

**RULES  
OF  
TENNESSEE DEPARTMENT OF HEALTH  
FAMILY HEALTH AND WELLNESS  
MATERNAL & CHILD HEALTH/NEWBORN SCREENING**

**CHAPTER 1200-15-01  
NEWBORN HEARING TESTING, SCREENING FOR METABOLIC/GENETIC  
DISORDERS AND CRITICAL CONGENITAL HEART DISEASE**

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**1200-15-01-.01 TESTS.** The Department of Health will designate the prescribed effective screening tests and examinations which will be performed on newborns in accordance with Rule 1200-15-01-.02 for the detection of hearing loss, critical congenital heart disease and metabolic/genetic disorders as designated by the Department of Health.

- (1) Exemptions for religious beliefs. Nothing in this part shall be construed to require the testing of or medical treatment for the minor child of any person who shall file with the Department of Health a signed, written statement that such tests or medical treatment conflict with such person's religious tenets and practices, affirmed under penalties of perjury pursuant to T.C.A. § 68-5-403. The newborn screening refusal form provided by the State should be completed, filed with the Department and retained in the medical record for the period of time defined by the hospital or provider policy.
- (2) Failure to have a child tested for the detection of hearing loss and metabolic/genetic disorders as designated by the Department of Health is a Class C misdemeanor pursuant to T.C.A. § 68-5-404.

**Authority:** T.C.A. §§ 4-5-202, 68-5-401 et seq., 68-5-501 et seq., and 68-5-901 et seq. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed September 1, 1982; effective October 1, 1982. Amendment filed September 16, 1996; effective January 28, 1997. Repeal and new rule filed December 30, 1999; effective March 14, 2000. Repeal and new rule filed September 26, 2003; effective January 28, 2004. Repeal and new rule filed December 13, 2012; effective May 31, 2013.

**1200-15-01-.02 PERSONS AND/OR INSTITUTIONS RESPONSIBLE FOR TESTS FOR NEWBORN INFANTS.** The following persons or institutions shall be responsible for hearing testing, critical congenital heart disease screening and blood specimen collection for metabolic/genetic disorders as designated by the Department of Health. Specimens and results shall be submitted in a manner as directed by the Department of Health; procedures are located on the Department's web page.

- (1) Every chief administrative officer of a hospital and the attending physician in each instance shall:
  - (a) Submit a satisfactory specimen of blood to the State Public Health Laboratory, Department of Health. This sample shall be collected between twenty-four and forty-eight (24-48) hours of age and mailed within twenty-four (24) hours of collection. In

(Rule 1200-15-01-.02, continued)

some cases it may be necessary to collect a specimen prior to twenty-four (24) hours of age if the infant is going to be discharged, transferred or transfused.

1. Recollect a specimen of blood if the infant was initially screened before twenty-four (24) hours of age. This repeat sample shall be collected between twenty-four and seventy-two (24-72) hours of age and mailed within twenty-four (24) hours of collection. If the infant has been discharged, instruct every parent, guardian, or custodian to bring the infant back to the hospital or to a physician or the nearest local health department to be re-screened
  - (b) Perform a physiologic hearing screen. The result of the hearing screen is to be reported to the Department of Health and should be done before hospital discharge or prior to one (1) month of age.
  - (c) Perform pulse oximetry tests on all newborns to screen for critical congenital heart disease between twenty-four and forty-eight (24-48) hours of age. The recommended protocol for screening is available online at the Department of Health's web page.
- (2) Any health care provider(s) of delivery services in a non-hospital setting shall:
- (a) Submit a satisfactory specimen of blood to the State Public Health Laboratory, Department of Health, in a manner as directed by the Department. This sample shall be collected between twenty-four and forty-eight (24-48) hours of age and mailed within twenty-four (24) hours of collection. In some cases it may be necessary to collect a specimen prior to twenty-four (24) hours of age if the infant is going to be discharged, transferred or transfused.
    1. Recollect a specimen of blood if the infant was initially screened before twenty-four (24) hours of age. This repeat sample shall be collected between twenty-four and seventy-two (24-72) hours of age and mailed within twenty-four (24) hours of collection. If the infant has been discharged, instruct every parent, guardian, or custodian to bring the infant back to the hospital or to a physician or the nearest local health department to be re-screened
  - (b) Instruct the parent, guardian or custodian to obtain a physiologic hearing screen prior to one (1) month of age. A referral may be made to the State Department of Health to assist in locating a hearing provider.
  - (c) Perform pulse oximetry tests on all newborns to screen for critical congenital heart disease between twenty-four and forty-eight (24-48) hours of age. The recommended protocol for screening is available online at the Department of Health's web page.
- (3) Any parent, guardian, or custodian residing in Tennessee, of an infant born in Tennessee, outside a Tennessee health care facility and without the assistance of a health care provider, shall:
- (a) Between twenty-four to forty-eight (24-48) hours of age present said infant to a primary care provider or local health department for blood specimen collection.
  - (b) Obtain a physiologic hearing screen prior to one (1) month of age. A referral may be made to the State Department of Health to assist in locating a hearing provider.
  - (c) Between twenty-four and forty-eight (24-48) hours of age present said infant to a primary care provider to perform pulse oximetry tests to screen for critical congenital

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heart disease. The recommended protocol for screening is available online at the Department of Health's web page.

**Authority:** T.C.A. §§ 4-5-202, 68-5-401 et seq., 68-5-501 et seq., and 68-5-901 et seq. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed September 1, 1982; effective October 1, 1982. Amendment filed September 16, 1996; effective January 28, 1997. Repeal and new rule filed December 30, 1999; effective March 14, 2000. Repeal and new rule filed September 26, 2003; effective January 28, 2004. Repeal and new rule filed December 12, 2012; effective May 31, 2013.

**1200-15-01-.03 NEWBORN SCREENING PAMPHLET PROVIDED TO PARENTS.** The chief administrative officer of each birthing facility shall order the distribution of a pamphlet to every parent, guardian or custodian of an infant screened. The pamphlet, distributed by the Department of Health, educates and prepares the family for newborn testing on their infant. If an infant's blood specimen was collected earlier than twenty-four (24) hours after birth and the patient is discharged home, the birthing facility must review the information on the back of the pamphlet with the family prior to discharge; the information requires the family to present the infant to the hospital, physician or health department within 24-72 hours for a repeat blood specimen. The pamphlet will have a perforated page that may be signed by the parent and placed in the medical record as documentation that the pamphlet was provided.

**Authority:** T.C.A. §§ 4-5-202, 68-5-401 et seq., 68-5-501 et seq., and 68-5-901 et seq. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed September 1, 1982; effective October 1, 1982. Amendment filed September 16, 1996; effective January 28, 1997. Repeal and new rule filed December 30, 1999; effective March 14, 2000. Repeal and new rule filed September 26, 2003; effective January 28, 2004. Repeal and new rule filed December 13, 2012; effective May 31, 2013.

**1200-15-01-.04 MEDICAL PROVIDERS AND LOCAL HEALTH DEPARTMENTS MUST ASSIST THE DEPARTMENT OF HEALTH.**

- (1) The primary care provider's responsibility is to:
  - (a) Ensure that all newborn screening tests were conducted and provide necessary follow up, if needed, as instructed by the Newborn Screening Program.
  - (b) Recollect a blood specimen before two (2) weeks of age, as instructed by the program or tertiary center staff, or send the infant to the local Health Department for recollection.
  - (c) Assist the Department of Health in contacting families, submitting follow up information, making appropriate referrals and/or notifying the Department immediately if they are not the provider. The Newborn Screening Program outlines the providers' responsibilities in the practitioner guide which is available online at the Department of Health's web page.
  - (d) Obtain further hearing tests prior to three (3) months of age if the infant did not pass the hearing screen. A referral may be made to the State Department of Health to assist in locating a hearing provider.
  - (e) Submit the critical congenital heart disease follow-up form on infants who did not pass the pulse oximetry screen.
- (2) Audiologists shall submit the hearing follow-up form on infants referred to them for further testing through the newborn screening process.
- (3) Cardiologists shall submit the critical congenital heart disease follow-up form on infants referred to them through the newborn screening process.

(Rule 1200-15-01-.04, continued)

- (4) Each local health department shall assist the Department of Health in contacting all parents or guardians of infants who are in need of further testing to confirm or disprove the presumptive screening results based on the prescribed effective tests and examinations designed to detect genetic disorders as determined by the Department of Health.

**Authority:** T.C.A. §§ 4-5-202, 68-5-401 et seq., 68-5-501 et seq., and 68-5-901 et seq. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed September 1, 1982; effective October 1, 1982. Amendment filed September 16, 1996; effective January 28, 1997. Repeal and new rule filed December 30, 1999; effective March 14, 2000. Repeal and new rule filed September 26, 2003; effective January 28, 2004. Repeal and new rule filed December 13, 2012; effective May 31, 2013.

#### **1200-15-01-.05 FEE FOR TESTING.**

- (1) Fee. A fee shall be due and payable to the Department of Health for conducting any one or all tests on a patient blood sample submitted to the Department for metabolic/genetic tests as designated by the Department of Health.

The Commissioner shall re-evaluate, update, and post the fee at least annually and from time to time as appropriate. The Commissioner shall post the annual update on or before November 15th of each year, and this new fee shall become effective starting January 1st of the following year. If the Commissioner posts an updated fee more frequently than on an annual basis, then the updated fee will become effective on the date stated in the fee notice. The fee shall be available online at the Department of Health's web page and in print.

- (2) Procedure. The health care facility collecting the blood sample for the purpose of receiving any or all of the tests set forth in paragraph (1) shall be billed by the State Public Health Laboratory, Department of Health.
- (3) Waiver. The fee shall be waived for patients who are unable to pay, based on information obtained at the time of admission to the health care facility, as determined by the health care provider.

**Authority:** T.C.A. §§ 4-5-202, 68-5-401 et seq., and 68-5-501 et seq. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed September 1, 1982; effective October 1, 1982. Repeal and new rule filed December 30, 1999; effective March 14, 2000. Repeal and new rule filed September 26, 2003; effective January 28, 2004. Amendment filed August 9, 2007; effective December 28, 2007. Repeal and new rule filed December 13, 2012; effective May 31, 2013.

#### **1200-15-01-.06 DEPARTMENT OF EDUCATION AND DEPARTMENT OF HEALTH RESPONSIBILITIES.**

- (1) In compliance with T.C.A. §§ 68-5-901 et seq. and the Individuals with Disabilities Education Act (IDEA) Child Find, the Tennessee Department of Health Newborn Hearing Screening program shall notify the Department of Education, IDEA Part C, Tennessee Early Intervention System (TEIS) of newborns identified to be in need of further hearing testing or who have been diagnosed with hearing loss.
- (2) The Department of Education, IDEA Part C, Tennessee Early Intervention System (TEIS), shall contact the health care provider, hearing provider, and/or family of the newborn to determine if further hearing testing has been completed or if the family is in need of assistance to obtain further testing to determine if there is a hearing loss.
- (3) The Department of Education, IDEA Part C, Tennessee Early Intervention System (TEIS) program shall report the results of follow-up to the Department of Health Newborn Hearing Screening program as outlined in policy developed in cooperation between the programs.

(Rule 1200-15-01-.06, continued)

- (4) The Tennessee Early Intervention System (TEIS) will assist the Newborn Hearing Screening Program in tracking children identified with risk indicators for hearing loss until three (3) years of age as outlined in policy developed in cooperation between the programs.

**Authority:** T.C.A. §§ 4-5-202, 68-5-401 et seq., 68-5-501 et seq., and 68-5-901 et seq.. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed September 1, 1982; effective October 1, 1982. Repeal filed December 30, 1999; effective March 14, 2000. New rule filed September 26, 2003; effective January 28, 2004. Repeal and new rule filed December 13, 2012; effective May 31, 2013.

**1200-15-01-.07 REPEALED.**

**Authority:** T.C.A. §§ 4-5-202, 53-626, 68-5-401 et. seq., and 68-5-501 et. seq.. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed September 1, 1982; effective October 1, 1982. Repeal filed December 30, 1999; effective March 14, 2000.