwarding address or information should be written on the form so that the State Perinatal Hepatitis B Prevention Program can pass on the information to the appropriate contacts.
- The Perinatal Hepatitis B Prevention Program In-State Case Transfer Form (Appendix D) may be used during this transfer process.
- The LHD should make every effort to provide the woman and her household with the information they will need should they change providers upon moving.

#### Interstate transfers

- If a case transfers out of the state of California, the county of origin should close the case and submit the appropriate paperwork to the State Perinatal Hepatitis B Prevention Program with the boxes “Out-of-State Transfer” and “Close” marked on the top of Page 1 (MOTHER). Any known forwarding address and all information about mother/infant and contacts should be written on the form so that the State Perinatal Hepatitis B Prevention Program can pass on the information to the appropriate contacts.
- The Perinatal Hepatitis B Prevention Program Out-of-State Case Transfer Form (Appendix D) may be used during this transfer process.
- The LHD should make every effort to provide the woman and her household with the information they will need to give to their new providers.

**Confidential HBsAg+ Case/Household Management Report  
Instructions for Page 1:  
MOTHER**

**New Report**       **Update**       **In-State Transfer**       **Out-of-State Transfer**  
 **Close**

- Check the appropriate box(es)
- New Report: The first report submitted to the state
- Update: Additional information on a mother, infant or household for a case already opened
- In-State Transfer: A case transferred to and from a county within the state
- Out-of-State Transfer: A case transferred to or from another state
- Close: The final report submitted to the state

**1. Case/Household Identification No. / / / - / / - / / - / / - / / / / (county of origin)**  
County mm yy

- All of the spaces in this field must be filled in. Leave no blanks.
- Insert your 2-digit county/jurisdiction code (see Appendix E) in the first two spaces marked "county." A list of all health jurisdiction codes can be found at the end of this instruction booklet.
- The second two spaces, labeled 'mm,' represent the month in which the case is opened (i.e., the month the HBsAg-positive report was received, the case report initiated and follow-up begun).
- The spaces labeled 'yy' represent the year in which the case is opened.
- The last three spaces in the field represent the chronological order in which cases are opened during each month. Most counties/jurisdictions will open somewhere between one (001) and 50 (050) cases each month.

*Examples:*

01-08-02-003: This number indicates that the case was opened in Alameda County (code 01), in August (08), 2002 (02), and that it was the third (003) case opened during the month of August.

36-02-02-020: This number indicates that the case was opened in San Bernardino County (code 36) in February (02), 2002 (02), and that it was the twentieth (020) case opened during the month of February.

**2. County: \_\_\_\_\_**

- Write in the name of your county or health jurisdiction. For intrastate transfer cases, the original county/jurisdiction that was entered on this line should be lined-out in red and the new or transfer county written in red above it.

**3. Case/Household Identification No. / / / - / / - / / - / / / / (transfer county)**  
County mm yy

- When a case is transferred from one contract county into another, it must be assigned a transfer case/household identification number. The county to which the case has transferred should enter its own identification number in the transfer county field, while the original identification number remains in its designated field. The numbering process should be exactly the same for the transfer county as it is for the county of origin (i.e., the month and year used in the seven-digit identification number should be the month and year that the transfer was received, the case opened, and follow-up began).

*Example:*

1. Case/Household Identification No. 30-01-02-014 (county of origin)
3. Case/Household Identification No. 48-06-02-008 (transfer county)

This case was originally opened in Orange County (code 30) in January 2002. However, the second identification number indicates that the case was transferred to Solano County (code 48) in June 2002. Solano will now be the jurisdiction responsible for following up with and closing the case. Orange County does not close the case to the state, as the case is still being actively followed in Solano, the transfer county.

**4. Date this report initiated**     /    /      
mm dd yyyy

- The date entered here (in MMDDYYYY format) should correspond to the date that the HBsAg-positive test result was reported to the local hepatitis B program and the case number was assigned and follow-up begun (the month and year should coincide with the case identification number).

**5. Name** \_\_\_\_\_  
Last First MI

- Enter mother's last name, first name and middle initial

**6. SSN** \_\_\_\_-\_\_\_\_-\_\_\_\_

- If it all possible, attain the mother's social security number and enter it correctly. This is a key identifier for assuring that there are no record duplications. If the woman does not have a social security number, leave the entry blank.

**7. City** \_\_\_\_\_ **8. Zip** \_\_\_\_\_

- Enter the city and zip code in which the mother primarily resides.

**9. Date of Mother's Birth**     /    /      
mm dd yyyy

- Enter the date of mother's birth in the MMDDYYYY format. If the month or day is a single-digit number, be sure to enter a "0" in the first field (e.g., 04 for April). If the month, day, or year of birth is unknown, leave the field blank. Do not enter "00" or "99" for any part of the birth date.

**10. Mother's Age When Screened** \_\_\_\_

- Enter the mother's age at the time she was screened for HBsAg. Do not leave this field blank. If the mother's exact age at time of screening is unknown, enter your best estimate.

**11. EDD**     /    /      
mm dd yyyy

- Enter the mother's estimated date of delivery (EDD) in the MMDDYYYY format.

**12. Is this the first case/household management report submitted to CA Perinatal Hepatitis B Program on this mother?**

1  Yes 2  No 9  Unknown

- This question will let the state Perinatal Hepatitis B Prevention Program know if there is currently a hepatitis B case/household management record on this woman with a previous pregnancy.





- For mothers who are Asian or Pacific Islanders, enter “Asian” or “Pacific Islander” and check the primary ethnic group with which they identify on the bottom of the report form. If the Asian or Pacific Islander ethnicity is unknown, leave the field blank and write “Unknown” in the margin of the form.
- Be sure to record the mother’s ethnic origin and not the ethnicity that is associated with the country from which she immigrated. For example, a woman of Chinese descent who is born in Vietnam is ethnically Chinese.
- A person may be coded as Hispanic, regardless of his/her race, if his/her ethnicity is of Spanish origin, such as Mexican/Mexican-American/Latino/Chicano, Puerto Rican, Cuban, Central/South American or other specified Spanish/Hispanic.

**20. Initial submit date:**      /      /       
mm    dd    yyyy

- Enter the date this form was initially submitted to the State in MMDDYYYY format. The date entered for the initial report submission should be a date within one month of the date the report is initiated.

**21. Close date:**      /      /       
mm    dd    yyyy

- Enter the date this case was closed in MMDDYYYY format. The close date should be the date that Pages 1, 2, and 3 (all pages should be submitted, whether completed or not) of the case/household management form for a closed case are submitted to the State.

**Instructions for Page 2:  
INFANT**

**1. Case/Household Identification No. / / / - / / / - / / / - / / / / (county of origin)**

**2. Case/Household Identification No. / / / - / / / - / / / - / / / / (transfer county)**

- Make sure that the identification number on the INFANT(S) page is identical to the identification numbers for the MOTHER (Page 1) and HOUSEHOLD CONTACTS (Page 3). If there is a transfer identification number, make sure that it also is identical to the transfer identification numbers on the other two pages of the report form.

**3. This pregnancy resulted in a: (Check all that apply)**

**a. Live birth** —————> **Number of live infant(s) born (1,2 etc):** \_\_\_\_

**b. Fetal death** —————> **Number of fetal deaths:** \_\_\_\_

**c. Miscarriage or abortion** —————>  **(check box if 'yes')**

- If a live birth occurs, enter the number of live births into field 3a
- If a fetal death occurs, enter the number of fetal deaths into field 3b. A fetal death is defined by the National Center for Health Statistics as “Death before the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles.” However, for the purposes of this program, fetal deaths should be differentiated from miscarriages or abortions by virtue of the fact that they occur after five months (twenty weeks) gestation.
- Under this program, any fetal death occurring prior to 20 weeks gestation will be considered a miscarriage or abortion. If a miscarriage or abortion occurs, check the box ‘yes’ in field 3c.
- Fields 3a-3c are not mutually exclusive. If a pregnancy results in one live birth and one fetal death, then 3a should be marked ‘1’, 3b should be marked ‘1’ and 3c left blank.

**4. Actual source of payment for delivery?**

**1**  **Medi-Cal**

**4**  **Self-pay**

**2**  **Other/Govt. 3<sup>rd</sup> party payer**

**5**  **Low income:** \_\_\_\_

**3**  **Private 3<sup>rd</sup> party payer**

**9**  **Other/Unk:** \_\_\_\_

- Note that the option selected in answer to this question may or may not be the same as that checked on Page 1 (MOTHER) for “Planned source of payment for delivery.”
- “Other/Govt. 3<sup>rd</sup> party payer” refers to programs similar to Medi-Cal, such as Medicare, CHDP, CCS or other forms of government subsidy that directly cover the delivery. “Private 3<sup>rd</sup> party” refers only to private insurers. “Low income” refers to public sector clients that are not eligible for Medi-Cal but still too low-income to pay for their care.

**5. Actual delivery hospital?**

**1**  **Public hospital**

**3**  **Outside of hospital**

**2**  **Private hospital**

**9**  **Unk**

- “Public hospital” is defined as a publicly supported and/or managed hospital that provides services to public sector clients.

Infant # \_\_\_\_\_

- Number each infant born during this pregnancy (live births only). If only one live infant is born, enter "1". If two or more live infants are born, attach additional page for each infant, assign the same case/household ID number on this form, number each infant accordingly (1, 2, 3 etc) and complete the infant section only.
- This field should correspond with the number of live births recorded in field 3a.

6. Name: \_\_\_\_\_ 7. Birth date: \_\_\_\_\_  
Last First MI mm / dd / yyyy

8. Sex: 1  Male 2  Female

- Enter the information for each live birth that occurred during this pregnancy. Birth date should be recorded in MM/DD/YYYY format.

**Immunization Record:**

- There is solid clinical evidence that the timing of the administration of hepatitis B immune globulin (HBIG) and vaccine doses is important in ensuring immunity to hepatitis B. As prescribed by the ACIP, HBIG and the first dose of vaccine should be given within twelve hours of the infant's birth. For infants receiving monovalent hepatitis B vaccine, the second dose should be given at 1-2 months of age and the third dose at six months of age. Please see Appendix F for information on combination immunization schedules and schedules for low-birth-weight infants.
- For those women whose HBsAg status is unknown, or for whom test results are pending, the infant should receive the first dose of hepatitis B vaccine within 12 hours of birth. If the mother is found to be HBsAg-positive, the infant should receive HBIG as soon as possible, but not later than seven days of age. If the mother's status is unknown and the infant weighs <2,000 grams, HBIG should be administered with hepatitis B vaccine within 12 hours of birth.

9. HBIG a.  Not given  
b. Age when given (hours) \_\_\_\_\_  
c. Date when given \_\_\_\_\_  
mm / dd / yyyy

- If no HBIG was given, check box 9a.
- If HBIG was given, enter the age of the infant in hours that HBIG was given (9b) and the date HBIG was given (9c) in MMDDYYYY format.

**10. Hep B Vac1**

a.  Not given  
b. Age when given (hours) \_\_\_\_\_  
c. Date when given \_\_\_\_\_  
mm / dd / yyyy

- If no doses of hepatitis B vaccine were given, check box 10a and record the reason that no doses of vaccine were given at the bottom of the page in field 19.
- If the first dose of hepatitis B vaccine was given, enter the age of the infant in hours that the first dose of the hepatitis B vaccine was given if less than or equal to twenty-four hours after the infant's birth (10b) and/or the date the first dose was given if more than twenty-four hours after birth (10c).

- If the first dose of hepatitis B vaccine was given at greater than 24 hours after birth, only the date the vaccine was given should be completed (10c) in MMDDYYYY format.

11. Hep B Vac2 Date when given      /      /       
mm dd yyyy

12. Hep B Vac3 Date when given      /      /       
mm dd yyyy

13. Hep B Vac4 Date when given      /      /       
(If applicable) mm dd yyyy

- Enter the dates that the second, third and fourth (if applicable) doses of the hepatitis B vaccine were given. If the exact date is not known, estimate if at all possible (e.g., the fifteenth of the month). If the date of vaccine administration is completely unknown, leave the field blank (Do not enter “00/00/00” or “99/99/99”) and write “Date Unknown” in the margin.
- Infants may be given four doses of hepatitis B vaccine if a combination vaccine schedule is being followed. Please see Appendix F for information on combination immunization schedules.

**Post-Vaccination Follow-up Serology Record:**

- All infants born to HBsAg-positive women should be tested 1-2 months after having received their third dose of hepatitis B vaccine, but not before 9 months of age. Infants should be tested for both HBsAg and hepatitis B surface antibody (anti-HBs).
- If HBsAg is not present and anti-HBs is present ( $\geq 10$  mL if quantitative test, or reactive if qualitative test), the infant can be considered immune.
- If neither HBsAg nor anti-HBs are present, the infant cannot be considered immune and should receive a second hepatitis B vaccine series.
- If HBsAg is present and anti-HBs is not present, the infant can be considered infected and should be reported as a case of Perinatal Hepatitis B Infection.
- For more information on interpreting hepatitis B lab tests, see Appendix G.

14. a. HBsAg test done? 1  Yes 2  No 9  Unk  
 If 'Yes': b. Date done      /      /       
mm dd yyyy

c. Result: 1  Pos 2  Neg 9  Unk

15. a. Anti-HBs test done? 1  Yes 2  No 9  Unk  
 If 'Yes': b. Date done      /      /       
mm dd yyyy

c. Result: 1  Pos 2  Neg 9  Unk

- If post-vaccine testing for HBsAg has been done, check “Yes” (14a) and enter the date of the test in MMDDYYYY format (14b) and the result of the test (14c).
- If post-vaccine testing for anti-HBs has been done, check “Yes” (15a) and enter the date of the test in MMDDYYYY format (15b) and the result of the test (15c).

**Second Series Immunization and Repeat Post-Vaccination Serology Record:**

16. a. If ‘Neg’, did infant receive a 2<sup>nd</sup> series of vaccine?  
 1  Yes 2  No 9  Unk



- If the infant does not complete the hepatitis B vaccine series or post-vaccination serologic testing, check all of the reasons that apply.

**a.  Infant completed hepatitis B vaccine series but was lost before post-vaccination serologic testing was performed**

- If the infant completed the entire hepatitis B vaccine series but was lost to follow-up before post-vaccine serology was completed, check field 19a.

**b.  Infant diagnosed with acute hepatitis B before vaccine series was completed**

- If the infant was diagnosed with acute hepatitis B before the vaccine series was completed, check field 19b and submit a CDC Perinatal Hepatitis B case report form.

**c.  Infant could not be located**

- If the mother/infant could not be located, check field 19c.

**d.  Located mother/household but later lost to follow-up**

- If the mother/household was initially contacted but then later lost to follow-up, check field 19d.

**e.  Infant moved or transferred to another county within the state for follow-up and don't know whether vaccination series was completed or not**

- If the infant/mother was enrolled but then moved or transferred to another county within California (that may or may not have a Perinatal Hepatitis B Prevention Program), and vaccine or post-vaccine serology information was not received, check field 19e.

**f.  Infant moved out of the state**

- If the infant moved out of the state, check field 19f and enter the new address in the space provided.

**g.  Infant moved out of the country**

- If the infant moved out of the country, check field 19g.
- Often there are situations where a woman will travel to the U.S. to deliver the infant, then return back to her home country with the baby. Follow-up on these infants is time-consuming and often infeasible. Checking field 19g will help track these scenarios.

**h.  Compliance problem with family**

- If the mother/household was contacted but refuses to participate or be compliant with the Perinatal Hepatitis B Prevention Program, check field 19h. Please contact the State Perinatal Hepatitis B Coordinator immediately if infant does not receive immunoprophylaxis at birth.

**i.  Infant died**

- Field 19i, "Infant died," refers to any death that is not considered a fetal death (i.e., stillbirth), miscarriage or abortion). This typically applies in circumstances where the infant dies some time after the first twenty-four hours of life, and usually after HBIG and one dose of the hepatitis B vaccine have been given.

**j.  Other (specify): \_\_\_\_\_**

- If the infant is lost to follow-up for other reasons that are not enumerated here, please check field 19j and specify in the space given.

## Instructions for Page 3: HOUSEHOLD

### 1. Case/Household Identification No. / / / - / / / - / / / - / / / / (county of origin)

### 2. Case/Household Identification No. / / / - / / / - / / / - / / / / (transfer county)

- Make sure that the identification number on the HOUSEHOLD CONTACTS page is identical to the identification numbers for the MOTHER (page 1) and INFANT(S) (page 2). If there is a transfer identification number, make sure that it also is identical to the transfer identification numbers on the other two pages of the report form.

### 3. All Household Contacts

- The first section of this page concerns summary data for all household contacts of each HBsAg-positive woman identified through the Perinatal Hepatitis B Prevention Program.
- While you will need additional locating and other information for case follow-up (see page 4: Optional Worksheet for Case/Household Management), the State Perinatal Hepatitis B Prevention Program collects only the consolidated data on page 3 All Household Contacts.
- Enter the immunization status of each household contact found during follow-up for this case only. For instance, if an HBsAg-positive woman is enrolled in the Perinatal Hepatitis B Prevention Program twice, for two separate pregnancies and a household contact was seroscreened and consequently immunized during follow-up for her first pregnancy (3d, 3h and 3i), that same household contact would be documented as previously immunized (3c) for the second pregnancy.

#### a. \_\_\_ Total number of household contacts identified (a = b+c+d+j+k)

- Enter the total number of adults and children (**excluding the newborn**) who are part of the HBsAg-positive woman's primary household or are a sexual contact. If the woman lives at more than one address, it is up to the program to decide which (i.e., how many) of her household contacts should be followed. The number entered in Field 3a should reflect all those contacts for whom information will be collected.
- The total number of household contacts identified (3a) should equal the sum of 3b, 3c, 3d, 3j and 3k.

#### b. \_\_\_ Number already known to be chronically infected or immune due to prior infection of Hepatitis B

- Enter the number of household contacts who have previously (i.e., prior to the opening of the current case) been screened for hepatitis B or have a history of hepatitis B illness, who are assumed positive for hepatitis B markers and for whom screening is not recommended. The individuals included in the total entered in this field should not be counted again in Field 3d, "Number seroscreened for Hep B markers."

#### c. \_\_\_ Number previously immunized

- Enter the number of household contacts who have a record of having already completed the hepatitis B immunization series prior to the opening of the current case, and who are assumed to be immune from hepatitis B.
- Persons in the middle of completing the vaccine series who need additional dose(s) of vaccine (without screening) should not be included in this field as previously immunized, but should be included in the total entered for Field 3j "Number vaccinated without screening."

- d. \_\_\_ **Number seroscreened for Hep B markers (usually anti-HBc)**
- e. \_\_\_ **Of those seroscreened, number age  $\leq$  5 years**
- f. \_\_\_ **Of those seroscreened, number age  $\geq$  6 years**
- g. \_\_\_ **Of those seroscreened, number found to be already infected or immune**
- h. \_\_\_ **Of those seroscreened, number found to be susceptible (i.e., negative for hepatitis B markers)**
- i. \_\_\_ **Of those found to be susceptible, number vaccinated**

- Enter the number of household contacts who had a laboratory test done during the follow-up for the current case to determine their hepatitis B status in Field 3d.
- The age category (3e or 3f) and test result (3g or 3h) should also be documented for each household contact included in this field.
- Enter the number of contacts who were seroscreened, found to be susceptible and were vaccinated in Field 3i.
- The total number of contacts seroscreened for hepatitis B markers (3d) should equal the sum of 3e and 3f and the sum of 3g and 3h.

**j. \_\_\_ Number vaccinated without screening**

- Enter the number of household contacts who are either: (1) not screened but considered susceptible (i.e., followed up for immunization during the follow-up of this current case); or (2) completing the vaccine series during the follow-up of this current case. The age and immunization information for each of these susceptible household contacts should also be documented in the grid for question 4, "Household Contacts Receiving Immunization (List in any order)," as described below.

**k. \_\_\_ Number lost to follow-up**

- Enter the number of household contacts who, during the follow-up of the current case, are either: (1) never located; (2) not screened; or (3) are eligible to receive immunization without screening, but are not immunized for whatever reason (e.g., refuse to be immunized).

#### 4. HOUSEHOLD CONTACTS RECEIVING IMMUNIZATION (List in any order)

Please enter the codes in ( ) into the spaces below.

	a. Name (optional)	b. Age 0-5 yrs (1) 6-21 yrs (2) ≥ 21 yrs (3)	c. Hep B Vac Dose #1 Given? Yes (1); No (2); Unk (9)	d. Hep B Vac Dose #2 Given? Yes (1); No (2); Unk (9)	e. Hep B Vac Dose #3 Given? Yes (1); No(2); Unk (9)
Contact 1					
Contact 2					
Contact 3					
Contact 4					
Contact 5					
Contact 6					

- Only the information for all household contacts included in Fields 3i (Of those found to be susceptible, number vaccinated) and 3j (Number vaccinated without screening) should be recorded in this grid.
- The primary purpose of this section is to determine the relative success in completing the 3-dose hepatitis B immunization series for household contacts who receive screening and are determined to be susceptible, who receive no screening but are assumed to be susceptible, or who have started the vaccine series elsewhere and need additional doses.
- Enter the information for Fields 4a–4e for each household contact receiving immunization.

##### 4a. Name (optional)

- The name of each household contact receiving immunization does not need to be listed. Please make sure, however, that each household contact's summary immunization information appearing on this page can be tied to working documents.

##### 4b. Age [when screened]: 0-5 yrs (1); 6-21 yrs (2); ≥ 21 yrs (3)

- Enter the household contact's age at the time that they are screened and identified as susceptible (i.e., in need of immunization), or, if no screening is done, their age at the time of first immunization.
  - If a household contact is age 0 to 5 years, enter a number "1" in Field 4b.
  - If a household contact is age 6 to 21 years, enter a number "2" in Field 4b.
  - If a household contact is age 21 years or older, enter a number "3" in Field 4b.

##### 4c–4e. Hep B Vac Dose #1, #2, #3 Given? Yes (1); No (2); Unk (9)

- Indicate whether or not each household contact needing vaccine (i.e., screened and known to be susceptible), received vaccine without screening, or needed to finish the vaccine series) received the first, second, and/or third doses. Enter a "1" for Yes, a "2" for No, or a "9" for Unknown.

- Specific dates of administration are not required for the purposes of this case/household management report.
- If a household contact needing immunization received any part of the vaccine series in another jurisdiction, a “1” (Yes) should be checked in the box for the appropriate dose. For instance, if a household contact receives only the third dose of the vaccine through the Perinatal Hepatitis B Prevention Program, but has documentation that doses 1 and 2 were received elsewhere, a “1” would be entered for doses one and two.
- If a household contact receiving immunization moves out of the jurisdiction or is lost to follow-up, enter “9” (Unk) for any remaining doses not yet given.

### **5. Lost to Follow-Up**

**If any of the household contacts listed above does not complete the 3-dose series, check all of the reasons that apply.**

- Contact(s) located but later lost to follow-up**
- Contact(s) found to be already infected or immune after series was started**
- Contact(s) moved to another county within the state for follow-up and don't know whether vaccination series was completed or not**
- Contact(s) moved out of the state**
- Contact(s) moved out of the country**
- Contact(s) died**
- Compliance problem with family**
- Other (specify): \_\_\_\_\_**

- This section applies only to those individuals who are listed in the grid for question #4, above. Complete this section if any one of the susceptible or assumed susceptible household contacts does not complete the 3-dose immunization series.
- More than one reason may be checked.

# WORKING WITH PROVIDERS

One of the core functions of perinatal hepatitis B programs is ensuring that birth hospitals, prenatal providers, and pediatric providers are aware of perinatal hepatitis B prevention recommendations. Counties with limited resources may be able to conduct provider outreach and education activities in collaboration with other programs that work with the same providers, such as the Vaccines for Children (VFC) program. All medical providers should be informed of how to access clinical resources as well as resources for patient education (see Appendix E).

## **Prenatal Care Providers**

All prenatal care providers should be aware of California's screening and reporting laws. The coordinator who receives hepatitis B case reports from laboratories can encourage providers to report directly to the health department by providing them with a reporting form (see Appendix D). A reference on interpretation of hepatitis B serologies is another important tool to give prenatal providers (see Appendix A).

## **Birth Hospitals**

Working with birth hospitals is an important way to promote perinatal hepatitis B prevention program goals, as birth hospitals are the focus of many case management activities. The coordinator should identify a contact person in each hospital such as infection control practitioner (ICP) or the nurse manager of labor and delivery. Potential venues for educating hospital staff are during regular physician and staff meetings.

## **Pediatric Care Providers**

The most immediate way to provide information on hepatitis B to pediatric providers is while working with them on individual cases. The case manager can provide written tools such as the hepatitis B vaccination schedule and information on post vaccination serologic testing and interpretation (see appendix A and F). It may also be useful to develop forms that make it easy for the provider to inform the coordinator of follow up vaccinations and post-vaccination serology test results.

## **POLICIES, PROCEDURES, AND PRACTICES FOR PRENATAL CARE, BIRTH HOSPITAL, AND PEDIATRIC CARE SETTINGS**

The coordinator performing follow up on perinatal hepatitis B cases should promote development of appropriate policies and procedures in birth hospitals and prenatal and pediatric care settings. By engaging stakeholders in overall prevention efforts and by providing education to obstetric, hospital, nursery, and pediatric care providers, the coordinator may be able to influence the development and implementation of these policies. The next section outlines the critical components of such policies in each of the different settings (see Appendix E).

## **PRENATAL CARE PROVIDER - Policies and Procedures**

The primary activity to promote among prenatal care practitioners is to **test ALL pregnant women for HBsAg during each pregnancy**. The ACIP recommendations state that prenatal care providers should test every woman for HBsAg during an early prenatal visit even if the provider knows she is HBsAg positive or if she has been previously vaccinated. In addition, prenatal care settings should incorporate each of the following actions into their policies and protocols:

### **For a pregnant woman with a positive HBsAg test result**

- Report the positive test result to the health department.
- Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg status to the hospital where the delivery is planned and to the healthcare provider who will care for the newborn.
- Attach an alert notice to the woman's medical record to remind the birth hospital/nursery that the infant will need hepatitis B vaccine and HBIG at birth.
- Educate the woman about the need for immunoprophylaxis of her infant at birth.
- Advise the woman that all household, sexual, and needle-sharing contacts should be tested for HBV infection and vaccinated if susceptible.
- Provide information about hepatitis B, including modes of transmission, prenatal concerns (e.g., infants born to HBsAg-positive mothers may be breastfed), medical evaluation and possible treatment of chronic hepatitis B, and substance abuse treatment (if appropriate).
- Refer the woman to a medical specialist for evaluation of chronic hepatitis B.

### **For a pregnant woman with a negative HBsAg test result**

- Provide a copy of the original laboratory report indicating the woman's HBsAg status to the hospital where the delivery is planned and to the healthcare provider who will care for the newborn.
- Inform the mother about the rationale for and importance of newborn hepatitis B vaccination.
- Administer the hepatitis B vaccine series if the woman has a risk factor for HBV infection during pregnancy (e.g., injection-drug use, more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually-transmitted disease [STD]).
- Repeat HBsAg testing upon admission to labor and delivery if an HBsAg-negative woman was at risk for HBV infection during pregnancy or if she had clinical hepatitis since previous testing.

## **BIRTH HOSPITAL - Policies, Procedures, and Standing Orders**

Policies and procedures for the nursery and labor and delivery units to prevent perinatal HBV transmission must ensure:

- *Identification of infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status*
- *Initiation of immunoprophylaxis for these infants.*

These policies should include the following **standing orders**:

- ✓ Review HBsAg test results of all pregnant women at the time of admission for delivery
- ✓ For women who do not have a documented HBsAg test result, perform the test as soon as possible after admission for delivery
- ✓ Identify and manage all infants born to HBsAg-positive mothers, including the provision of postexposure immunoprophylaxis
- ✓ For infants born to mothers with unknown HBsAg status, administer hepatitis B vaccine within 12 hours of birth
- ✓ For all infants, document in the infant's medical record the maternal HBsAg test results, infant hepatitis B vaccine administration, and administration of HBIG (if applicable)

In addition to policies and procedures to prevent perinatal hepatitis B transmission, ***all birth hospitals should implement standing orders for administration of hepatitis B vaccination before hospital discharge as part of routine medical care*** of all medically stable infants weighing  $\geq 2,000$  grams at birth.

The Immunization Action Coalition has developed a document that hospitals can use to establish standing orders entitled *Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent Hepatitis B Virus Transmission to Newborns*. The document is available at

<http://www.immunize.org/catg.d/p2130.pdf>

*Additional elements of delivery hospital policies and procedures to prevent perinatal HBV transmission:*

## **Birth Hospital Policies and Procedures to Prevent Perinatal Hepatitis B Transmission**

### **At time of admission for delivery**

- Review hepatitis B surface antigen (HBsAg) status of all pregnant women.
- Record maternal HBsAg test results on both labor and delivery record and on infant's delivery summary sheet.
- Perform HBsAg testing as soon as possible on women who;
  - do not have a documented HBsAg test result;
  - were at risk for hepatitis B infection during 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 previous testing.

### **After delivery**

#### *HBsAg-positive mothers and their infants*

- Administer single-antigen hepatitis B vaccine and hepatitis B immune globulin (HBIG) to all infants born to HBsAg-positive mothers  $\leq 12$  hours after birth and record date and time of administration of HBIG and hepatitis B vaccine in infant's medical record.
- Provide information regarding hepatitis B to HBsAg-positive mothers, including;
  - advice that they may breast feed their infants upon delivery;
  - modes of hepatitis B transmission;
  - need for vaccination of their susceptible household, sexual, and needle-sharing contacts;
  - need for substance abuse treatment, if appropriate; and
  - need for medical management and possible treatment for chronic hepatitis B.

#### *Mothers with unknown HBsAg status and their infants*

- Administer single-antigen hepatitis B vaccine (without HBIG) to all infants born to mothers with unknown HBsAg status  $\leq 12$  hours after birth and record date and time of administration of hepatitis B vaccine on infant's medical record.
- Alert infant's pediatric health-care provider if an infant is discharged before the mother's HBsAg test result is available; if the mother is determined to be HBsAg positive, HBIG should be administered to the infant as soon as possible, but no later than age 7 days.

#### *All mothers and their infants*

- Administer a dose of single-antigen hepatitis B vaccine to all infants weighing  $\geq 2,000$  g.
- Ensure that all mothers have been tested for HBsAg prenatally or at the time of admission for delivery, and document test results.

### **At time infant is discharged**

Provide infant's immunization record to mother and remind her to take it to the infant's first visit to pediatric healthcare provider.

**Source:** CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: immunization of infants, children, and adolescents. *MMWR* 2005;54(RR16). <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm>

On a case-by-case basis and only in rare circumstances, the first dose of hepatitis B vaccine may be delayed until after hospital discharge for an infant who weighs at least 2,000 grams and whose mother is HBsAg negative. When such a decision is made, a physician's order to withhold the birth dose and a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record. For infants who do not receive a first dose before hospital discharge, the first dose should be administered no later than age 2 months.

For a pre-term infant weighing <2,000 grams whose mother is HBsAg negative, the first dose of hepatitis B vaccine may be held until chronologic age 1 month, or may be given at discharge if medically stable and gaining weight consistently.

The birth dose should not be delayed if the mother had any risk factors for exposure to hepatitis B during pregnancy or who had clinical hepatitis during pregnancy. In addition, the birth dose should not be delayed if the mother is expected to be non-compliant in getting her infant vaccinated.

### **Improving Identification of Infants Born to Women of Unknown Status**

Perinatal hepatitis B coordinators should work with birth hospitals to implement protocols and procedures to ensure that:

- pregnant women who were not screened prenatally are identified and tested as soon as possible after admission for delivery;
- infants born to women without documentation of HBsAg test results receive the first dose of hepatitis B vaccine within 12 hours of birth; and
- pediatric care providers are contacted to provide follow-up for infants whose mothers have unknown HBsAg status at the time of hospital discharge, including review of maternal HBsAg test results and appropriate management of infants on the basis of those test results.

## PEDIATRIC CARE PROVIDER - Policies and Practices

Pediatric care providers should establish practices for ***ensuring appropriate follow-up of infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status at the time of delivery.*** These practices should include the following:

- **For all infants, complete the hepatitis B vaccine series** according to a recommended vaccination schedule (see appendix F), and document the date of administration of each dose of the vaccine series.
- **Identify and manage infants born to mothers who did not have a documented HBsAg test at the time of delivery.** Obtain maternal HBsAg test results from the delivery hospital laboratory and provide appropriate management on the basis of those results. Test results should be managed as follows:
  - ❖ If the mother is found to be HBsAg **positive**, her infant should receive HBIG as soon as possible but no later than age 7 days, and the vaccine series should be completed according to a schedule for infants born to HBsAg-positive mothers.
  - ❖ If the mother is found to be HBsAg **negative**, the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-negative mothers.
- **It is recommended that infants whose mothers are HBsAg positive receive the third dose of hepatitis B vaccine by 6 months of age.**
- **For preterm infants weighing <2,000 grams at birth**, the initial vaccine dose should not be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants. Three additional doses of vaccine (for a total of four doses) should be administered beginning when the infant reaches the chronological age of 1 month.
- **For infants born to HBsAg-positive mothers, perform post-vaccination serologic testing** for anti-HBs and HBsAg 1-2 months after administration of the 3<sup>rd</sup> or 4<sup>th</sup> vaccine dose, but no earlier than 9 months of age. Test results should be managed as follows:
  - ❖ HBsAg-negative infants with anti-HBs concentrations of  $\geq 10$  mIU/mL are protected and need no further medical management.
  - ❖ HBsAg-negative infants with anti-HBs concentrations of  $< 10$  mIU/mL should be revaccinated with a second three-dose series and retested 1–2 months after the last dose of vaccine.
  - ❖ Infants who are HBsAg positive should receive appropriate follow-up and should be reported to the health department.

# HEPATITIS B VACCINATION AND PROPHYLAXIS

## PROPHYLAXIS

Two types of products are available for prophylaxis against hepatitis B infection.

1. **Hepatitis B vaccine**, which provides long-term protection against HBV infection, is recommended for pre-exposure and post-exposure prophylaxis.
2. **Hepatitis B Immune Globulin (HBIG)** provides temporary protection (i.e., three to six months) and is used as passive immunization for discrete, identifiable percutaneous or mucosal exposures and for perinatal exposure.

Infants born to women who are acutely or chronically infected with hepatitis B are at high risk of developing chronic hepatitis B infection. When hepatitis B vaccine and HBIG are administered within 24 hours of birth, followed by completion of a 3-dose series of hepatitis B vaccine, PEP is 85%-95% effective in preventing acute and chronic HBV infection. HBIG and hepatitis B vaccine should be administered intramuscularly at separate sites in the anterolateral thigh. HBIG should preferably be given within 12 hours of birth but may be given up to 7 days after birth.

## HBIG

HBIG is prepared from plasma from selected donors with high titer of antibody against HBsAg (anti-HBs). The human plasma from which HBIG is prepared is screened for HBsAg, antibodies to HIV and HCV and for HCV RNA. In addition, the process used to manufacture HBIG inactivates viruses (e.g., HBV, HCV, HIV) from the final product. There is no evidence that HIV can be transmitted by HBIG. HBIG does not contain thimerosal. HBIG given at birth does not interfere with other vaccines given at 2 months of age.

## HEPATITIS B VACCINE

Hepatitis B vaccines currently licensed in the U.S. are produced by using recombinant DNA technology. Hepatitis B infection cannot result from use of the recombinant vaccine, as no potentially infectious viral DNA or complete viral particles are produced in the recombinant system. Since early 2000, hepatitis B vaccines produced for distribution in the U.S. have not contained thimerosal as a preservative, although Engerix-B contains a trace of thimerosal as residual from the manufacturing process. Hepatitis B vaccine is currently produced by two manufacturers in the United States, Merck (Recombivax HB) and GlaxoSmithKline Pharmaceuticals (Engerix-B). Both are available in pediatric and adult formulations. Only Recombivax HB is approved for the two-dose schedule for adolescents aged 11-15 years. Both the pediatric and adult formulations of Recombivax HB are approved for use in any age group. The pediatric form of Engerix-B is approved for children and adolescents less than 20 years of age but not for adults. The adult formulation of Engerix-B is approved for adolescents 11-19 years of age but not for infants and children. In general, the brands of age-appropriate hepatitis B vaccines are interchangeable within an immunization series. See Table “**Recommended Dosages of Hepatitis B Vaccines**” below for recommended dosages of vaccines and also Appendix F.

### **Immunogenicity and Vaccine Efficacy**

Hepatitis B vaccine is highly effective. After three intramuscular doses of hepatitis B vaccines more than 95% of infants, children, and adolescents (to 19 years of age) and more than 90% of healthy adults develop adequate antibody responses. However, there is an age-specific decline in immunogenicity. By age 60 years, only 75% of recipients completing a three-dose series develop protective antibody titers. If a protective antibody response develops after three doses of vaccination, vaccine recipients are virtually 100% protected against clinical illness. Routine booster doses are not recommended for children or adults with normal immune status.

### **VACCINATION SCHEDULE AND USE**

#### **Infants and children**

Hepatitis B vaccine is recommended for all infants >2000 grams soon after birth and before hospital discharge. Only monovalent hepatitis B vaccine is approved for infants less than 6 weeks of age. Routine immunization with hepatitis B vaccine is also recommended for children less than 12 years of age who have not been previously immunized. The usual vaccination schedule is 0, 1-2, and 6-18 months (Appendix F).

The highest titers of antibodies to hepatitis B surface antigen (anti-HBs) are achieved when the last two doses of vaccine are spaced at least 4 months apart. When it is difficult to ensure that an infant will be brought back for vaccinations it is acceptable follow a schedule with 2 month intervals between doses.

- The minimum interval between the first and second dose is four weeks.
- The minimum interval between the second and third dose is eight weeks.
- The third dose should be separated from the first by at least four months and should not be given to an infant before 24 weeks of age.

Pediarix and Comvax are multivalent vaccines containing hepatitis B that are approved for use in infants and children. They are both approved for use for infants with HBsAg-infected mothers and mothers with unknown HBsAg status.

**Comvax**<sup>®</sup> is produced by Merck and Company and consists of Hepatitis B vaccine combined with *Haemophilus influenzae* type b (Hib). Each dose contains 7.5 micrograms of Hib vaccine and 5 micrograms of hepatitis B surface antigen (the same dose as Recombivax). The immunogenicity of the combination vaccine is equivalent to that of the individual antigens administered at separate sites. Comvax may be given at 2, 4, and 12-15 months of age. It must not be administered to infants younger than 6 weeks of age (and therefore cannot be used for birth doses).

**Pediarix** is produced by GlaxoSmithKline Pharmaceuticals. Pediarix is a pentavalent vaccine containing DTaP (diphtheria, tetanus, pertussis), hepatitis B, and IPV (inactivated poliovirus) vaccines.

The efficacy of Pediarix is similar to the monovalent vaccine for HBV. Pediarix is usually given at 2, 4, and 6 months of age. The minimum age for the first dose is 6 weeks.

When the infant receives the birth dose and combination vaccine is desired to complete the series, a total of four doses will be given. This schedule has been shown to be safe in clinical trials and is endorsed by the ACIP.

The immune response when one or two doses of a vaccine produced by one manufacturer are followed by subsequent doses from a different manufacturer has been shown to be comparable with that resulting from a full course of vaccination with vaccine from the same manufacturer.

### **Adolescents (11-19 Years of Age)**

Hepatitis B vaccination is recommended for all children and adolescents through age 18 years. All children not previously vaccinated with hepatitis B should be vaccinated with an appropriate dose and schedule. The usual schedule for adolescents is two doses separated by no less than 4 weeks, and a third dose 4-6 months after the second dose. Adolescents age 11-15 may receive hepatitis B vaccination on an alternate schedule of two 1.0 mL doses of Recombivax HB separated by 4-6 months. This schedule should be completed by age 16 years.

### **Adults (20 Years of Age and Older)**

Pre-exposure vaccination should be considered for groups of adults who are at increased risk for HBV infection and for adults requesting protection from HBV infection. Adults should be vaccinated with 1 mL of pediatric or adult formulation Recombivax HB or 1 mL of adult formulation Engerix-B. The usual schedule for adults is two doses separated by at least 4 weeks and a third dose 4-6 months after the second dose.

**Twinrix** is a combination hepatitis B and hepatitis A vaccine approved for use in persons 18 years and older with indications for both hepatitis A and B vaccines. The hepatitis B component in Twinrix is equivalent to a standard dose of hepatitis B vaccine.

Twinrix is produced by GlaxoSmithKline Pharmaceuticals. Twinrix consists of a combination of hepatitis B (20 mcg) and hepatitis A (720 EL.U.) and is licensed for use in persons 18 years and older. The vaccine is administered as a three-dose series at 0, 1, and 6 months. The first and second dose must be separated by one month, the second and third dose by five months, and the first and third dose by at least six months. Because Twinrix contains the same component of hepatitis B as the single-antigen vaccine, they are interchangeable. However, because a smaller (pediatric) dosage of hepatitis A vaccine is used, those who require hepatitis A vaccination must receive all three doses of Twinrix to be adequately vaccinated.

### **Routes and Sites of Administration**

Hepatitis B vaccine should be administered only in the deltoid muscle of adults and children or in the anterolateral thigh muscle of neonates and infants. When hepatitis B

vaccine is administered to infants simultaneously with other vaccines, separate sites in the anterolateral thigh should be used for the multiple injections, with injections separated by 1-2". Hepatitis B vaccine administered by any other route or site should not be counted as valid and should be repeated, unless serologic testing indicates that an adequate response has been achieved. A 5/8", 22-25 gauge needle should be used for infants < 28 days of age and a 1", 22-25 gauge needle used for infants 1-12 months of age. Hepatitis B vaccine may be given simultaneously and at any interval with all other childhood vaccines without interfering with antibody response.

### **Interrupted Schedules**

In any age group, when the hepatitis B vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be given as soon as possible, and the second and third doses should be separated by an interval of at least 8 weeks. If only the third dose is delayed, it should be administered as soon as possible.

### **Adverse Reactions Following Vaccination**

Hepatitis B vaccine has been shown to be safe when administered to both adults and children. There is no evidence that administration of hepatitis B vaccine at or shortly after birth increases the number of febrile episodes, evaluation for sepsis, or allergic or neurologic events in the newborn period. Any presumed risk of adverse events possibly associated with hepatitis B vaccination must be balanced against the expected risk of acute and chronic liver disease associated with the lifetime risk of HBV infection.

The safety of hepatitis B vaccine will continue to be assessed through ongoing monitoring of data from the Vaccine Adverse Events Reporting System (VAERS) and other surveillance systems. All adverse events suspected to be associated with hepatitis B vaccination should be reported to VAERS. Report forms and assistance are available by calling 1-800-822-7967 or at <http://www.cdc.gov/vaccinesafety/vaers/>

### **Contraindications and Precautions**

Hepatitis B vaccine is contraindicated for persons with a history of hypersensitivity to yeast or any vaccine component. Serious allergic reaction to a prior dose of hepatitis B vaccine or a vaccine component is a contraindication to further doses of vaccine. Such allergic reactions are rare.

People with moderate to severe acute illness should not be vaccinated until their condition improves. However, minor illnesses, such as upper respiratory infections are not a contraindication to vaccination. Hepatitis B vaccine so it may be used in people with immunodeficiency but response to vaccination in such people may be suboptimal.

### **Immunization during Pregnancy and Lactation**

Experience with inadvertent administration of hepatitis B vaccine to pregnant women has not identified vaccine safety issues for either the woman or the fetus. Since HBV infection may result in severe disease for the mother and chronic infection for the

newborn, pregnancy is not a contraindication for women who are at risk for hepatitis B infection. Lactation is not a contraindication to immunization.

### Post-vaccination Serologic Testing

Post-vaccination serologic testing is recommended for individuals whose management depends on knowledge of their immune status. This includes sex partners of HBsAg positive persons, immunocompromised persons, and healthcare workers. Post-vaccination serologic testing is not recommended for routine vaccination of infants, children or adolescents.

### RECOMMENDED DOSAGES OF HEPATITIS B VACCINES

<b>Single-antigen Hepatitis B Vaccines</b>				
<b>Vaccine</b>	<b>Age Group</b>	<b>Dose</b>	<b>Volume</b>	<b># Doses</b>
<b>Engerix-B</b>	0-19 years	10 µg	0.5 ml	3
	20 years and older	20 µg	1.0 ml	3
	Adult hemodialysis and predialysis patients	40 µg	2.0 ml	3 or more
<b>Recombivax HB</b>	0-19 years	5 µg	0.5 ml	3
	11 thru 15 years	10 µg	1.0 ml	2
	20 years and older	10 µg	1.0 ml	3
	Adult hemodialysis and predialysis patients	40 µg	1.0 ml	3 or more
<b>Combination Hepatitis B Vaccines</b>				
<b>Vaccine</b>	<b>Age Group</b>	<b>Antigens Used</b>	<b>Volume</b>	<b># Doses</b>
<b>Comvax</b>	6 weeks thru 15 months	Recombivax HB 5 µg combined with PedvaxHib	0.5 ml	3
<b>Pediarix</b>	6 weeks thru 6 years.	Engerix-B 10 µg, Infanrix (DTaP), and IPV	0.5 ml	3
<b>Twinrix</b>	18 years and older	Engerix-B 20 µg combined with Havrix	1.0 ml	3

For additional information on hepatitis B vaccination see the Pink Book:  
<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/hepb-508.pdf>

# Appendix A

## Hepatitis B Facts

Hepatitis B Facts and Serology Information (IAC)

# Hepatitis B Facts: Testing and Vaccination

## — Who should be vaccinated? —

The following persons should receive routine hepatitis B vaccination, according to the Centers for Disease Control and Prevention (CDC):

### Routine vaccination:

- All newborns at birth prior to hospital discharge
- All children and teens ages 0 through 18 years
- All persons who wish to be protected from hepatitis B virus (HBV) infection. CDC states it is not necessary for the patient to disclose a risk factor to receive hepatitis B vaccine.

### Persons who are at risk for sexual exposure:

- Sexually active persons who are not in long-term, mutually monogamous relationships
- Sex partners of HBsAg-positive persons
- Persons seeking evaluation or treatment for an STD
- Men who have sex with men

### Persons at risk for infection by percutaneous or mucosal exposure to blood:

- Current or recent injection-drug users
- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally challenged persons
- Healthcare and public safety workers with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
- Persons with end-stage renal disease and those receiving dialysis

### Others:

- Travelers to areas with moderate or high rates of HBV infection
- Persons with chronic (life-long) liver disease
- Persons with HIV infection

Refugees, immigrants, and adoptees from countries where HBV infection is endemic should be screened. Adults should discuss their need or desire for hepatitis B vaccination with their healthcare providers.

For certain people at risk, postvaccination testing is recommended. Consult ACIP recommendations for details (see references).

## — Hepatitis B lab nomenclature —

**HBsAg:** *Hepatitis B surface antigen* is a marker of infectivity. Its presence indicates either acute or chronic HBV infection.

**Anti-HBs:** *Antibody to hepatitis B surface antigen* is a marker of immunity. Its presence indicates an immune response to HBV infection, an immune response to vaccination, or the presence of passively acquired antibody. (It is also known as **HBsAb**, but this abbreviation is best avoided since it is often confused with abbreviations such as HBsAg.)

**Anti-HBc (total):** *Antibody to hepatitis B core antigen* is a nonspecific marker of acute, chronic, or resolved HBV infection. It is *not* a marker of vaccine-induced immunity. It may be used in prevaccination testing to determine previous exposure to HBV infection. (It is also known as **HBcAb**, but this abbreviation is best avoided since it is often confused with other abbreviations.)

**IgM anti-HBc:** *IgM antibody subclass of anti-HBc*. Positivity indicates recent infection with HBV (within the past 6 mos). Its presence indicates acute infection.

**HBeAg:** *Hepatitis B “e” antigen* is a marker of a high degree of HBV infectivity, and it correlates with a high level of HBV replication. It is primarily used to help determine the clinical management of patients with chronic HBV infection.

**Anti-HBe:** *Antibody to hepatitis B “e” antigen* may be present in an infected or immune person. In persons with chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity.

**HBV-DNA:** *HBV Deoxyribonucleic acid* is a marker of viral replication. It correlates well with infectivity. It is used to assess and monitor the treatment of patients with chronic HBV infection.

## — Screening before vaccination —

Serologic testing prior to vaccination may be undertaken based on your assessment of your patient’s level of risk and your or your patient’s need for definitive information (see information in the left column). If you decide to test, draw the blood first, and then give the first dose of vaccine at the same office visit. Vaccination can then be continued, if needed, based on the results of the tests. If you are not sure who needs hepatitis B screening, consult your state or local health department.

Tests	Results	Interpretation	Vaccinate?
HBsAg anti-HBc anti-HBs	negative negative negative	susceptible	vaccinate if indicated
HBsAg anti-HBc anti-HBs	negative negative positive with $\geq 10$ mIU/mL	immune due to vaccination	no vaccination necessary
HBsAg anti-HBc anti-HBs	negative positive positive	immune due to natural infection	no vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	acutely infected	no vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	chronically infected	no vaccination necessary (may need treatment)
HBsAg anti-HBc anti-HBs	negative positive negative	four interpretations possible*	use clinical judgment

- \*1. May be recovering from acute HBV infection
2. May be distantly immune, but the test may not be sensitive enough to detect a very low level of anti-HBs in serum
3. May be susceptible with a false positive anti-HBc
4. May be chronically infected and have an undetectable level of HBsAg present in the serum

## — Managing chronic HBV infection —

When you identify a patient who is chronically infected with HBV, make sure you consult a specialist knowledgeable in the treatment of liver disease so your patient’s care is optimized. Chronically infected persons need medical evaluation every 6–12 mos to assess the status of their liver health and their need for antiviral therapy, as well as to screen for liver cancer. In addition, persons with chronic HBV infection should be educated about their disease and how to protect others.

Household members and sex partners should be tested for HBV infection and given the first dose of hepatitis B vaccine at the same visit. (Vaccinating a person who has already been infected will do no harm). If testing indicates HBV susceptibility, complete the hepatitis B vaccination series. If testing indicates HBV infection, consultation and further care with a physician knowledgeable about chronic hepatitis B is needed.

### References

1. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the U.S.: Recommendations of the ACIP, Part I: Immunization of Infants, Children and Adolescents, *MMWR*, Dec. 23, 2005, Vol. 54(RR-16)
2. A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the U.S.: Recommendations of the ACIP, Part II: Immunization of Adults, *MMWR*, Dec. 8, 2006, Vol. 55(RR-16)

# Appendix B

## Law

Notification by Laboratories

California Code of Regulations, Title 17

Maternal HBsAg Screening Law

California Health and Safety Code, Section 125085-12590

HIPAA docs (CDC)

**Title 17, California Code of Regulations (CCR), Section 2505**  
**REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES**

(edited date: 09/26/2007)

California Code of Regulations, Title 17, Section 2505 requires laboratories to report laboratory testing results suggestive of the following diseases of public health importance to the local health department:

<b>List (e)(1)</b>	<b>List (e)(2)</b>
<b>Anthrax</b> <b>Avian influenza</b> <b>Botulism</b> <b>Brucellosis</b> <b><i>Burkholderia mallei</i> and <i>pseudomallei</i></b> <b>Plague</b> , animal or human <b>Smallpox</b> (Variola) <b>Tularemia</b> <b>Viral hemorrhagic fever agents</b> (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)	<b>Acid-fast bacilli</b> <b><i>Bordetella pertussis</i></b> <b><i>Borrelia burgdorferi</i></b> <b>Chlamydial infections, including Lymphogranuloma Venereum</b> <b>Cryptosporidiosis</b> <b><i>Cyclospora cayetenensis</i></b> <b>Diphtheria</b> <b>Encephalitis, arboviral</b> <b><i>Escherichia coli</i> STEC, including O157:H7 infection</b> <b>Gonorrhea</b> <b><i>Haemophilus influenzae</i></b> (from sterile site in patient <15 years old) <b>Hepatitis A, acute infection</b> , by IgM antibody test or positive viral antigen test <b>Hepatitis B, acute infection</b> , by IgM anti-HBc antibody test <b>Hepatitis B surface antigen positivity</b> (specify gender of case) <b>Hepatitis C</b> (see instructions below) <b><i>Legionella pneumophila</i></b> <b><i>Listeria monocytogenes</i></b> <b>Malaria</b> <b>Measles (Rubeola), acute infection</b> , by IgM antibody test or positive viral antigen test <b><i>Mycobacterium tuberculosis</i></b> (see instructions below) <b><i>Neisseria meningitidis</i></b> (from sterile site) <b>Rabies</b> , animal or human <b>Rubella</b> , acute infection by IgM antibody test or culture <b><i>Salmonella</i> species, including <i>S. typhi</i></b> (Section 2612 – see below) <b>Shiga toxin</b> (in feces) <b>Syphilis</b> <b><i>Vibrio</i> species infections</b> <b>West Nile virus infection</b>

**WHEN TO REPORT**

These laboratory findings are reportable to the local health officer of the health jurisdiction where the health care provider who first submitted the specimen is located within one (1) hour (List (e)(1) diseases) or within one (1) working day (List (e)(2) diseases) from the time that the laboratory notifies that health care provider or other person authorized to receive the report. If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall notify the local health officer of the jurisdiction in which the health care provider is located within the time specified above from the time the laboratory notifies the referring laboratory that submitted the specimen. If the laboratory is an out-of-state laboratory, the California laboratory that receives a report of such findings shall notify the local health officer in the same way as if the finding had been made by the California laboratory.

## HOW TO REPORT

Laboratory reports must be made in writing and give the following information:

- the date the specimen was obtained,
- the patient identification number,
- the specimen accession number or other unique specimen identifier,
- the laboratory findings for the test performed,
- the date that any positive laboratory findings were identified,
- the name, gender, address, telephone number (if known), and age or date of birth of the patient,
- the name, address, and telephone number of the health care provider who ordered the test.

The notification for **List (e)(1) diseases** shall be reported by telephone within **one (1) hour**, followed by a written report submitted by electronic facsimile transmission or electronic mail within **one (1) working day**, to the local health officer in the jurisdiction where the health care provider who submitted the specimen is located. The notification for **List (e)(2) diseases** shall be submitted by courier, mail, electronic facsimile transmission or electronic mail within **one (1) working day** to the local health officer in the jurisdiction where the health care provider who submitted the specimen is located. Whenever the specimen, or an isolate there from, is transferred between laboratories, a test requisition with the above patient and submitter information shall accompany the specimen. The laboratory that first receives a specimen shall be responsible for obtaining the patient and submitter information at the time the specimen is received by that laboratory.

## ADDITIONAL REPORTING REQUIREMENTS

### **ANTHRAX, AVIAN INFLUENZA, BOTULISM, BRUCELLOSIS, GLANDERS, MELIOIDOSIS, PLAGUE, SMALLPOX, TULAREMIA, and VIRAL HEMORRHAGIC FEVERS**

Whenever a laboratory **receives a specimen** for the laboratory diagnosis of a suspected human case of one of these diseases, such laboratory shall **communicate immediately by telephone** with the Microbial Diseases Laboratory (or, for Avian Influenza, Smallpox or Viral Hemorrhagic Fevers, with the Viral and Rickettsial Disease Laboratory) of the Department of Public Health for instruction.

### **TUBERCULOSIS**

Any laboratory that isolates *Mycobacterium tuberculosis* from a patient specimen must submit a culture to the local public health laboratory for the local health jurisdiction in which the health care provider's office is located as soon as available from the primary isolate on which a diagnosis of tuberculosis was established.

The information listed under "HOW TO REPORT" above must be submitted with the culture.

Unless drug susceptibility testing has been performed by the clinical laboratory on a strain obtained from the same patient within the previous three months or the health care provider who submitted the specimen for laboratory examination informs the laboratory that such drug susceptibility testing has been performed by another laboratory on a culture obtained from that patient within the previous three months, the clinical laboratory must do the following:

- Perform or refer for drug susceptibility testing on at least one isolate from each patient from whom *Mycobacterium tuberculosis* was isolated,
- Report the results of drug susceptibility testing to the local health officer of the city or county where the submitting physician's office is located within **one (1) working day** from the time the health care provider or other authorized person who submitted the specimen is notified, and
- If the drug susceptibility testing determines the culture to be resistant to at least isoniazid and rifampin, in addition, submit one culture or subculture from each patient from whom multidrug-resistant *Mycobacterium tuberculosis* was isolated to the local public health laboratory (as described above).

Whenever a clinical laboratory finds that a specimen from a patient with known or suspected tuberculosis tests positive for acid fast bacillus (AFB) staining and the patient has not had a culture which identifies that acid fast organism within the past 30 days, the clinical laboratory shall culture and identify the acid fast bacteria or refer a subculture to another laboratory for those purposes.

## **MALARIA**

Any clinical laboratory that makes a finding of malaria parasites in the blood film of a patient shall immediately submit one or more such blood film slides for confirmation to the local public health laboratory for the local health jurisdiction where the health care provider is located. When requested, all blood films will be returned to the submitter.

## **HEPATITIS C**

Any laboratory with a positive hepatitis C virus (HCV) test that meets the CDC laboratory criteria for diagnosis of HCV infection in a California resident shall report the positive test to the local health officer.

The following test results are reportable:

- (1) All HCV positive recombinant immunoblot assay (RIBA) tests;
- (2) All HCV RNA positive tests [e.g., nucleic acid tests (NAT)];
- (3) All HCV genotype reports; and
- (4) Anti-HCV reactive by a screening test (e.g., enzyme immunoassay [EIA] or chemiluminescence immunoassay [CIA] with either:
  - (A) The exact signal-to-cut-off (s/co) ratio or index value; or
  - (B) A comment that indicates whether or not the screening test s/co ratio or index value is predictive of a true positive as determined for the particular assay as defined by the CDC in the case definition for "laboratory criteria for diagnosis" of Hepatitis C virus infection, past or present. The url for the s/co ratios that meet the CDC case definition is: [http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc\\_ratios.htm](http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm).

If a laboratory chooses to report a reactive anti-HCV screening test (e.g., EIA or CIA test) with a s/co or index value that is lower than required to meet the CDC case definitions AND does not report the exact s/co or index value (i.e., the laboratory report is positive without a specific s/co or index value reported), then the laboratory report must include a comment to indicate the s/co or index value is low and that supplemental testing (e.g., RIBA or NAT) is recommended by the CDC.

## **SALMONELLA**

California Code of Regulations, Title 17, Section 2612 requires that a culture of the organisms on which a diagnosis of salmonellosis is established must be submitted to the local public health laboratory and then to the State's Microbial Diseases Laboratory for definitive identification.

**All laboratory notifications are acquired in confidence. The confidentiality of patient information is always protected.**



## Maternal HBsAg Screening Law

### California Health and Safety Code Section 125085-12590

125085: As early as possible during prenatal care, a blood specimen obtained pursuant to Section 125080 shall be submitted to a clinical laboratory licensed by the department or to an approved public health laboratory for a test **to determine the presence of hepatitis B surface antigen** and the human immunodeficiency virus (HIV), and the **results shall be reported to** both of the following:

(A) The physician and surgeon or other person engaged in the prenatal care of the women or attending the woman at the time of delivery who ordered the test, and who shall subsequently inform the woman tested.

(B) A positive test result shall be reported to the local health officer, with the information required and within the timeframes established by the department, pursuant to Chapter 4 (commencing with Section 2500) of Title 17 of the California Code of Regulations.

125090. (d) If, during the final prenatal care standard medical tests, the medical records of the pregnant woman do not document a test for rhesus (Rh) blood type, a test for hepatitis B, or a test for HIV, the physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman **at the time of labor or delivery** shall obtain a blood specimen from the woman for the test that has not been documented. . . . **The blood shall be tested by a method that will ensure the earliest possible results**, and the results shall be reported to both of the following: (1) The physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman at the time of delivery. (2) The woman tested.

(e) After the results of the tests done pursuant to this section and Section 125085 have been received, the physician and surgeon or other person engaged in the prenatal care of the pregnant woman or attending the woman at the time of labor, delivery, or postpartum care at the time the results are received shall ensure that the woman receives information and counseling, as appropriate, to explain the results and the implications for the mother's and infant's health, including any follow-up care that is indicated.

**CALIFORNIA**  
**HEALTH AND SAFETY CODE SECTION 125050-125119.5**

**125050.** The department shall administer a statewide program for the prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing for genetic disorders and birth defects.

**125055.** The department shall:

**(a)** Establish criteria for eligibility for the prenatal testing program. Eligibility shall include definition of conditions and circumstances that result in a high risk of a detectable genetic disorder or birth defect.

**(b)** Develop an education program designed to educate physicians and surgeons and the public concerning the uses of prenatal testing and the availability of the program.

**(c)** Ensure that genetic counseling be given in conjunction with prenatal testing at the approved prenatal diagnosis centers.

**(d)** Designate sufficient prenatal diagnosis centers to meet the need for these services. Prenatal diagnosis centers shall have equipment and staff trained and capable of providing genetic counseling and performing prenatal diagnostic procedures and tests, including the interpretation of the results of the procedures and tests.

**(e)** Administer a program of subsidy grants for approved nonprofit prenatal diagnosis centers. The subsidy grants shall be awarded based on the reported number of low-income women referred to the center, the number of prenatal diagnoses performed in the previous year at that center, and the estimated size of unmet need for prenatal diagnostic procedures and tests in its service area. This subsidy shall be in addition to fees collected under other state programs.

**(f)** Establish any rules, regulations, and standards for prenatal diagnostic testing and the allocation of subsidies as the director deems necessary to promote and protect the public health and safety and to implement the Hereditary Disorders Act (Section 27).

**(g)**

**(1)** The department shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibit

**(2)** The prenatal screening fee increase for expanding prenatal screening to include those tests described in paragraph (1) is forty dollars (\$40)

**(3)** The department shall report to the Legislature regarding the progress of the program with regard to implementing prenatal screening for those tests described in paragraph (1) on or before July 1, 2007. The report shall include the costs of screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program

**(4)**

**(A)** The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include the expansion of prenatal screenings, pursuant to paragraph (1), may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts, and shall not be subject to Chapter 2 (commencing with Section 10290) or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology

projects or approval of increases in the duration or costs of information technology projects. This paragraph shall apply to the design, development, and implementation of the expansion, and to the maintenance and operation of the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.

**(B)(i)** The department may adopt emergency regulations to implement and make specific the amendments to this section made during the 2006 portion of the 2005-06 Regular Session in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Section 11346.1 and Section 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

**(ii)** The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

**125060.** The participation by any individual in the prenatal testing program shall be wholly voluntary and shall not be a prerequisite to eligibility for, or receipt of, any other service or assistance from, or to participation in, any other program.

**125065.** All prenatal diagnosis centers shall meet standards developed by the department and shall agree to accept patients from state funded or administered programs, including, but not limited to, Medi-Cal, Regional Centers, Maternal and Child Health, California Children's Services, Genetically Handicapped Persons Program, and Family Planning. Only prenatal diagnosis centers meeting standards developed by the department shall be eligible for reimbursement under these state programs.

**125070.** Laboratories licensed by the department shall not offer the maternal serum-alpha fetoprotein screening test for prenatal detection of neural tube defects of the fetus until the department has developed regulations, under the authorization granted by Section 124980. However, laboratories providing this testing, as of July 21, 1983, may continue to provide this testing until these regulations become operative. The department shall adopt regulations pursuant to this section.

**125075.** Every licensed physician and surgeon or other person attending a newborn infant diagnosed as having had rhesus (Rh) isoimmunization hemolytic disease shall report the condition to the department on report forms prescribed by the department.

**125080.** A licensed physician and surgeon or other person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery shall obtain or cause to be obtained a blood specimen of the woman. Prior to obtaining the blood specimen, the woman shall be notified of the fact that the blood specimen is going to be obtained. If the blood specimen is not obtained prior to delivery, it shall be obtained at the time of delivery.

**125085.**

**(a)** As early as possible during prenatal care, a blood specimen obtained pursuant to Section 125080 shall be submitted to a clinical laboratory licensed by the department or to an approved public health laboratory for a determination of rhesus (Rh) blood type and the results shall be reported to both of the following:

**(1)** The physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman at the time of delivery.

**(2)** The woman tested.

**(b)**

**(1)** In addition, as early as possible during prenatal care, a blood specimen obtained pursuant to Section 125080 shall be submitted to a clinical laboratory licensed by the department or to an approved public health laboratory for a test to determine the presence of hepatitis B surface antigen and the human immunodeficiency virus (HIV), and the results shall be reported to both of the following:

**(A)** The physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman at the time of delivery who ordered the test, and who shall subsequently inform the woman tested.

**(B)** A positive test result shall be reported to the local health officer, with the information required and within the timeframes established by the department, pursuant to Chapter 4 (commencing with Section 2500) of Title 17 of the California Code of Regulations.

**(2)** In the event that other tests to determine hepatitis B infection or HIV infection become available, the department may approve additional tests.

**125090.**

**(a)** Subdivision (a) of Section 125085 shall not be applicable if the licensed physician and surgeon or other person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery has knowledge of the woman's blood type and accepts responsibility for the accuracy of the information.

**(b)** Subdivision (b) of Section 125085 shall not be applicable if the licensed physician and surgeon or other person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery has knowledge that the woman has previously been determined to be chronically infected with hepatitis B or human immunodeficiency virus (HIV) and accepts responsibility for the accuracy of the information.

**(c)** Prior to obtaining a blood specimen collected pursuant to subdivision (b) of Section 125085 or this section, the physician and surgeon or other person engaged in the prenatal care of a pregnant woman, or attending the woman at the time of labor or delivery, shall ensure that the woman is informed of the intent to perform a test for HIV infection, the routine nature of the test, the purpose of the testing, the risks and benefits of the test, the risk of perinatal transmission of HIV, that approved treatments are known to decrease the risk of perinatal transmission of HIV, and that the woman has a right to decline this testing.

**(d)** If, during the final review of standard of prenatal care medical tests, the medical records of the pregnant woman do not document a test for rhesus (Rh) antibody blood type, a test for hepatitis B, or a test for HIV, the physician and surgeon or other person engaged in the prenatal care of the woman, or attending the woman at the time of labor or delivery, shall obtain a blood specimen from the woman for the tests that have not been documented. Prior to obtaining this blood specimen, the provider shall ensure that the woman is informed of the intent to perform the tests that have not been documented prior to this visit, including a test for HIV infection, the routine nature of the test, the purpose of the testing, the risks and benefits of the test, the risk of perinatal transmission of HIV, that approved treatments are known to decrease the risk of perinatal transmission of HIV, and that the woman has a right to decline the HIV test. The blood shall be tested by a method that will ensure the earliest possible results, and the results shall be reported to both of the following:

**(1)** The physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman at the time of delivery.

**(2)** The woman tested.

**(e)** After the results of the tests done pursuant to this section and Section 125085 have been received, the physician and surgeon or other person engaged in the prenatal care of the pregnant woman or attending the woman at the time of labor, delivery, or post partum care at the time the results are received shall ensure that the woman receives information and counseling, as appropriate, to explain the results and the implications for the mother's and infant's health, including any followup testing and care that are indicated.

**(f)** The provisions of Section 125107 for counseling are equally applicable to every pregnant patient covered by subdivisions (c) and (d).

**125095.** The department may adopt regulations as it determines are reasonably necessary for the implementation of the Maternal and Child Health Program Act (Section 27).

**125100.** (a) Clinical laboratories licensed by the department, approved public health laboratories, local health departments, physicians and surgeons, or other persons engaged in the prenatal care of a pregnant woman or in the care of an infant shall maintain and make available to the department information necessary to evaluate, for public health purposes, the effectiveness of testing and followup treatment for the prevention of perinatally transmitted hepatitis B infection.



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service**

**Centers for Disease Control  
and Prevention (CDC)  
Atlanta, GA 30333  
June 21, 2005**

Re: Public Health Implications of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

Dear Colleague:

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule has been in effect since April 14, 2003. The intent of HIPAA is to establish national standards for consumer privacy protection and insurance market reform. Initially, a lack of information and misinterpretation of some HIPAA provisions had a negative impact on the conduct of some time-honored public health activities. In some instances, confusion about the intent and implementation of the rules resulted in health-care providers refusing access by public health officials to patient records for immunization assessment and surveillance purposes. The National Immunization Program (NIP) of the Centers for Disease Control and Prevention (CDC) recognizes that providers are concerned about compliance, and they need clear and accurate information about the practical application of the HIPAA Privacy Rule on public health practices.

NIP has worked closely with Health and Human Services (HHS) Office for Civil Rights, which is the lead agency for interpreting and enforcing HIPAA, and the CDC legal counsel to clarify public health provisions of the Privacy Rule and to disseminate information to our partners at the state and local levels. In August 2003, NIP sent the first of a series of guidance statements to Immunization Program Managers and State Epidemiologists in response to states' requests for clarification regarding access to patient records to conduct VFC and AFIX site visits. The mailing included a one-page *HIPAA and Public Health Fact Sheet* that provided a brief summary of HIPAA and Privacy Rule definitions, and *HIPAA and Public Health Site Visits: Access to Patient Records during AFIX and VFC Visits*, a short document containing responses to specific questions asked by the states regarding disclosure of patient health information without prior authorization during VFC and AFIX provider site visits. The CDC Office of General Counsel, which provides legal advice for CDC programs on issues such as implementation of HIPAA, prepared the responses to these questions. These materials have been very effective in addressing providers' concerns about HIPAA and facilitating traditional public health practice.

Almost two years after the effective date of the Privacy Rule, several states have requested written materials clarifying other questions and concerns about HIPAA. Enclosed is the second in the series of guidance statements, *HIPAA and Perinatal Hepatitis B Prevention*. The original *HIPAA and Public Health Fact Sheet* is also enclosed. Additional information is available on the Office for Civil Rights website at <http://www.hhs.gov/ocr/hipaa> and in the MMWR, HIPAA Privacy Rule and Public Health: <http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf>. We hope you will find this information helpful as you educate your provider groups and work with your respective legal offices on HIPAA issues.

Sincerely,

Stephen L. Cochi, M.D., M.P.H.  
Captain, United States Public Health Service  
Acting Director  
National Immunization Program

Enclosures

cc:

President, Association of State and Territorial Health Officials  
President, Association of Immunization Managers  
President, Council of State and Territorial Epidemiologists

# **Centers for Disease Control and Prevention National Immunization Program**

## **HIPAA and Perinatal Hepatitis B Prevention**

### **Responses to Frequently Asked Questions about Perinatal Hepatitis B Prevention**

This guidance is intended to give health care providers and public health agencies specific information regarding the HIPAA Privacy Rule and how it impacts perinatal hepatitis B prevention. Several frequently asked questions posed to the CDC legal counsel for interpretation are presented below. Additional sources of information and reference materials available on the internet are also included.

**Q. 1. Does HIPAA permit providers, hospitals, and laboratories to report HBsAg-positive women to state and local health departments (including local health agencies and local boards of health) without the authorization of the individual, regardless of whether the state has a reporting law?**

**A. 1. Yes.** Under 45 CFR §164.512(b)(1)(i) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes. In addition, under 45 CFR §164.512(a), covered entities may disclose protected health information to public health authorities if the disclosure is required by law. A specific mandate to report is not required for disclosure. In states that do not have a law that specifically mandates the reporting of maternal HBsAg status, notifiable disease reporting laws mandate reporting of hepatitis B.

**Q. 2. Does HIPAA permit providers and hospitals to disclose patient information to state and local health departments ((including local health agencies and local boards of health) without the authorization of the individual, for perinatal case management (e.g. immunization, prophylaxis, and post vaccination serology)?**

**A. 2. Yes.** Under 45 CFR §164.512(b)(1)(i) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes including disease prevention or control.

**Q. 3. Can patient records be reviewed by state and local health department staff and their contractual agents when conducting quality assurance activities (e.g. chart reviews to assess HBsAg screening rates and appropriate prophylaxis), case investigations and/or disease outbreak activities?**

**A. 3. Yes.** As explained above, under 45 CFR §164.512(b)(1)(i) of the HIPAA Privacy Rule, covered entities may disclose protected health information without authorization to public health authorities that are authorized by law to collect such information for public health purposes.

**Q. 4. Does the HIPAA Privacy Rule apply to Indian Health Services and tribal clinics?**

**A. 4.** Yes. The HIPAA Privacy Rule governs the use and disclosure of protected health information by covered entities (health plans, clearinghouses, and providers who transmit specified transactions electronically). The definition of health plans (45 CFR §160.103) includes the Indian Health Service (IHS) and programs under the Indian Health Care Improvement Act, 25 U.S.C. 1601 et seq. (45 CFR 160.103(1)(xii)).

**Resources**

Office for Civil Rights (responsible for enforcing the Privacy Rule) website:  
([www.hhs.gov/ocr/hipaa](http://www.hhs.gov/ocr/hipaa))

CDC/DHHS guidance on the Privacy Rule and Public Health, available at  
<http://www.cdc.gov/mmwr/pdf/other/m2e411.pdf>.

# **Centers for Disease Control and Prevention National Immunization Program**

## **Health Insurance Portability and Accountability Act and Public Health**

### **Fact Sheet**

#### **What is HIPAA?**

The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191) established a national floor of consumer privacy protection and marketplace reform. Some key provisions include: insurance reforms, privacy and security, administrative simplification, and cost savings.

#### **What is the HIPAA Privacy Rule?**

HIPAA required Congress to enact privacy legislation by August 1999 or the Secretary of DHHS was to develop regulations protecting privacy. The HIPAA Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) sets national minimal standards for protected health information.

#### **Implications for Public Health**

The Privacy Rule strikes a balance between protecting patient information and allowing traditional public health activities to continue. Disclosure of patient health information without the authorization of the individual is permitted for purposes including but not limited to 1) disclosures required by law (45 CFR § 164.512(a)) or 2) for “public health activities and purposes.” This includes disclosure to “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. . . , and the conduct of public health surveillance, . . . investigations, and. . . interventions.” (45 CFR § 164.512(b)(i))

#### **Definition of Public Health Authority**

Defined as “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 mandates.” (45 CFR § 164.501)

# Appendix C

## Case Management

Components of Case Management Programs to Prevent Perinatal Hepatitis  
B Virus Infection

Hepatitis Infection Control Measures

### ***Parent letters***

- Baby Care (Santa Barbara)
- Vaccine reminder letter (NH)
- Vaccine/serology letter



## **Components of Case Management Programs to Prevent Perinatal Hepatitis B Virus (HBV) Infection**

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### **Test all pregnant women for hepatitis B surface antigen (HBsAg)**

- Health-care providers should test all pregnant women for HBsAg during each pregnancy.
- HBsAg testing should be incorporated into standard prenatal testing panels (e.g., blood type, HIV infection, Rh factor, rubella antibody titer, syphilis infection) used by all practitioners caring for pregnant women.
- Women who test negative for HBsAg but have risk factors (>1 sex partner in past 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, HBsAg-positive sex partner) should be vaccinated against hepatitis B and should be retested in the third trimester.
- Delivery hospitals should ensure that all pregnant or delivering women have been tested for HBsAg before hospital discharge.
- Reporting of maternal HBsAg test status should be included on hospital-based electronic birth certificates or newborn metabolic screening results.

### **Report and track HBsAg-positive women**

- All HBsAg-positive test results for pregnant women and women of childbearing age should be reported to state or local perinatal hepatitis B prevention programs.
- Case data for HBsAg-positive pregnant women should be entered into case management tracking systems.

### **Provide prenatal HBsAg testing records to delivery hospitals**

- HBsAg test results should be included on all forms (hard copy and electronic) used by practitioners to record and transmit information about care during pregnancy.
- For all pregnant women, a copy of the original laboratory report of HBsAg test results should be transferred from the prenatal care provider to the delivery hospital.
- Health-care providers should document that HBsAg-positive pregnant women have received a copy of the original laboratory report, that a copy of the original laboratory report has been transferred from the prenatal care provider to the delivery hospital, and that patients have been informed of their HBsAg test result and advised to notify delivery staff.

### **Identify and manage infants born to HBsAg-positive mothers**

- Delivery hospitals should implement policies and procedures to ensure identification and initiation of postexposure immunization of infants born to HBsAg-positive mothers.
- Delivery hospitals should document the date and time of birth and the date and time of administration of hepatitis B immune globulin (HBIG) and hepatitis B

**Source:** CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: immunization of infants, children, and adolescents. *MMWR* 2005 (RR-16).



vaccine for all infants born to HBsAg-positive mothers and provide this information to both the parent and the pediatrician.

### **Identify and manage infants born to mothers without HBsAg test results**

- Delivery hospitals should implement policies and procedures to ensure identification of and initiation of postexposure vaccination of infants born to mothers with unknown HBsAg status at delivery.
- Delivery hospitals should document the date and time of birth, date and time of administration of hepatitis B vaccine, and maternal HBsAg test results for all infants born to mothers with unknown HBsAg status at time the of delivery.

### **Complete the hepatitis B vaccine series**

- Pediatric care providers should document the dates of administration of all doses of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers.

### **Complete post-vaccination testing**

- Pediatric care providers should document the results of testing for HBsAg and anti-HBs after completion of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers.
- HBsAg-positive test results in infants should be reported to CDC via the National Notifiable Diseases Surveillance System.

### **Monitor and evaluate the case management program**

- Annually, each program should track
  - the number of HBsAg-positive pregnant women
  - the number of infants born to HBsAg-positive pregnant women
  - the proportion of infants born to HBsAg-positive mothers receiving postexposure immunoprophylaxis within 12 hours of birth, on-time completion of the vaccination series, and post-vaccination serologic testing for HBsAg and anti-HBs
  - the number of delivering mothers with unknown HBsAg status
  - the proportion of infants born to mothers with unknown HBsAg status receiving hepatitis B vaccine within 12 hours of birth
- Programs should determine reasons for
  - >10% difference between expected and identified number of HBsAg-positive pregnant women
  - <90% completion rates for administration of HBIG and hepatitis B vaccine within 12 hours of birth, on-time completion of the vaccination series, and post-vaccination testing for infants born to HBsAg-positive mothers
  - <90% completion rates for administration of hepatitis B vaccine within 12 hours of birth for infants born to mothers with unknown HBsAg status

**Source:** CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: immunization of infants, children, and adolescents. *MMWR* 2005 (RR-16).

# Hepatitis B Infection Control Measures

## The HBV-infected person should be advised to

- Inform sex partners of their status
- Use methods (e.g. condoms) to prevent sexual transmission of HBV to a partner who is not known to be immune
- Inform dentists and doctors they are hepatitis B positive so they can be evaluated and managed appropriately
- Avoid sharing personal items such as toothbrushes and razors that may have come in contact with blood
- Never share syringes and needles
- Avoid donating blood, plasma, body organs, tissue, or sperm
- Cover all cuts and open sores

## Contacts of the HBV-infected person should be advised to

- Use methods (e.g. condoms) to protect themselves from exposure to semen or vaginal secretions, unless they have been found to be immune after vaccination or due to previous infection
- Avoid sharing personal items such as toothbrushes and razors with the infected person
- Never share syringes and needles

## HBV is not spread by

- Breastfeeding, kissing, sharing eating utensils or dishes, or casual contact

**Date**

**Mom's Name**

**Address**

**Address**

Dear Ms. **Mom's Name**

This letter is being given to you so that you may inform your baby's doctor that your baby is at high risk for hepatitis B. Your blood test showed that you have been infected with hepatitis B and you may be infectious to others.

To protect your baby from infection, it is important that your new infant receive a series of hepatitis B shots. Your baby should also get a shot of hepatitis B immune globulin at birth. Make sure that your baby receives all the hepatitis B vaccine shots. A blood test will be done a few months after the third dose is given to make sure that your baby is protected against hepatitis B.

Other members of your household and your partner may also need to receive the hepatitis B vaccine shots, or be tested to see if they are protected against hepatitis B.

Please take this letter to your baby's doctor on the baby's first visit. Also take the yellow immunization card given to you at the hospital. If you change your baby's doctor please contact us and also inform the new doctor that your baby is at **high risk** for hepatitis B.

If you have any additional questions or concerns, please discuss them with your doctor, or call me at **(###) ###-####**. Thank you very much.

Sincerely,

**Coordinator's Name**

Perinatal Hepatitis B Coordinator

**DATE**

*Note: revise wording depending on which dose is due, or if using for serologic testing*

**MOTHER'S NAME**  
**STREET ADDRESS**  
**CITY, STATE ZIP**

Dear MS **LASTNAME**:

Your child, (**BABY'S NAME**), is due for his/her (*second, third, or fourth*) *hepatitis B immunization (OR is due for his/her hepatitis test)*. To make sure your baby is protected from hepatitis B disease, it is very important that he/she receives all hepatitis B shots on schedule and is tested to make sure he/she is protected.

Please make an appointment as soon as possible with your baby's health care provider for your baby to get this important shot (*OR test*).

I understand that your child's health care provider is (**DOCTOR'S NAME**). If there has been a change in your child's health care provider or if you have questions, please call me at (###) ###-####

Thank you.

Sincerely,

**COORDINATOR NAME**  
Perinatal Hepatitis B Coordinator  
\_\_\_\_\_ Department, Health Jurisdiction or County

Cc: HEALTH CARE PROVIDER

**Date**

Dear **Mom's Name**

Our records indicate that your baby is now due for the hepatitis B vaccine. Mothers who are hepatitis B positive can pass the hepatitis B virus to their babies at birth. For complete protection, your baby needs (X) additional doses of hepatitis B vaccine. After your baby receives all of the vaccines and is at least 9 months of age she or he will need to be tested to make sure that *she or he* is protected against hepatitis B.

At this time, our records indicate that your baby needs the following:

- \_\_\_\_\_ Hepatitis B vaccine # 2
- \_\_\_\_\_ Hepatitis B vaccine # 3
- \_\_\_\_\_ Hepatitis B vaccine # 4

You can take this letter to your physician. **Please call me when your baby receives his or her shots and/or testing so I can update our records.** If you do not have a pediatrician your child can be vaccinated at the **Project Name** Health Department free of charge.

Because of your hepatitis B status, it is very important for your baby to receive the shots on the recommended schedule. Please remember to return to your pediatrician when your baby is 9 months of age for the post-test; this test is the only sure way of knowing whether or not your child is immune to the Hepatitis B virus.

If you have any questions, you can call me at **(###) ###-####**.

Sincerely,

**Coordinator's Name**

Perinatal Hepatitis B Prevention Program



# Appendix D

## Reporting

Confidential HBsAg+ Case/Household Management Report Form

Perinatal Hepatitis B Case Report Form

Case Transfer Forms- in state

Case Transfer Forms- out of state

California County/Jurisdiction Codes





**INFANT(S)**

1. **Case/Household Identification No.** \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (county of origin)  
County mm yy

2. **Case/Household Identification No.** \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_ (transfer county)  
County mm yy

3. **This pregnancy resulted in a: (Check all that apply)**

- a. Live birth → Number of live infant(s) born (1,2 etc): \_\_\_\_\_
- b. Fetal death → Number of fetal deaths: \_\_\_\_\_
- c. Miscarriage or abortion →  (check box if 'yes')

4. **Actual source of payment for delivery?**

- 1  Medi-Cal
- 2  Other/Govt. 3<sup>rd</sup> party payer
- 3  Private 3<sup>rd</sup> party payer
- 4  Self-pay
- 5  Low income: \_\_\_\_\_
- 9  Other/Unk: \_\_\_\_\_

5. **Actual delivery hospital?**

- 1  Public hospital
- 2  Private hospital
- 3  Outside of hospital
- 9  Unknown

**Infant #** \_\_\_\_ If only one live infant, enter "1". If two or more live infants, attach additional page for each infant, assign the same case/household ID number on this form, number each infant accordingly (1, 2, 3 etc.) and complete the infant section only.

6. **Name:** \_\_\_\_\_  
Last First MI

7. **Birth date:** \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy

8. **Sex:** 1  Male 2  Female

**Immunization Record:**

9. **HBIG**
- a.  Not given
  - b. Age when given (hours) \_\_\_\_\_
  - c. Date when given \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
10. **Hep B Vac1**
- a.  Not given
  - b. Age when given (hours) \_\_\_\_\_
  - c. Date when given \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
11. **Hep B Vac2** Date when given \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
12. **Hep B Vac3** Date when given \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
13. **Hep B Vac4** Date when given \_\_\_\_/\_\_\_\_/\_\_\_\_  
(If applicable) mm dd yyyy

**Post-Vaccination Follow-up Serology Record:**

14. a. **HBsAg test done?** 1  Yes 2  No 9  Unk
- If 'Yes': b. Date done \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
- c. Result: 1  Pos 2  Neg 9  Unk
15. a. **Anti-HBs test done?** 1  Yes 2  No 9  Unk
- If 'Yes': b. Date done \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
- c. Result: 1  Pos 2  Neg 9  Unk

**Second Series Immunization and Repeat Post-Vaccination Serology Record:**

16. a. **If 'Neg', did infant receive a 2<sup>nd</sup> series of vaccine?**
- 1  Yes 2  No 9  Unk
- b. **Hep B Vac1** \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
- c. **Hep B Vac2** \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
- d. **Hep B Vac3** \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
17. a. **Was HBsAg test done after 2<sup>nd</sup> series?**
- 1  Yes 2  No 9  Unk
- b. Date done \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
- c. Result: 1  Pos 2  Neg 9  Unk
18. a. **Was Anti-HBs test done after 2<sup>nd</sup> series?**
- 1  Yes 2  No 9  Unk
- b. Date done \_\_\_\_/\_\_\_\_/\_\_\_\_  
mm dd yyyy
- c. Result: 1  Pos 2  Neg 9  Unk

**Lost to Follow-up (for mother and infant):**

19. If infant does not complete the Hep B vaccine series or post-vaccination serology testing, check all of the reasons that apply.
- a.  Infant completed Hep B series but was lost before serology testing was completed
  - b.  Infant diagnosed with acute Hep B before vaccine series was completed
  - c.  Infant could never be located
  - d.  Located mother/household but later lost to follow-up
  - e.  Infant moved or transferred to another county within the state for follow-up and don't know whether vaccination series was completed or not
  - f.  Infant moved out of the state  
new address: \_\_\_\_\_
  - g.  Infant moved out of the country
  - h.  Compliance problem with family
  - i.  Infant died
  - j.  Other (specify): \_\_\_\_\_

**CONTACTS**

1. **Case/Household Identification No.** \_\_\_\_ - \_\_\_\_ - \_\_\_\_ - \_\_\_\_ (county of origin)  
County mm yy

2. **Case/Household Identification No.** \_\_\_\_ - \_\_\_\_ - \_\_\_\_ - \_\_\_\_ (transfer county)  
County mm yy

**3. All Household Contacts**

- a. \_\_\_\_ Total number of household contacts identified (a = b+c+d+j+k)
- b. \_\_\_\_ Number already known to be chronically infected or immune due to prior infection of Hep B
- c. \_\_\_\_ Number previously immunized
- d. \_\_\_\_ Number seroscreened for Hep B markers (usually anti-HBc)
  - e. \_\_\_\_ Of those seroscreened, number age ≤ 5 years
  - f. \_\_\_\_ Of those seroscreened, number age ≥ 6 years
  - g. \_\_\_\_ Of those seroscreened, number found to be already infected or immune
  - h. \_\_\_\_ Of those seroscreened, number found to be susceptible (i.e. negative for Hep B markers)
    - i. \_\_\_\_ Of those found to be susceptible, number vaccinated
- j. \_\_\_\_ Number vaccinated without screening
- k. \_\_\_\_ Number lost to follow-up

**4. Household Contacts Receiving Immunization (list in any order)**

Please enter the codes in ( ) into the spaces below.

	a.	b.	c.	d.	e.
	Name (optional)	Age: 0-5 yrs (1); 6-21 yrs (2); ≥22 yrs. (3)	Hep B Vac 1 given? Yes (1); No (2); Unk (9)	Hep B Vac 2 given? Yes (1); No (2); Unk (9)	Hep B Vac 3 given? Yes (1); No (2); Unk (9)
Contact 1					
Contact 2					
Contact 3					
Contact 4					
Contact 5					
Contact 6					

**5. Lost to Follow-Up**

If any of the household contacts listed above does not complete the 3-dose series, check all of the reasons that apply.

- a.  Contact(s) located but later lost to follow-up
- b.  Contact(s) found to be already infected or immune after series was started
- c.  Contact(s) moved to another county within the state for follow-up and don't know whether vaccination series was completed or not
- d.  Contact(s) moved out of the state
- e.  Contact(s) moved out of the country
- f.  Contact(s) died
- g.  Compliance problem with family
- h.  Other (specify): \_\_\_\_\_

1 Case/Household Identification No. \_\_\_\_ - \_\_\_\_ - \_\_\_\_ (county of origin)  
County mm yy

2 Case/Household Identification No. \_\_\_\_ - \_\_\_\_ - \_\_\_\_ (transfer county)  
County mm yy

**Optional worksheet (Do not send to State)**

Name \_\_\_\_\_

Household address(es)/phone(s) \_\_\_\_\_  
 \_\_\_\_\_

Translator needed?  YES  NO Mother's language \_\_\_\_\_

Staff person assigned to case/household \_\_\_\_\_ Delivery hospital \_\_\_\_\_

Provider type \_\_\_\_\_ Provider type \_\_\_\_\_

Physician name \_\_\_\_\_ Physician name \_\_\_\_\_

Clinic address(es) \_\_\_\_\_ Clinic address(es) \_\_\_\_\_

Phone(s) \_\_\_\_\_ Phone(s) \_\_\_\_\_

**Infant(s)**      Dates Doses Due/Given= 

Due
Given

Name(s)	Date of Birth	HBIG/Vac #1	Vac #2	Vac #3	Vac 4	PVS*
1.						
2.						

\*Post Vaccination Serology Testing

**Household Contacts**      Dates Doses Due/Given= 

Due
Given

Name(s)	DOB	Sex	Date Referred	Serology Results	Vac #1	Vac #2	Vac #3	Notes
1.								
2.								
3.								
4.								
5.								
6.								



# PERINATAL HEPATITIS B CASE REPORT

Mail to: California Department of Public Health  
 Immunization Branch  
 850 Marina Bay Parkway  
 Building P, 2<sup>nd</sup> Floor, MS 7313  
 Richmond, CA 94804-6403  
 OR Fax to: (510) 620-3949

*This form is to be used for infants aged 1-24 months found to be infected with hepatitis B virus*

## CASE IDENTIFICATION AND DEMOGRAPHICS

PATIENT'S NAME—Last		First	Middle initial	PHONE ( )	
STREET ADDRESS		CITY	STATE	ZIP	COUNTY
DOB (month/day/year) / /	AGE (enter age and check one) <input type="checkbox"/> Days <input type="checkbox"/> Weeks <input type="checkbox"/> Months <input type="checkbox"/> Years		SEX <input type="checkbox"/> M <input type="checkbox"/> F	COUNTRY OF BIRTH <input type="checkbox"/> USA <input type="checkbox"/> OTHER: _____	DATE OF REPORT / /
ETHNICITY (check one) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Non-Hispanic/Non-Latino <input type="checkbox"/> Unknown	RACE (check all that apply) <input type="checkbox"/> Black/African-American <input type="checkbox"/> Asian: Please specify: _____ <input type="checkbox"/> Pacific Islander: Please specify: _____ <input type="checkbox"/> Native American/Alaskan Native <input type="checkbox"/> Asian Indian <input type="checkbox"/> Hmong <input type="checkbox"/> Thai <input type="checkbox"/> Native Hawaiian <input type="checkbox"/> White <input type="checkbox"/> Cambodian <input type="checkbox"/> Japanese <input type="checkbox"/> Vietnamese <input type="checkbox"/> Guamanian <input type="checkbox"/> Unknown <input type="checkbox"/> Chinese <input type="checkbox"/> Korean <input type="checkbox"/> Other Asian: _____ <input type="checkbox"/> Samoan <input type="checkbox"/> Other: _____ <input type="checkbox"/> Filipino <input type="checkbox"/> Laotian <input type="checkbox"/> Other Pacific Islander: _____				
REASONS FOR TESTING (check all that apply) <input type="checkbox"/> Symptoms of acute hepatitis <input type="checkbox"/> Evaluation of liver enzymes <input type="checkbox"/> Postvaccination serologic testing <input type="checkbox"/> Other: _____			WAS INFANT ENROLLED IN CA PHPP? (If 'Yes' enter ID below) <input type="checkbox"/> Yes <input type="checkbox"/> No: Why not enrolled? : _____ <input type="checkbox"/> Unknown		
PHYSICIAN NAME (name, facility)		PHYSICIAN PHONE ( )	CMR ID	PHPP ID	

## CLINICAL AND DIAGNOSTIC DATA

SYMPTOMATIC? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	SYMPTOMS (check all) <input type="checkbox"/> Jaundice <input type="checkbox"/> Diarrhea <input type="checkbox"/> Dark urine <input type="checkbox"/> Anorexia <input type="checkbox"/> Other: _____	ONSET OF SYMPTOMS / /	HOSPITALIZED? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk	DIED OF HEPATITIS? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk
		DIAGNOSIS DATE (test date) / /	ADMIT DATE / /	DATE OF DEATH / /

INFANT'S HEPATITIS B DIAGNOSTIC TESTS (required)					MOTHER'S INFORMATION				
	Positive	Negative	Unk	Month/Day/Year	MOTHER'S ETHNICITY <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Non-Hispanic/Non-Latino <input type="checkbox"/> Unknown			MOTHER'S RACE (please specify) <input type="checkbox"/> Asian: _____ <input type="checkbox"/> Black/African-American <input type="checkbox"/> Native American/Alaskan Native <input type="checkbox"/> Pacific Islander: _____ <input type="checkbox"/> White <input type="checkbox"/> Unknown <input type="checkbox"/> Other: _____	
HBsAg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___					
anti-HBs	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___					
anti-HBc total	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___					
anti-HBc IgM	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___					
HBeAg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___					
Anti-HBe	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___					
Other _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___					

INFANT'S LIVER ENZYME LEVELS AT DIAGNOSIS				Month/Day/Year	MOTHER'S COUNTRY OF BIRTH <input type="checkbox"/> USA <input type="checkbox"/> OTHER: _____			
ALT [SGPT] Result _____	Upper limit normal _____			___/___/___	WAS MOTHER CONFIRMED HBsAg POSITIVE PRIOR TO OR AT DELIVERY? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk			
AST [SGOT] Result _____	Upper limit normal _____			___/___/___	IF 'No', WAS MOTHER CONFIRMED HBsAg POSITIVE AFTER DELIVERY? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk			
Billirubin _____				___/___/___				

INFANT'S HEPATITIS B VACCINE HISTORY					MOTHER'S HEPATITIS B DIAGNOSTIC TESTS				
Dose received	Age in hours if <24	Month/Day/Year	Date unk			Positive	Negative	Unk	MM/DD/YYYY
<input type="checkbox"/> HBIG	_____	___/___/___	<input type="checkbox"/>			HBsAg <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___
<input type="checkbox"/> Dose #1	_____	___/___/___	<input type="checkbox"/>			HBeAg <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___
<input type="checkbox"/> Dose #2	_____	___/___/___	<input type="checkbox"/>			anti-HBe <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___
<input type="checkbox"/> Dose #3	_____	___/___/___	<input type="checkbox"/>			Other _____ <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	___/___/___
<input type="checkbox"/> Dose #4	_____	___/___/___	<input type="checkbox"/>			HBV DNA _____			___/___/___
<input type="checkbox"/> None	<input type="checkbox"/> Unknown								

PERINATAL HEPATITIS B INFORMATION*					DID MOTHER RECEIVE ANTIVIRAL TREATMENT (e.g. lamivudine) OR HBIG DURING PREGNANCY? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk				
<p><b>Case definition:</b> HBsAg positivity in any infant aged &gt;1-24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother</p> <p><b>Postexposure prophylaxis:</b> All infants born to HBsAg-positive women should receive single-antigen hepatitis B vaccine and HBIG ≤12 hours of birth and complete the vaccine series according to the recommended schedule with the final dose administered after age 24 weeks.</p> <p><b>Postvaccination serologic testing:</b> Testing for anti-HBs and HBsAg should be performed after completion of the vaccine series (or 3<sup>rd</sup> dose), at age 9—18 months.</p>					NOTES				
COMPLETED BY		LHD	DATE COMPLETED / /	PHONE ( )	REPORT TO CDPH / /				

\*See the Hepatitis B Quicksheet for additional information

**OPTIONAL HOUSEHOLD MANAGEMENT/FOLLOW-UP**

<i>Name</i>	Age	Gender	Relationship to case	Hepatitis B status			CA PHPP ID (if applicable)
				Immune (anti-HBs positive)	Infected (HBsAg positive)	Unknown	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**NOTES**



# Perinatal Hepatitis B Prevention Program In-State Case Transfer Form

This form is for case transfers within California.

**County of Transfer Information:** \_\_\_\_\_  
Name of County

Name of Coordinator \_\_\_\_\_

E-mail \_\_\_\_\_ Phone ( \_\_\_\_\_ ) \_\_\_\_\_

Fax ( \_\_\_\_\_ ) \_\_\_\_\_

Date of Transfer \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Case Transfer ID number \_\_\_\_\_  
co mm yy

**County of Origin Information:** \_\_\_\_\_  
Name of County

Name of Coordinator \_\_\_\_\_

E-mail \_\_\_\_\_ Phone ( \_\_\_\_\_ ) \_\_\_\_\_

Fax ( \_\_\_\_\_ ) \_\_\_\_\_

Name of Mother \_\_\_\_\_ Name of Infant \_\_\_\_\_

New Contact information \_\_\_\_\_

Date of Transfer \_\_\_\_ / \_\_\_\_ / \_\_\_\_

Case ID Number \_\_\_\_\_  
co mm yy

The State Perinatal Hepatitis B Program  HAS  HAS NOT been notified of this transfer

- |                      |  |
|----------------------|--|
| <b>Instructions:</b> | <ul style="list-style-type: none"> <li>• This form is for case transfers within the state.</li> <li>• Both counties (County of Transfer and County of Origin) should keep a copy of this transfer form in their respective records.</li> <li>• For County of Transfer - Send completed form to County of Origin to acknowledge receipt of transfer.</li> <li>• For County of Origin - If form has <u>not</u> been received within 2 weeks from date of transfer, then follow-up with the coordinator in the County of Transfer.</li> </ul> |
|----------------------|--|



# Perinatal Hepatitis B Prevention Program Out-of-State Case Transfer Form

This form is for case transfers out of California.

**State of Transfer Information:** \_\_\_\_\_  
Name of State

Name of Coordinator \_\_\_\_\_

E-mail \_\_\_\_\_ Phone ( \_\_\_\_\_ ) \_\_\_\_\_

Fax ( \_\_\_\_\_ ) \_\_\_\_\_

Date of Transfer \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

**California County of Origin Information:** \_\_\_\_\_  
Name of County

Name of Coordinator \_\_\_\_\_

E-mail \_\_\_\_\_ Phone ( \_\_\_\_\_ ) \_\_\_\_\_

Fax ( \_\_\_\_\_ ) \_\_\_\_\_

Name of Mother \_\_\_\_\_ Name of Infant \_\_\_\_\_

New Contact information \_\_\_\_\_

Date of Transfer \_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_

Case ID Number \_\_\_\_\_  
co mm yy

- Instructions:**
- This form is for case transfers out of California.
  - The County of Origin should keep a copy of this transfer form in their record.
  - Send completed form to the state Perinatal Hepatitis B Prevention Program.

## California County/Jurisdiction Codes

<u>Code</u>	<u>County/Jurisdiction</u>	<u>Code</u>	<u>County/Jurisdiction</u>
01	Alameda	32	Plumas
02	Alpine	33	Riverside
03	Amador	34	Sacramento
04	Butte	35	San Benito
05	Calaveras	36	San Bernardino
06	Colusa	37	San Diego
07	Contra Costa	38	San Francisco
08	Del Norte	39	San Joaquin
09	El Dorado	40	San Luis Obispo
10	Fresno	41	San Mateo
11	Glenn	42	Santa Barbara
12	Humboldt	43	Santa Clara
13	Imperial	44	Santa Cruz
14	Inyo	45	Shasta
15	Kern	46	Sierra
16	Kings	47	Siskiyou
17	Lake	48	Solano
18	Lassen	49	Sonoma
19	Los Angeles	50	Stanislaus
20	Madera	51	Sutter
21	Marin	52	Tehama
22	Mariposa	53	Trinity
23	Mendocino	54	Tulare
24	Merced	55	Tuolumne
25	Modoc	56	Ventura
26	Mono	57	Yolo
27	Monterey	58	Yuba
28	Napa	59	Berkeley City
29	Nevada	60	Long Beach City
30	Orange	61	Pasadena City
31	Placer		



# Appendix E

## Working with Providers

### ***Prenatal provider***

- Prenatal provider PHPP Quicksheet
- CDC Prenatal Care Provider Procedures
- Follow-up on HBsAg+ Woman (LA)
- Delivery Alert (CC Co)
- Provider HBsAg+ Report to LHD Fax (MN)

### ***Birth Hospital***

- Labor & Delivery PHPP Quicksheet
- Sample birth dose letter to hospital decision makers (Santa Barbara)
- Guidelines for Standing Orders in Labor & Delivery Units (IAC)
- Preventing Perinatal Hepatitis B (ALC)
- List of Women Expected to Deliver (FL)
- Please fax delivery info to LHD (NH)
- Hospital Report Form (MN)

### ***Pediatric provider***

- PHPP Pediatric Quicksheet
- What does the PHBP do? (Contra Costa)
- Vaccine and serology info (NH)
- PVS reminder letter (FL)





# Preventing Perinatal Hepatitis B

## *Guidelines for Prenatal Care Providers*

From the Advisory Committee on Immunization Practices (ACIP) Recommendations, December 2005\*

### TEST

- **California law requires that physicians test all pregnant women for hepatitis B surface antigen (HBsAg)** before or at the time of delivery. HBsAg testing should be part of a standard prenatal panel used by all practitioners caring for pregnant women.
- **Laboratories** that provide HBsAg testing of pregnant women should use a test that is approved or licensed by the FDA and should follow the manufacturer's labeling. Repeat testing and confirmation of positive HBsAg results are required.
- **Test HBsAg-positive pregnant women for HBeAg** (hepatitis B e antigen), because HBeAg positive women are at increased risk of transmitting hepatitis B to their infants. HBeAg-positive pregnant women should be referred to a gastroenterologist for possible antiviral treatment during pregnancy.
- **Repeat HBsAg testing on HBsAg-negative women at the time of delivery if** the woman has clinical hepatitis or if she was at risk for hepatitis B exposure during pregnancy. Risk factors include recent intravenous drug use, an HBsAg-positive sex partner, more than one sex partner in the past 6 months, or treatment for a sexually transmitted disease [ACIP, American College of Obstetrics and Gynecology (ACOG)].

### REPORT

- **Report any pregnant woman with a positive HBsAg** result to the local health department. Screening pregnant women and reporting HBsAg-positive persons are legal requirements of the state of California (CA Code of Regulations, Section 125085).
- **Send a copy of the lab report** documenting the woman's HBsAg status to the birth hospital and to the health care provider who will care for the infant, if known.

### VACCINATE

- **Vaccinate** pregnant women who are HBsAg-negative, have not been vaccinated, and are at risk for infection with hepatitis B virus.

### REFER AND INFORM

- **Refer** HBsAg positive women to appropriate counseling and medical management.
- **Inform** the HBsAg positive woman that it is safe to begin breastfeeding after delivery. Administration of HBIG and the recommended hepatitis B vaccine series should eliminate any theoretical risk of transmission through breastfeeding.

**Infants born to HBsAg-positive mothers** should receive hepatitis B immunoglobulin (HBIG) and a dose of single-antigen hepatitis B vaccine within 12 hours of birth.

\* A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States, Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: Immunization of Infants, Children, and Adolescents, MMWR, December 23, 2005 / 54(RR16);1-23 [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s\\_cid=rr5416a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s_cid=rr5416a1_e)



## **Prenatal Care Provider Policies and Procedures to Prevent Perinatal Hepatitis B Virus Transmission**

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Prenatal care providers should test every woman for hepatitis B surface antigen (HBsAg) during an early prenatal visit (e.g., in the first trimester), even if a woman has been previously vaccinated or tested.

In addition, prenatal care settings should incorporate each of the following actions into their policies and protocols:

### **For a pregnant woman with a *positive* HBsAg test result**

- Report the positive test result to the health department.
- Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg status to the hospital where the delivery is planned and to the health-care provider who will care for the newborn.
- Attach an alert notice or sticker to the woman's medical record to remind the delivery hospital/nursery that the infant will need hepatitis B vaccine and HBIG at birth.
- Educate the mother about the need for immunoprophylaxis of her infant at birth, and obtain consent for immunoprophylaxis before delivery. Consider printing additional reminder notices for mothers about the importance of immunoprophylaxis for infants and attaching the notices to the inside front or back cover of the medical record.
- Advise the mother that all household, sexual, and needle-sharing contacts should be tested for HBV infection and vaccinated if susceptible.
- Provide information to the mother about hepatitis B, including modes of transmission, prenatal concerns (e.g., infants born to HBsAg-positive mothers may be breastfed), medical evaluation and possible treatment of chronic hepatitis B, and substance abuse treatment (if appropriate).
- Refer the mother to a medical specialist for evaluation of chronic hepatitis B.

### **For a pregnant woman with a *negative* HBsAg test result**

- Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg status to the hospital where the delivery is planned and to the health-care provider who will care for the newborn.
- Include information in prenatal care education about the rationale for and importance of newborn hepatitis B vaccination for all infants.
- Administer the hepatitis B vaccine series if the patient has a risk factor for HBV infection during pregnancy (e.g., injection-drug use, more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually-transmitted disease [STD]).
- Repeat HBsAg testing upon admission to labor and delivery for HBsAg-negative women who are at risk for HBV infection during pregnancy or who have had clinical hepatitis since previous testing.

**Date**

**Provider Name**  
**Address**  
**Address**

Dear **Provider Name**

Our office recently received a laboratory report of an **HBsAg-positive patient**, which identified you as her medical provider. However, the report did not include certain information necessary for the public health follow-up of this patient. Please provide the indicated information for the patient named below. The information will be kept strictly confidential and will be used only for necessary public health follow-up for communicable disease control. Public health reporting is exempted from HIPAA restrictions.

Please complete this form and fax it back to our program at (###) ###-####. Thank you for your cooperation.

Sincerely,

**Coordinator Name**

-----  
**PATIENT INFORMATION**

Name: \_\_\_\_\_ HBsAg-positive on \_\_\_\_/\_\_\_\_/\_\_\_\_

Address: \_\_\_\_\_ Date Received: \_\_\_\_/\_\_\_\_/\_\_\_\_  
\_\_\_\_\_

Phone: (Home) \_\_\_\_\_ (Work) \_\_\_\_\_ (Other) \_\_\_\_\_

Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_ Social Security #: \_\_\_\_\_ - \_\_\_\_\_ - \_\_\_\_\_

**Is patient PREGNANT?** \_\_\_\_ Yes \_\_\_\_ No \_\_\_\_ Don't Know EDD: \_\_\_\_/\_\_\_\_/\_\_\_\_

Is this an acute case of hepatitis B? \_\_\_\_ Yes \_\_\_\_ No \_\_\_\_ Don't Know

Language best understood by patient: \_\_\_\_\_

Health Insurance: \_\_\_\_ Medi Cal \_\_\_\_ Uninsured/Low income \_\_\_\_ Private Insurance/HMO \_\_\_\_ Unknown

Delivery Hospital: \_\_\_\_\_ Phone: \_\_\_\_\_

Pediatrician: \_\_\_\_\_ Phone: \_\_\_\_\_

WILLIAM B. WALKER, M.D.  
HEALTH SERVICES DIRECTOR

WENDEL BRUNNER, M.D.  
PUBLIC HEALTH DIRECTOR



CONTRA COSTA PUBLIC HEALTH  
COMMUNICABLE DISEASE PROGRAMS  
597 CENTER AVENUE, SUITE 200-A  
MARTINEZ, CALIFORNIA 94553  
PH (925) 313-6740  
FAX (925) 313-6465

## Delivery Alert

Mom is chronically infected with Hepatitis B

**\*Please place in prenatal chart\***

Reply **NEEDED** after baby is born and receives prophylaxis.

Mother: \_\_\_\_\_

BD: \_\_\_\_\_

Baby's name: \_\_\_\_\_

Physician: \_\_\_\_\_

Address/Phone: (attach face sheet)

Per CDC and American Academy of Pediatrics (AAP) Guidelines:

Infants (including infants weighing <2000 grams) born to HBsAg positive mothers **must** receive HBIG and HB dose # 1 within 12 hours of birth.

Date and *time* of birth: \_\_\_\_\_

HBIG given on: \_\_\_\_\_ at \_\_\_\_\_ am/pm  
Date Time

HB vaccine given on: \_\_\_\_\_ at \_\_\_\_\_ am/pm  
Date Time

Please fax or phone this information (along with patient's *FACE SHEET* which includes address, phone #, and doctor or pediatrician assigned) to:

\_\_\_\_\_ PHN  
Perinatal Hepatitis B Program Coordinator  
Phone:  
Fax:

*Thank you for helping prevent the spread of Hepatitis B Disease*



**PERINATAL HEPATITIS B CARRIER FOLLOW-UP REPORT**

(Please complete the information that applies, mail or FAX to MDH at the address or number below)

TO: **Coordinator Name**, Perinatal Hepatitis B Coordinator  
 Program Name  
 Address  
 Address  
 Address

**PERSON FAXING:** \_\_\_\_\_

**DATE FAX:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

PHONE: (###) ### #### or FAX: (###) ### ####      MEDICAL RECORD # \_\_\_\_\_

<b>CLIENT INFORMATION</b>		DATE OF HBsAg(+) TEST: CURRENT ____/____/____ PREVIOUS ____/____/____	
LAST NAME		FIRST NAME:	MI:
ADDRESS:		CITY:	ZIPCODE:
COUNTY:		HOME PHONE: (    )	
DATE OF BIRTH:		WORK PHONE: (    )	
IS CLIENT ENGLISH SPEAKING? YES NO IS CLIENT FOREIGN BORN? YES NO IF YES: COUNTRY OF ORIGIN: _____ IS CLIENT A REFUGEE? YES NO		RACE: <input type="checkbox"/> ASIAN/ PACIFIC ISLANDER <input type="checkbox"/> BLACK <input type="checkbox"/> WHITE <input type="checkbox"/> AMERICAN INDIAN <input type="checkbox"/> UNKNOWN OTHER _____	
		ETHNICITY: <input type="checkbox"/> HMONG <input type="checkbox"/> SOMALI <input type="checkbox"/> VIETNAMESE <input type="checkbox"/> HISPANIC OTHER _____	
<b>CLIENT'S PHYSICIAN INFORMATION:</b>		CURRENTLY PREGNANT? YES NO	
NAME: _____		ESTIMATED DATE OF DELIVERY: ____/____/____	
CLINIC NAME: _____		EXPECTED LOCATION OF DELIVERY:	
LOCATION OF CLINIC (CITY): _____		HOSPITAL: _____	
PHYSICIAN PHONE #: (    ) _____		CITY: _____	
CARRIER STATUS BASED ON:		DOES CLIENT KNOW SHE'S A CARRIER? YES NO UNKNOWN	

NOTES:





# Preventing Perinatal Hepatitis B

## *Guidelines for Labor and Delivery Units*

From the Advisory Committee on Immunization Practices (ACIP) Recommendations, December 2005\*

### **AT THE TIME OF ADMISSION**

- Review the hepatitis B surface antigen (HBsAg) status of all pregnant women admitted for labor and delivery.
- Accept only laboratory reports as documentation of hepatitis B status.
- Perform HBsAg testing as soon as possible if there is no documentation of the woman's HBsAg status or if she has clinical hepatitis.
- Retest women who are known to have engaged in behaviors that put them at risk for acquiring hepatitis B infection during pregnancy (e.g., recent intravenous drug use, an HBsAg-positive sex partner, more than one sex partner in the past 6 months, or treatment for a sexually transmitted disease).

### **AFTER DELIVERY**

#### **Infants Born to HBsAg-positive Mothers**

- Administer single-antigen hepatitis B vaccine and hepatitis B immune globulin (HBIG) to all infants within 12 hours of birth.
- Allow mothers to begin breastfeeding without delay. Administration of HBIG and the recommended hepatitis B vaccine series should eliminate any theoretical risk of transmission through breastfeeding.

#### **Infants Born to Mothers with Unknown HBsAg Status**

- Administer single-antigen hepatitis B vaccine to all infants within 12 hours of birth.
- **Infants weighing <2,000 g at birth:** administer HBIG if mother tests HBsAg positive or if mother's HBsAg result is not available within 12 hours of birth.
- **Infants weighing  $\geq 2,000$  g at birth:** if the mother is found to be HBsAg positive, administer HBIG as soon as possible but within 7 days of birth.
- If the mother is found to be HBsAg positive, notify the infant's health care provider of the need to provide follow up.

#### **Infants Born to Mothers with Negative HBsAg Status**

- **Infants weighing <2,000 g at birth:** administer first dose of hepatitis B vaccine at 1-30 days of chronologic age if medically stable or at hospital discharge if before 30 days of chronologic age.
- **Infants weighing  $\geq 2,000$  g at birth:** administer a dose of single-antigen hepatitis B vaccine at hospital discharge.<sup>†</sup>

### **AT HOSPITAL DISCHARGE**

- Give the infant's immunization record to the mother and remind her to take it to the infant's first healthcare provider visit. Birth hospitals are encouraged to use their regional immunization registry to record infant hepatitis B immunizations.
- Notify the local health department of all births to women with positive or unknown HBsAg status.

\*[www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm](http://www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm)

<sup>†</sup>The first dose may be delayed until after hospital discharge for an infant who weighs  $\geq 2,000$  g and whose mother is HBsAg negative, but only if a physician's order to withhold the birth dose and a copy of the mother's original HBsAg-negative laboratory report are documented in the medical record.



**Elliot Schulman, MD, MPH** Director/Health Officer  
**Anne M. Fearon** Deputy Director  
**Suzanne Jacobson, CPA** Chief Financial Officer  
**Michele Micklewicz, MPH** Deputy Director  
**Jane Overbaugh** Deputy Director  
**Peter Hasler, MD** Medical Director

September 24, 2008

Ms. Linda Bacon  
Director Maternity Services  
Cottage Health System  
Santa Barbara Cottage Hospital  
PO Box 689  
Santa Barbara, CA 93102-0689

Dear Ms. Bacon,

My name is Nancy Rosenberg and I am the Perinatal Hepatitis B Prevention Program Coordinator for County of Santa Barbara Public Health. Enclosed you will find a Delivery Alert for one of our patients who is due to deliver at your hospital on 10/15/08. I case manage all pregnant women identified as Hepatitis B Surface Antigen Positive, and follow them and their newborns through the baby's receipt of their Hepatitis B vaccination series and post-serology testing.

One of the crucial elements of the program is to assure the newborn receives their birth doses of Hepatitis B Immunoglobulin (HBIG) and Hepatitis B vaccine within 12 hr of birth. To assist with follow-up of this process, I am requesting that you or an appointed staff fax the completed "Delivery Alert" back to me.

I would also like to schedule a time for us to get together for an hour or so meeting to discuss our Perinatal Hepatitis B Prevention Program and your hospitals policies regarding this. Would you please give me a call at your convenience to discuss this?

Thank-you so much for your assistance.

Sincerely,

Nancy Rosenberg  
Immunizations Program Administrator  
County of Santa Barbara Public Health  
2125 S. Centerpointe Pkwy. Rm. 314  
Santa Maria, Ca. 93455  
805-346-8472- Office  
805-346-7377 - Fax  
805-331-9483 - Cell  
[Nancy.Rosenberg@sbcphd.org](mailto:Nancy.Rosenberg@sbcphd.org)

# Guidelines for Standing Orders in Labor & Delivery & Nursery Units to Prevent Hepatitis B Virus (HBV) Transmission to Newborns

To obtain the Centers for Disease Control and Prevention (CDC) recommendations for preventing hepatitis B in infants and children, visit CDC's website at [www.cdc.gov/mmwr/PDF/rr/rr5416.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf)

In December 2005, the Centers for Disease Control and Prevention (CDC) published new recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in infants and children. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have endorsed these recommendations. To obtain a copy, go to [www.cdc.gov/mmwr/PDF/rr/rr5416.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf).

The guidelines below were developed to help all hospitals establish standing orders and protocols in their labor and delivery and nursery units. The content has been reviewed by CDC staff for consistency with CDC recommendations.

To protect all infants, CDC recommends that all delivery hospitals institute standing orders and protocols to ensure healthcare professionals do the following:

- Administer hepatitis B vaccine to all newborns who weigh at least 2 kg (4.4 lb) before discharge from the nursery.
- 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 all these infants.

## Labor and Delivery (L&D) Procedures

Upon admission, review the HBsAg<sup>1</sup> status of all pregnant women. Be sure to review a copy of the mother's *original* laboratory report to verify that the correct test was performed during this pregnancy and to verify the test date. Do not rely on a transcribed test result!

### For women with a documented HBsAg lab report

- Place a copy of the *original* laboratory report of the mother's HBsAg<sup>1</sup> test result into (1) the mother's L&D record and (2) the infant's medical record.
- If the mother is HBsAg positive, alert the nursery staff.
- If the mother is HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., not in a long-term, mutually monogamous relationship; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drugs), perform a repeat test for HBsAg.<sup>1</sup> Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

### For women without a documented HBsAg lab report

- Perform HBsAg<sup>1</sup> testing ASAP on women who do not have a documented HBsAg test result from the current pregnancy.
- Instruct the lab to call L&D and the nursery with the newly obtained HBsAg test result ASAP.

## Nursery Procedures

### Procedures to follow for ALL newborns

1. Review a copy of the mother's *original* HBsAg<sup>1</sup> lab report to ensure test was ordered and interpreted accurately.
2. Provide appropriate management based on (1) the mother's HBsAg status and (2) the infant's birth weight. Manage infants who weigh less than 2 kg differently from those who weigh 2 kg or more. See descriptions below and footnotes 2, 5, 6.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.

### For infants born to HBsAg-negative mothers

Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before discharge to all infants weighing at least 2 kg at birth.<sup>2,3,4</sup> Document the hepatitis B vaccine dose in the infant's medical record, including date, time, site of administration, and lot number.

### For infants born to mothers with unknown HBsAg status

Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.<sup>3,5</sup> Do not wait for test results to return before giving this dose of vaccine. Document the hepatitis B vaccine dose appropriately.

- Confirm that the laboratory has received serum for the mother's HBsAg<sup>1</sup> test. Verify when the HBsAg result will be available and that it will be reported to L&D and the nursery ASAP. If the nursery does not receive the report at the expected time, call the laboratory for the result.
- If the mother's HBsAg<sup>1</sup> test result is positive, do the following:
  - Administer hepatitis B immune globulin (HBIG 0.5 mL, IM) to the infant ASAP. Document the HBIG dose appropriately in the infant's medical record. There is little benefit in giving HBIG if more than 7 days have elapsed since birth.
  - Alert the mother's and infant's physician(s) of the test result.
  - Follow the instructions below for infants born to HBsAg-positive mothers.
- If the infant must be discharged before the HBsAg result is known:
  - Document contact information for the parents (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed.
  - Obtain the name, address, and phone number of the mother's

(continued on next page)

and the infant's healthcare providers.

- Notify the mother's and the infant's healthcare providers that the mother's HBsAg test result is pending.

#### **For infants born to HBsAg-positive mothers**

- Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine<sup>3, 6</sup> (0.5 mL, IM) at separate injection sites within 12 hours of birth. Document the hepatitis B vaccine and HBIG doses appropriately in the infant's medical record.
- 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.
- Obtain the name, address, and phone number of the infant's primary care provider. Notify the provider of the infant's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination and postvaccination testing of the infant for HBsAg and antibody to HBsAg after completion of the hepatitis B vaccine series.
- Provide advice to the mother. Tell her
  - That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given
  - About the importance of her infant completing the full hepatitis B vaccine series on schedule
  - That blood will need to be drawn from the infant after completion of at least 3 doses of the hepatitis B vaccine series at age 9–18 months (generally at the next well-child visit) to determine if the infant needs further management
  - About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts
  - That she needs to have a medical evaluation for chronic hepatitis

B, including an assessment of whether she is eligible 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 whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge. The mother's HBsAg status must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the IAC website at [www.immunize.org/vis](http://www.immunize.org/vis) or call your state health department.
4. Exceptions to giving the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. If a 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 don't 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 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 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.

**To access a CDC web page that includes a text version of the recommendations, a “Dear Colleague” letter that explains details of the recommendations, an archived net conference, brochures, slide sets, and more, go to: [www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm](http://www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm)**

# Preventing Perinatal Hepatitis B

## ACIP & CDC Guidelines for Labor and Delivery and Newborn Nursery Units

Santa Clara Department of Public Health and Asian Liver Center at Stanford University

### AT THE TIME OF ADMISSION

- Review the hepatitis B surface antigen (HBsAg) status of all pregnant women
- Refer to laboratory report for documentation of hepatitis B status  
(handwritten notes are subject to transcription errors)
- Perform HBsAg testing ASAP if there is no documentation of HBsAg status
- Women who test negative in early pregnancy (>6 months before delivery) may need retesting if they have engaged in behaviors that place them at risk for acquiring hepatitis B infection during pregnancy  
(eg. recent intravenous drug use, HBsAg-positive sex partner, multiple sex partners, recent treatment for a sexually transmitted disease)

### AFTER DELIVERY

#### Recommended Administration of Birth Dose Hepatitis B Vaccine and Hepatitis B Immunoglobulin (HBIG) to be Given within 12 Hours of Birth

Maternal HBsAg <sup>§</sup> Status	Recommendation			
	Infants ≥ 2,000 grams		Preterm infants < 2,000 grams	
	Birth Dose HBV Vaccine	HBIG	Birth Dose HBV Vaccine <sup>†</sup>	HBIG
<b>HBsAg positive</b>	✓	✓	✓	✓
<b>HBsAg status unknown or pending</b>	✓	Wait for HBsAg result*	✓	✓
<b>HBsAg negative</b>	✓		✓ @ 1 month	

§ Hepatitis B surface antigen

\* May give up to 7 days after birth

† Because of the potentially decreased immunogenicity of vaccine in preterm infants weighing <2,000grams, the birth dose vaccine should not be counted as part of the 3 doses received to complete the HBV vaccine series. A total of 4 doses should be given.

#### Hepatitis B Vaccines Acceptable for Birth Dose Administration: Single-Antigen Vaccine

- Recombivax HBV
- Engerix-B

### AT HOSPITAL DISCHARGE

- Give infant's immunization record to mother and remind her to take it to infant's first pediatrician visit
- Encourage mother to make sure her infant completes 3-shot HBV vaccination series within 6 months
- Notify Perinatal Hepatitis B Prevention Program of Santa Clara County Public Health Department of all births to women with positive or unknown HBsAg status by faxing the "Hospital Report" form within 24 hours to (408)885-2413. Forms can be obtained at [www.sccphd.org/perinatalhepb](http://www.sccphd.org/perinatalhepb)

For more information, visit: <http://liver.stanford.edu> or [www.cdc.gov/mmwr/PDF/rr/rr5416.pdf](http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf)

Guidelines are abridged from the recommendations set forth by the Advisory Committee on Immunization Practices (ACIP) in the Morbidity and Mortality Weekly Report (MMWR), published by the Centers for Disease Control and Prevention (CDC), Coordinating Center for Health Information and Service, U.S. Department of Health and Human Services. MMWR 2005;54(No.RR-16)

Date:

Hospital Name

**Infection Control**

Attn: **Infection Control Contact Name**

**Address**

**City, State, Zip**

**RE: Hepatitis B surface antigen positive (HBsAg+) pregnant women  
expected to deliver at *Hospital Name***

Dear **Contact Name**:

Following is a list of HBsAg+ women expected to deliver at your hospital. Please ensure this information is available at time of delivery so that the newborns can receive the appropriate doses of Hepatitis B Immune Globulin (HBIG) and Hepatitis B Vaccine. Attached is the Perinatal Hepatitis B Case Report.

Additionally, please call or fax me with the newborn infant data following the child's birth and receipt of hepatitis B immune globulin (HBIG) and hepatitis B vaccine. You can reach my voice mail 24 hours: ###-###-####; or fax the information to ###-###-####.

<b>Prenatal Woman</b>	<b>SS#</b>	<b>Date of Birth</b>	<b>+HBsAg</b>	<b>EDC</b>

Sincerely,

**Coordinator's Name**

Hepatitis B Prevention Program

attachments

## Perinatal Hepatitis B Program

The New Hampshire Perinatal Hepatitis Program follows up on all reports of pregnant women who test positive for hepatitis B, and the infants of these women to ensure that they receive the appropriate recommended vaccines. This is reportable to us by NH statute (RSA 141-C).

The following is needed to update our records and ensure timely follow-up for the infant. **Please complete the information below and fax it back at your earliest convenience. The confidential fax number is (###) ###-####.**

If you have any questions, or prefer to report this by phone, please call **COORDINATOR NAME**, Perinatal Hepatitis B Coordinator, at (###) ###-####. Thank you.

---

---

Name of client: *CLIENT NAME*

Client's date of birth: ##/##/##

Expected delivery date: ##/##/##

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---

Delivery date: \_\_\_\_\_

Delivery time: \_\_\_\_\_

Infant's sex:  Male  Female

Infant's name: \_\_\_\_\_

---

**HBIG (hepatitis B immune globulin)**

Date given: \_\_\_\_\_

Time given: \_\_\_\_\_

---

**Hepatitis B vaccine**

Date given: \_\_\_\_\_

Time given: \_\_\_\_\_

---

Infant's health care provider: \_\_\_\_\_





# Preventing Perinatal Hepatitis B

## *Guidelines for Pediatric Care Providers*

From the Advisory Committee on Immunization Practices (ACIP) Recommendations, December 2005\*  
Endorsed by the American Academy of Pediatrics (AAP).

### HEPATITIS B PROPHYLAXIS AT BIRTH

- Infants born to mothers who are hepatitis B surface antigen (**HBsAg**) **positive** should receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) <12 hours of birth.
- Infants born to mothers whose **HBsAg status is unknown** should receive hepatitis B vaccine <12 hours of birth.
  - Preterm infants weighing <2,000 g should receive HBIG <12 hours of birth.
  - Term infants weighing  $\geq 2,000$  g should receive HBIG as soon as possible if the mother is determined to be **HBsAg positive**, but not >7 days after birth.
- Medically stable infants weighing  $\geq 2,000$  g born to **HBsAg negative** mothers should receive the first dose of hepatitis B vaccine before hospital discharge.
- Preterm infants weighing <2,000 g and born to **HBsAg negative** mothers should receive the first dose of hepatitis B vaccine 1 month after birth.
- Single-antigen hepatitis B vaccine must be used in infants <6 weeks of age.

### AFTER THE BIRTH DOSE

- All infants should complete the hepatitis B vaccine series using either single-antigen or combination vaccine, according to the recommended vaccination schedule (see the December 2005 ACIP Recommendations, Tables 3 and 4 for details).\*
- The last dose in the vaccine series should not be administered before age 24 weeks (164 days).

### POST VACCINE SEROLOGIC TESTING

- Infants of HBsAg-positive mothers should be tested for both HBsAg and antibody to HBsAg (anti-HBs) 1-2 months after completing the vaccine series, but not before 9 months of age. Note: testing that is delayed after series completion can lead to falsely negative anti-HBs test results.
- Testing should be performed using a method that allows determination of a protective level of anti-HBs, i.e.,  $\geq 10$  mIU/ml.
- HBsAg-negative infants with anti-HBs levels <10 mIU/mL should be revaccinated with a second three-dose series and retested 1-2 months after the last dose of vaccine.
- HBsAg positive infants should receive appropriate medical follow-up and should be reported to the local health department as a perinatal hepatitis B case.

\* A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part 1: Immunization of Infants, Children, and Adolescents, MMWR, December 23, 2005 / 54(RR16);1-23 [http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s\\_cid=rr5416a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s_cid=rr5416a1_e)



## THE PERINATAL HEPATITIS B PROGRAM

### ***What does the Perinatal Hepatitis B Program do?***

As required by the Centers for Disease Control and Prevention (CDC), the Contra Costa Health Services Perinatal Hepatitis B Program tracks infants born to Hepatitis B surface antigen (HBsAg) positive mothers to ensure they receive appropriate treatment at birth, complete the recommended series of Hepatitis B and receive post-vaccination serologic testing. It ensures that infants enrolled in the Program complete a second Hepatitis B vaccine series and a second post-vaccination serologic testing if the HBsAg and anti-HBs tests results are negative.

### ***Are medical providers legally required to release information regarding follow-up and tracking of infants born to HBsAg positive mothers if the Perinatal Hepatitis B Program requests it?***

**Yes.** This data is necessary for the surveillance and prevention of Hepatitis B. The Program is authorized by Title 17, Section 2500 of the California Code of Regulations to request, receive or collect the mentioned data. Per the Health Insurance Portability and Accountability Act (HIPAA), Standards for Privacy of Individually Identifiable Health Information, Final Rule (Privacy Rule) [45 CFR § 164.501] medical providers may disclose, without individual authorization information requested by the Department of Public Health when the data is necessary to perform the duties of its programs. You may verify this statement by visiting the HIPAA website of the Office for Civil Rights <http://www.hhs.gov/ocr/hipaa>.

### ***What is the Hepatitis B vaccination schedule for infants born to HBsAg positive mothers?***

There are three vaccine schedule options:

	Option 1	Option 2	Option 3
<b>Dose</b>	<b>Single antigen vaccine</b>	<b>PEDIARIX</b>	<b>COMVAX</b>
1	Birth	Birth (single antigen)	Birth (single antigen)
2	4 weeks	6-8 weeks	6-8 weeks
3	6 months	16 weeks	16 weeks
4	NA	6 months	12-15 months

CDC and the Perinatal Hepatitis B Programs encourage options 1 and 2, as they allow for the completion of *post-vaccination serologic testing* at the recommended age of **9 months -15 months**. The timeliness of the information on the HBsAg and anti-HBs tests is extremely important for the early identification of infants who may need revaccination or long-term medical management of Hepatitis B chronic infection.

### ***Thank you for protecting our children from Hepatitis B.***

For information on the Perinatal Hepatitis B Program, please contact: Sheilah Zarate RN, PHN by phone: (925) 313-6450, fax: (925) 313-6465, or e-mail: [szarate@hsd.cccounty.us](mailto:szarate@hsd.cccounty.us)



DATE

MD NAME  
ADDRESS  
ADDRESS

Dear Dr. LASTNAME:

The New Hampshire Department of Health and Human Services' Perinatal Hepatitis B Program follows infants born to hepatitis B surface antigen positive mothers to ensure that the infant receives appropriate doses of hepatitis B immune globulin and the 3 hepatitis B immunizations, as well as post-testing to ensure the child has developed immunity. The recommended post-testing is done 3 months after the child receives the 3<sup>rd</sup> dose of hepatitis B vaccine, and includes hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (anti-HBs).

In order to update our records, please complete the following information and return it to me in the envelope provided. *NOTE: The following is updated and/or deleted as appropriate*

Name of child: CHILD NAME                      **DOB: 00/00/00**

Dates of hepatitis B vaccinations:      **Hep B #1 and HBIG: 00/00/00**

**Hep B #2: \_\_\_\_\_**

**Hep B #3: \_\_\_\_\_**

**Date of post-testing: \_\_\_\_\_**

**Post-testing results:    HBsAg (hepatitis B surface antigen) \_\_\_\_\_**

**Anti-HBs (hepatitis B surface antibody) \_\_\_\_\_**

**Comments: \_\_\_\_\_**

---

If you have questions or would like further information, please don't hesitate to call me at (###) ###-####. Thank you very much.

Sincerely,

COORDINATOR NAME  
Perinatal Hepatitis B Coordinator  
Communicable Disease Surveillance  
Section

DATE

Dear Doctor:

Thank you for providing us with the dates of your patients' hepatitis B immunization series. **Now that the series is complete, a serologic specimen should be drawn. Hepatitis B serologies should be drawn no earlier than 9 months of age and approximately 1-2 months after administration of the 3<sup>rd</sup> or final dose of hepatitis B vaccine. The infant should be tested for hepatitis B surface antigen (HBsAg) AND hepatitis B surface antibodies (HbsAb or anti-HBs).** These two tests will insure your patient is not infected with hepatitis B and is protected from future infection with hepatitis B.

**The post-vaccination serology tests for children born to HBsAg-positive mothers are an integral part of patient management.** Since these children will be at risk of exposure to the hepatitis B virus, it is paramount that they successfully respond to vaccination (seroconvert). For those infants who do not seroconvert, three additional doses of vaccine should be administered and post-vaccination testing for the serologic response should be repeated.

If you have any questions, please contact *Coordinator* at (XXX) XXX-XXXX.

Sincerely,

COORDINATOR'S NAME

# Appendix F

## Hepatitis B Vaccination and Prophylaxis

Give the Birth Dose (IAC)

Hepatitis B Immunization Schedules- Infants <2000 g

Hepatitis B Immunization Schedules- Infants  $\geq$ 2000 g

# Give the birth dose . . .

## Hepatitis B vaccine at birth saves lives!

By **Deborah L. Wexler, MD**, Executive Director, Immunization Action Coalition

On Dec. 23, 2005, CDC issued new recommendations on hepatitis B vaccination that were published in the MMWR. The recommendations strongly support the birth dose of hepatitis B vaccine for every newborn prior to hospital discharge and also recommend the use of standing orders for giving the birth dose. Copies of original maternal hepatitis B lab reports are also recommended (instead of transcribed test results). According to the new recommendations, the birth dose should only be withheld in "rare circumstances," and if doing so, physicians should write an order **not** to give the dose, and a copy of the mother's original HBsAg-negative lab report must be on the infant's chart. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists endorse these new recommendations.

The Immunization Action Coalition (IAC) urges all health professionals and hospitals to protect all infants from hepatitis B virus (HBV) infection by administering the first dose of hepatitis B vaccine to every infant at birth and no later than hospital discharge.

Approximately 19,000 women with chronic hepatitis B virus infection give birth in the U.S. each year. Up to 95% of perinatal infections can be prevented by postexposure prophylaxis given within 12 hours of birth. Tragically, many babies are exposed to HBV at birth but do not receive appropriate postexposure prophylaxis.

### **The primary advantage of giving the first dose at birth is that IT SAVES LIVES.**

**Why is such a policy necessary? Following are some of the ways infants who are not vaccinated at birth can become infected:**

- The pregnant woman is tested and found to be hepatitis B surface antigen (HBsAg) positive, but her status is not communicated to the newborn nursery. The infant receives neither hepatitis B vaccine nor HBIG protection at birth.
- A chronically infected pregnant woman is tested with the wrong test. For example, antibody to hepatitis B surface antigen is sometimes ordered in error instead of HBsAg. This can happen because some laboratories use the improper and 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 have actually been 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. Her infant does not receive HBIG or hepatitis B vaccine.
- The pregnant woman is not tested for HBsAg ei-

ther prenatally or in the hospital at the time of delivery. Women in this group have a higher likelihood of being HBsAg-positive (in one study, women who didn't receive prenatal care were 8 times more likely to be HBsAg positive than women who received such care). Her infant does not receive hepatitis B vaccine in the hospital, even though it is recommended within 12 hours of birth for infants whose mothers' test results are unknown.

- The woman is tested in early pregnancy for HBsAg and is found to be negative. She develops HBV infection later in pregnancy, but it is not detected, even though it is recommended by CDC that high-risk women be retested later in pregnancy. Because the infection is not clinically detected by her health care provider, 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.

**While there are certain advantages to giving the first dose at a later well-baby visit, these are advantages of administrative convenience. The primary advantage of giving the first dose at birth is that it saves lives.**

In 2001 and 2002, IAC surveyed hepatitis coordinators at every state health department as well as at city and county CDC projects to express their views about providing hepatitis B vaccine in the hospital. Their responses contained many examples of children who were unprotected or inadequately protected because health professionals failed to order or misordered the hepatitis B blood test or misinterpreted, mistranscribed, or miscommunicated the test results of the children's mothers.

These state coordinators' reports tell us that no matter how well healthcare providers think they are doing with HBsAg screening of all pregnant women, serious mistakes continue to occur; children are unnecessarily being exposed without the benefit of postexposure prophylaxis, and at least

To obtain the CDC recommendations (12/23/05) for hepatitis B immunization of infants, children, and adolescents, go to: [www.cdc.gov/mmwr/pdf/rr/rr5416.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5416.pdf).

For more information on the importance of giving the birth dose, and results from IAC's survey of state hepatitis B coordinators, go to: [www.immunize.org/birthdose](http://www.immunize.org/birthdose).

one baby has died. In order to overcome these failures, all 50 state hepatitis B coordinators overwhelmingly endorse providing a birth dose.

To maximally protect every newborn, ACIP recommends we vaccinate *all* infants (regardless of the mother's HBsAg status) prior to hospital discharge with Engerix-B<sup>®</sup> or Recombivax HB<sup>®</sup>. Providers who wish to complete the series using hepatitis B-containing combination vaccines (Comvax<sup>®</sup>, Pediarix<sup>®</sup>), may do so by giving three additional doses. Giving a total of four doses of hepatitis B vaccine to infants is acceptable to CDC, AAP, AAFP, and these vaccine doses are covered under the Vaccines for Children (VFC) program.

### **All 50 state hepatitis B coordinators overwhelmingly endorse providing a birth dose.**

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 up to 95% of cases, essentially the same level of protection afforded by administering hepatitis B vaccine in addition to HBIG. Even higher rates of protection with postexposure prophylaxis have been demonstrated in infants born to less infectious mothers (those who are HBsAg positive and HBeAg negative).

Please read the hepatitis coordinators' survey results (see the web address box above), including descriptions of their experiences with failures of the current system—failures that largely will be prevented by administering hepatitis B vaccine to infants before they go home from the hospital.

Your support for providing a birth dose of hepatitis B vaccine to infants while still in the hospital will protect and save lives that are now being put at risk. ♦

[www.immunize.org/catg.d/p2125.pdf](http://www.immunize.org/catg.d/p2125.pdf) • Item #P2125 (5/06)

**Hepatitis B Vaccine Schedules for Preterm Infants Weighing < 2000 gm  
by Maternal Hepatitis B Surface Antigen (HBsAg) Status<sup>o</sup>**

MATERNAL HBsAg STATUS	RECOMMENDATION	
	DOSE	AGE
POSITIVE	Hep B vaccine & Hepatitis B immune globulin (HBIG) <sup>+</sup>	≤ 12 hours
	Vac1 Hep B vaccine*	1 month
	Vac2 Hep B vaccine	2-4 months
	Vac3 Hep B vaccine <sup>o</sup>	6-7 months (Pediarix or monovalent vaccine) 12-15 months (Comvax)
	Serology testing	9 months or 1-2 months after Vac 3. Do not test before 9 months of age or ≤ 4 weeks of the most recent vaccine dose.
UNKNOWN	Hep B vaccine & HBIG <sup>+</sup>	≤ 12 hours of birth
	<b>Test mother for HBsAg immediately:</b> If positive, continue series as above↑ If negative, continue series as below↓	
NEGATIVE	Vac1 Hep B vaccine	At 1 month, or at hospital discharge*
	Vac2 Hep B vaccine	2-4 months
	Vac3 Hep B vaccine	6-18 months <sup>o</sup>

<sup>o</sup> 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 (ACIP) Part I: Immunization of Infants, Children, and Adolescents,” <http://www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm>  
CDC version of Table 4 is available at <http://www.cdc.gov/hepatitis/hbv/pdfs/correctedtable4.pdf>

<sup>+</sup> Do not count the birth dose as part of the vaccine series.

\* Single-antigen vaccine should be used for doses administered before 6 weeks (42 days) of age. Either single or combination vaccine may be used for doses administered at ≥ 6 weeks of age.

<sup>o</sup> The final dose in the vaccine series should not be given before 24 weeks of age (164 days).

**HEPATITIS B VACCINE SCHEDULES FOR NEWBORN INFANTS ≥ 2000 gm<sup>♠</sup>**

MOTHER'S HBsAg RESULT	SINGLE ANTIGEN VACCINE		SINGLE ANTIGEN + COMBINATION VACCINE	
	DOSE	AGE	DOSE	AGE
POSITIVE	1 Hep B vaccine and HBIG	within 12 hrs of birth	1 Hep B vaccine and HBIG*	within 12 hrs of birth
	2 Hep B vaccine	1-2 months	2 Combination vaccine*	2 months
	3 Hep B vaccine	6 months <sup>⊖</sup>	3 Combination vaccine	4 months
	Serology testing for HBsAg and anti-HBs	9 months	9 months	6 months (Pediatrix) or 12-15 months (Comvax)
			Serology testing for HBsAg and anti-HBs	9 months (Pediatrix) or 1-2 months after Comvax
UNKNOWN	1 Hep B vaccine	within 12 hrs of birth	1 Hep B vaccine*	within 12 hrs of birth
	HBIG, if test result is positive	within 7 days	HBIG, if test result is positive	within 7 days
	<b>Test mother for HBsAg immediately.</b> If positive, continue series as above <sup>↑</sup> . If negative, continue series as below <sup>↓</sup>		<b>Test mother for HBsAg immediately.</b> If positive, continue series as above <sup>↑</sup> . If negative, continue series as below <sup>↓</sup> .	
NEGATIVE	1 Hep B vaccine <sup>√</sup>	Before discharge	1 Hep B vaccine* <sup>√</sup>	Before discharge
	2 Hep B vaccine	1-2 months	2 Combination vaccine*	2 months
	3 Hep B vaccine <sup>⊖</sup>	6-18 months	3 Combination vaccine	4 months
			4 Combination vaccine <sup>⊖</sup>	6 months (Pediatrix) or 12-15 months (Comvax) <sup>⊖</sup>

♠ From Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part I, Immunization of Infants, Children and Adolescents, 12/05.

\* Combination vaccines should not be given before 6 weeks of age.

⊖ The final dose in the series should not be given before age 24 weeks.

√ On a case-by-case basis, the first dose of hepatitis vaccine may be delayed until after hospital discharge for an infant who weighs ≥ 2000 g and whose mother is HBsAg negative, but only if the physician's order and the mother's original HBsAg lab report are documented in the infant's medical record.

# Appendix G

## Other Resources

## **Perinatal Hepatitis B Resources**

### **Government**

Center for Disease Control and Prevention webpage, Vaccine Preventable Diseases, Hepatitis B  
<http://www.cdc.gov/vaccines/vpd-vac/hepb/default.htm>

National Center for, HIV/AIDS, viral hepatitis, STD and TB prevention (NCIDOD):  
<http://www.cdc.gov/ncidod/diseases/hepatitis/b/index.htm>

CDPH Immunization Branch webpage <http://www.dhs.ca.gov/ps/dcdc/izgroup/default.htm>

Vaccine Preventable Diseases (VPD) Surveillance and Reporting in California:  
<http://ww2.cdph.ca.gov/programs/immunize/Pages/VaccinePreventableDiseaseSurveillance.aspx>

CDPH Disease and Conditions webpage- Hepatitis B  
<http://ww2.cdph.ca.gov/HealthInfo/discond/Pages/HepatitisB.aspx>

CDPH Communicable Disease Control Forms webpage – Perinatal Hepatitis B  
<http://ww2.cdph.ca.gov/pubsforms/forms/Pages/CD-Report-Forms.aspx>

Vaccines for Children- California  
<http://www.eziz.org/pages/VFCoverview.html>

California Immunization Registry Website  
<http://www.ca-siis.org>

IZ Coordinators' Website: (Password: izzy)  
<http://www.izcoordinator.org/>  
With a webpage for Perinatal Hepatitis Coordinators

### **Vaccine Recommendations**

A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States:

Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR, December 23, 2005 / 54(RR16);1-23  
[http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s\\_cid=rr5416a1\\_e](http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm?s_cid=rr5416a1_e)

General Recommendations on Immunization:

Recommendations of the Advisory Committee on Immunization Practices (ACIP), MMWR, December 1, 2006 / 55(RR15);1-48  
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5515a1.htm>

### **Hepatitis B Organizations**

Immunization Action Coalition (IAC) webpage:  
<http://www.immunize.org/>

Many resources!

Immunization Action Coalition (IAC) webpage with specific diseases and vaccines that prevent them: <http://www.vaccineinformation.org/>

Asian Liver Center: resources for health care providers and the community available in a number of Asian languages: [http://liver.stanford.edu/ALC/ALC\\_message.php](http://liver.stanford.edu/ALC/ALC_message.php)

Hepatitis Foundation International: publishes *Hepatitis Alert* newsletter with research information. Includes educational resources for health care providers and others: <http://www.hepfi.org/>

## **Newsletters**

*Hep B Express*

<http://www.hepprograms.org/hepexpress>

Viral hepatitis information from the IAC.

*IAC Express.*

<http://www.immunize.org/express>

Weekly immunization news:

*Needle Tips*

<http://www.immunize.org/nt/>

Semiannual publication of the IAC for health professionals.