

Hepatitis B Business Rules for Investigation and Reporting in NC EDSS

1) INVESTIGATION AND DOCUMENTATION IN NC EDSS ARE REQUIRED FOR:

- i) All persons who have no prior hepatitis B event in NC EDSS and have a positive test result for any of the hepatitis B lab results that are required by law to be reported to public health (*HBsAg, HBeAg, Hep B DNA and anti-HBc IgM*) must be reported in NC EDSS.
 - (a) If the lab report is received in paper format, it must be manually entered into NC EDSS. Review the lab results to determine if the event is best entered as an **Acute (15)** or **Confirmed Chronic (115)** hepatitis B event. Once that determination is made and the event type selected, the question packages can be answered.
 - (b) If the lab report is received by Electronic Lab Report (ELR), it will create a **Hepatitis B Lab/Condition Report (16)** event. Again, review the lab results to determine if the event is best entered as an **Acute (15)** or **Confirmed Chronic (115)** hepatitis B event. Once that determination is made and the event type selected, the question packages can be answered.
 - (c) Whether the lab is manually entered or is a direct feed by ELR, the local health department (LHD) must ensure the event reflects the correct disease type, (i.e. acute, chronic carrier), complete all question packages, and assign the event in the investigation trail to the State Disease Registrar.
 - (d) Household, sexual contacts and needle sharing contacts to Hepatitis B positive women who are currently pregnant or have given birth within the last 24 months must be entered into NC EDSS as linked contacts to the woman's event. These events should contain vaccination and testing data and be assigned to state Perinatal Hep B Case Management for follow-up. If one of these contacts is found through testing to be HBsAg positive, the case must be reported to the State Disease Registrar as a new event.
 - (e) Household, sexual contacts and needle sharing contacts to initial acute or chronic cases who are *not* pregnant or have *not* given birth in the last 24 months may be entered into NC EDSS at the discretion of the LHD.
- ii) All persons who have previously been reported in NC EDSS with **Hepatitis B Acute (15)** or with **Hepatitis B Perinatally-Acquired (116)** disease that now have an additional lab test result for any of the hepatitis B lab results that are required by law to be reported to public health (*HBsAg, HBeAg, Hep B DNA and anti-HBc IgM*) which may indicate progression to chronic disease, must be investigated.
 - (a) When testing indicates a progression of disease from **Hepatitis B Acute (15)** or **Hepatitis B Perinatally-Acquired (116)** to Hepatitis B Confirmed Chronic Carrier status, the **Confirmed Chronic Carrier (115)** state must be reported as a new event.
 1. If the lab is received into NC EDSS by ELR, the system will create a **Hepatitis B Lab/Condition Report (16)** event. This event must be changed to **Hepatitis B Chronic Carrier (115)**, the question packages completed, and the event assigned to the State Disease Registrar.
 2. If the lab report which confirms the chronic carrier state is received as a paper copy, a **Hepatitis B Chronic Carrier (115)** event must be created, the lab manually entered into the new event, the question packages completed, and the event assigned to the State Disease Registrar.

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- iii) All events which have previously been reported in NC EDSS as **Hepatitis B Chronic Carrier (115)** with a classification of **Probable** that now have an additional lab test result for any of the hepatitis B lab results that are required by law to be reported to public health (*HBsAg, HBeAg, Hep B DNA and anti-HBc IgM*), which confirms the carrier status, must be updated to a classification of confirmed.
- (a) When a lab result confirming a previously reported Hepatitis B Probable Chronic Carrier is received by a LHD, a **Hepatitis B Lab/Condition Report** event must be sent to the State Disease Registrar to update the classification status of the existing chronic event.
1. When the additional lab is received as an ELR by a LHD, a **Hepatitis B Lab/Condition Report (16)** event is automatically created and will appear in the Lab Review workflow. Complete the questions in the **Subsequent Report Package**, change the classification to *Confirmed* in the investigation trail, and assign the event to the State Disease Registrar, **leaving the event as a Hepatitis B Lab/Condition Report (16)**.
 2. If the lab is received as a paper copy by a LHD, a **Hepatitis B Lab/Condition Report (16)** event must be created, the lab manually entered into the event, the **Subsequent Report Package** completed, case classification in the investigation trail changed to *Confirmed*, and the event assigned to the State Disease Registrar, **leaving it as a Hepatitis B Lab/Condition Report (16)**.
- (b) When a paper report or ELR received by the State is recognized as confirming a previously reported probable event, the State Disease Registrar may update the existing **Hepatitis B Chronic Carrier (115)** event classification to *Confirmed*. The state will take this action only if the source of the report does not indicate a violation of control measures (i.e. test performed by a laboratory connected to blood or tissue donation), the patient is male, or the patient is a female outside of the child bearing years (aged < 14 years or > 50). If received as an ELR, the **Hepatitis B Lab/Condition Report (16)** created by the new lab will be merged into the existing Hepatitis B Chronic Carrier event *by the state only*. LHDs will still be required to mark the event containing the ELR as reviewed in the **Lab Results - HepB - Lab result review required (local)** workflow.
- iv) All females of childbearing age (14 - 50) regardless of previous report classification, who have a positive test result for any of the hepatitis B lab results that are required by law to be reported to public health (*HBsAg, HBeAg, Hep B DNA and anti-HBc IgM*) must be investigated to determine pregnancy status. *NOTE: There may be occasions in which newly identified cases of hepatitis B will be reported in females younger than 14. Again, it is important to consult with the provider to determine why testing was done. If the exposure was through sexual intercourse and the female is sexually active, then it follows that pregnancy status should be determined through conversation with the provider.*
- (a) With reports of **Hepatitis B Acute (15)** or **initial** reports of **Hepatitis B Chronic Carrier (115)**, LHDs should document pregnancy status, and, if the female is currently pregnant, the estimated delivery date (EDD) in the clinical package. Once all question packages are complete, the event should be assigned to the State Disease Registrar.
- (b) For women *previously* reported as **Hepatitis B Chronic Carrier (115)**, confirmation of a current pregnancy, as well as estimated delivery date (EDD), should be documented in the **Subsequent Report Package** of the **Hepatitis B Lab/Condition Report (16)** event. These events should be left as Lab/Condition Reports and assigned to the State Disease Registrar.

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- (c) LHDs should initiate case management for pregnant females with positive *HBsAg*, *HBeAg*, *Hep B DNA* or *anti-HBc IgM* lab results. If *HBsAg* status is unknown in a pregnant female, this testing should be done and documented in NC EDSS as soon as possible.
- (d) Events with pending deliveries should be assigned to the State Disease Registrar as quickly as possible for reporting. These events will be reassigned by the State Disease Registrar to state Perinatal Hep B Case Management. Perinatal Case Management will then reassign the event to the LHD for tracking.
- (e) LHDs should follow pregnant females with positive *HBsAg* throughout the pregnancy and up to delivery. The event will appear in the Pending Risk Birth Notification workflow 2 months prior to the EDD to alert the LHD to the upcoming delivery.
- (f) If *HBsAg* status is unknown and cannot be obtained, the LHD should follow pregnant females until delivery *if any of the following tests are positive: HBeAg or Hep B DNA or anti-HBc IgM.*
- (g) If the pregnancy is terminated without a live birth or the mother leaves North Carolina to live in another state or country, the date and reason for termination should be entered and the event assigned to Perinatal Hep B Case Management.
- (h) When delivery information becomes available, the LHD should enter the information into the mother's event, create a linked **Hepatitis B Perinatally Acquired (116)** contact event for the infant, and assign the mother's event to Perinatal Hep B Case Management.
- (i) LHDs should follow the infant(s) born to hepatitis B-infected women in the linked event to ensure:
 1. Infant post-exposure prophylaxis with HBIG and hepatitis B vaccine are administered within 12 hours of birth and documented in NC EDSS.
 2. Infant hepatitis B vaccination series is completed at 6 months of age and documented in NC EDSS.
 3. Infant post-vaccination testing is done at 9-15 months of age and documented in NC EDSS.
 - a. When an ELR for post-vaccination serology of a current perinatal case enters NC EDSS, creating a new **Hepatitis B Lab/Condition Report (16)**, the Subsequent Event Package should be marked to indicate the event is currently being followed, and then re-assigned to Hep B Perinatal Case Management, who will merge the **Hepatitis B Lab/Condition Report (16)** into the active **Hepatitis B Perinatally Acquired (116)** event. **LHDs should never merge any Hepatitis B events!**
 - b. When a paper lab for a current **Hepatitis B Perinatally Acquired (116)** event is received, the lab should be manually entered into the event.
 4. LHDs should assign the infant's event to Perinatal Hep B Case Management for review after each vaccination in the series is received, upon completion of post-vaccination testing, and if the infant is lost to follow up.

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- v) Persons previously reported with a **Hepatitis B Chronic Carrier (115)** condition who are reported by laboratories normally associated with blood, plasma or tissue donation must be investigated.
 - (a) LHDs should determine if control measures were violated.
 - (b) If it is determined that control measure were violated, LHDs should take actions in accordance with their policy and procedure for control measure violations.

2) INVESTIGATION IS NOT REQUIRED FOR:

- i) Persons who are male or are non-child-bearing age females (<14 or > 50 years) and have *previously* been documented in NC EDSS as **Hepatitis B Confirmed Carriers (115)** and the lab source is not associated with blood, plasma or tissue bank.
 - (a) If the lab is received as a paper report, **do not** enter it into NC EDSS.
 - (b) If the lab is received as an ELR in NC EDSS and generates a **Hepatitis B Lab/Condition Report (115)** event, complete the questions in the **Subsequent Report Package** and assign the event to the State Disease Registrar as a **Lab/Condition Report (115)**.
- ii) Non-reportable Hepatitis B lab results, (those not named in paragraph 1) i) of this business rule), do not require investigation.
 - (a) If a non-reportable lab result is received as a paper report, **do not** enter it into NC EDSS.
 - (b) If a non-reportable lab result is received as an ELR, NC EDSS will not create a new event for the non-reportable lab. If a Hepatitis B event already exists for the person, the ELR will update the event. The update will cause previously reported events that are closed to appear in the Hepatitis B – Lab Result Review Required Workflow. These events can be marked as reviewed without further action. If the ELR updates a currently open event, the event should continue through the reporting process.

3) RESPONSIBILITY FOR INVESTIGATION:

- i) Reported cases of communicable disease are to be investigated and reported by the county health department in which the patient currently resides.
- ii) For previously reported chronic carrier cases, the original county of residence shall be maintained in the original reported event. The current county of residence will create a Lab/Condition Report (16) in order to update classification, pregnancy status, conduct perinatal/contact tracking and/or reinforce control measures. The event should then be assigned to the State Disease Registrar as a Lab/Condition Report.
- iii) Direct liaison between counties for exchange of information and coordination of investigation is encouraged.

4) DEDUPLICATION OF HEPATITIS B EVENTS:

- i) **Deduplication/merging of Hepatitis B events is to be done at the state level only.** LHDs with events that need deduplication/merging should contact the NC EDSS Help Desk.

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- ii) The State Disease Registrar will routinely merge **Hepatitis B Lab/Condition Report (16)** events into the previously reported event at the time the event is assigned to the state for closure. This will result in one complete event with a chronological listing of labs and subsequent events, such as pregnancies.

5) CORRECTION OF DATA IN PREVIOUSLY REPORTED EVENTS:

- i) LHDs can provide updates to a previously reported case by creating a **Hepatitis B Lab/Condition Report (16)** event, entering the new information into the Subsequent Report package, and assigning the event to the State Disease Registrar. The State Disease Registrar will then merge the Lab/Condition Report event into the original event.
- ii) Other requests for corrections to closed events should be made to the State Disease Registrar via the NC EDSS Help Desk. Closed events will not be opened to LHDs for editing.

6) STATE SURVEILLANCE FUNCTIONS

- i) The Communicable Disease Branch will act as the State Disease Registrar for all Hepatitis B cases. As the State Disease Registrar, the Communicable Disease Branch will:
 - (1) Review all Hepatitis B events assigned to the State Disease Registrar for classification, mark the event for reporting to CDC if appropriate, merge the event into an original event if needed, and close the event.
 - (2) Review all Hepatitis B events assigned to the State Disease Registrar for an indicated pregnancy and process as follows:
 - (i) Hepatitis B events received by the State Disease Registrar missing required information will be returned to the LHD for completion.
 - (ii) Hepatitis B events for women in which a birth is indicated in the last 24 months, but have no link to an event(s) re: the treatment of the child or children, will be assigned to Perinatal Hep B Case Management.
 - (3) Paper laboratory test results for positive, reportable Hepatitis B labs received by the state by mail or fax will be reviewed and entered by the State Disease Registrar as **Lab/Condition Report (16)** events.

7) STATE CASE MANAGEMENT FUNCTIONS FOR PREVENTION OF PERINATAL TRANSMISSION

- i) The Immunization Branch will perform case management activities to prevent perinatal transmission of Hepatitis B.
 - (1) Events for Perinatal hepatitis B contacts will be assigned to the State Disease Registrar for reporting and closure when complete. State Disease Registrar will close the event using the final case classification indicated by Perinatal Hep B Case Management.
 - (2) All case management activities will be recorded in the event assigned to Perinatal Hep B Case Management. The event will remain open until reassigned to the State Disease Registrar for merging, reporting, and closure as appropriate.

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- (3) Events requiring assignment to a LHD during case management will be assigned by Perinatal Hep B Case Management with directions for the LHD to reassign the event to Perinatal Hep B Case Management when the event is complete.
- (4) Interstate referrals of currently pregnant Hepatitis B positive females or infants being followed for perinatal exposure to Hepatitis B will be entered into NC EDSS and assigned to LHDs for case management.

8) Hepatitis B Events – Best Practice Guidelines

Complete information must be provided in the designated packages.

- i) Demographic package
 - (1) First and last name of patient
 - (2) Date of birth
 - (3) Address
 - (4) County of residence for the event
 - (5) Race
 - (6) Gender
- ii) Clinical package...complete *all* sections, with emphasis on the following:
 - (1) Is/was patient symptomatic for this disease? If YES, check all symptoms that apply.
 - (2) Pregnancy status for all females aged 14-50. If currently pregnant, provide estimated delivery date (EDD).
 - (3) Reason for testing
 - (4) Document that control measures were given, if applicable. For additional guidance, see "Documenting Hepatitis B Control Measures" in the 2011 Hepatitis B Manual.
- iii) Risk History package...Please list all known possible exposures.
- iv) Vaccine Information package...provide complete documentation of all vaccinations received, if applicable
- v) Administrative package
 - (1) Initial source of report to public health
 - (2) Date of initial report to public health
 - (3) NC county of residence for the event
 - (4) Correct assignment of the event, as follows:
 - (a) Assign all hepatitis B events to the State Disease Registrar once case investigation is complete.
 - (b) Assign all Perinatally-Acquired hepatitis B events to state Perinatal Hep B Case Management.
 - (c) If an event has been assigned to you by the State Disease Registrar, please provide the requested information, and return the event to the State Disease Registrar.
 - (d) If an event has been assigned to you by state Perinatal Hep B Case Management, please provide the requested information, and return the event to state Perinatal Hep B Case Management.

NOTE:

- All Hepatitis B events with pregnancies resulting in live births must have a linked Hepatitis B Perinatally-Acquired event (116) for each infant.
- **NEVER** merge hepatitis B events (this is also known as deduplication).