



STATE OF TENNESSEE
DEPARTMENT OF HEALTH
LABORATORY SERVICES
630 HART LANE
NASHVILLE, TN 37243

January 28, 2008

Subject: Increase in Fee for Newborn Screening Test

Dear Hospital Administrator,

On December 28, 2007, new rules governing newborn screening testing went into effect. These new rules raise the fee for newborn screening from \$47.50 to \$75.00. This fee increase is necessary to provide expanded newborn screening testing and follow-up. This fee increase was reviewed by the Tennessee Department of Health (TDH) Genetic Advisory Committee, the Commissioner of Health, the formal rules review and implementation procedures, and a joint Committee of the State Legislature. This fee will allow for implementation of expanded Tandem Mass Spectrometry tests, Cystic Fibrosis screening, and funds for state genetic centers for case management and treatment.

You will see the increase fee reflected in the next billing mailed the first week of February. The first specimen for each infant from your hospital will be charged \$75.00 each. We have also included a copy of the new TDH rules (TCA 1200-15-1-.05) addressing the increased fee.

Sincerely,

David L. Smalley, PH.D., M.S.S., BCLD
Laboratory Director
Tennessee Department of Health
Laboratory Services
630 Hart Lane
Nashville, Tennessee 37247-0801
(615) 262-6300

**RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
HEALTH SERVICES ADMINISTRATION
MATERNAL & CHILD HEALTH/NEWBORN SCREENING**

**CHAPTER 1200-15-1
PHENYLKETONURIA, HYPOTHYROIDISM AND OTHER
METABOLIC/GENETIC DEFECTS**

TABLE OF CONTENTS

1200-15-1-.01	Tests	1200-15-1-.05	Fee for Testing
1200-15-1-.02	Institutions Responsible for Tests for Newborn Infants	1200-15-1-.06	Department of Education and Department of Health Responsibilities
1200-15-1-.03	Metabolic/Genetic Newborn Screening, Pamphlet Provided to Parents	1200-15-1-.07	Repealed
1200-15-1-.04	Local Health Departments must Assist the Department of Health		

1200-15-1-.01 TESTS. The Department of Health will designate the prescribed effective screening tests and examinations which will be performed on the blood samples submitted in accordance with 1200-15-1-.02 for the detection of metabolic/genetic disorders in newborns. Tests are to be conducted for Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism, Galactosemia, Hemoglobinopathies, Homocystinuria, Maple Syrup Urine Disease (MSUD), Medium-Chain Acyl CoA Dehydrogenase (MCAD) Deficiency, Phenylketonuria (PKU), and other metabolic/genetic tests as designated by the Department of Health. Results of the Newborn Hearing Screening, if conducted, are to be submitted in conjunction with the blood sample procedure for the detection of disorders in accordance with 1200-15-1-.02.

- (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 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 genetic/metabolic disorders is a Class C misdemeanor. Reporting of hearing screening is not to be construed as mandatory testing, therefore, failure to have a child tested for hearing loss will not be considered a misdemeanor pursuant to T.C.A.68-5-404.

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. 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.

1200-15-1-.02 INSTITUTIONS RESPONSIBLE FOR TESTS FOR NEWBORN INFANTS. The following persons or institutions shall be responsible for having tests made on newborn infants:

- (1) Every chief administrative officer of a hospital and the attending physician in each instance shall be responsible for submitting a specimen of blood to the State of Tennessee Laboratory, State Department of Health, in a manner as directed by the Department. This sample shall be collected before newborn infants are discharged from the nursery, regardless of age.
- (2) Every chief administrative officer of a hospital and the attending physician shall direct every parent, guardian, or custodian to bring the infant, if the infant was initially screened before twenty-four (24) hours of age, back to the hospital or to a physician or the nearest local health department to be re-

(Rule 1200-15-1-.02, continued)

screened for Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism, Galactosemia, Hemoglobinopathies, Homocystinuria, Maple Syrup Urine Disease (MSUD), Medium-Chain Acyl CoA Dehydrogenase (MCAD) Deficiency, Phenylketonuria (PKU), and other metabolic/genetic tests as designated by the Department of Health, within twenty-four to forty-eight (24-48) hours after birth. In the case of a premature infant, an infant on parenteral feeding or any newborn treated for an illness, who is not discharged from the nursery in a timely manner, the sample should be collected not later than the infant's seventh (7th) day of age.

- (3) Any health care provider(s) of delivery services in a non-hospital setting shall be responsible for submitting a specimen of blood to the State of Tennessee Laboratory, or directing every parent, guardian, or custodian to bring the infant, between twenty-four to forty-eight (24-48) hours of age, to a hospital, physician or local health department to be screened for Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism, Galactosemia, Hemoglobinopathies, Homocystinuria, Maple Syrup Urine Disease (MSUD), Medium-Chain Acyl CoA Dehydrogenase (MCAD) Deficiency, Phenylketonuria (PKU), and other metabolic/genetic tests as designated by the Department of Health.
- (4) 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 between twenty-four to forty-eight (24-48) hours of the birth of said infant present said infant to a physician or local health department for testing for the purpose of detecting Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism, Galactosemia, Hemoglobinopathies, Homocystinuria, Maple Syrup Urine Disease (MSUD), Medium-Chain Acyl CoA Dehydrogenase (MCAD) Deficiency, Phenylketonuria (PKU), and other metabolic/genetic tests as designated by the Department of Health.
- (5) The original blood specimen shall be collected between twenty-four and forty-eight (24-48) hours of age. Repeat blood specimens shall be collected before two (2) weeks of age.
- (6) Every chief administrative officer of a hospital that performs physiologic newborn hearing screening shall be responsible for reporting the results of the newborn hearing screening test performed prior to discharge from the health care facility. Results of the hearing screening are to be reported to the Department of Health on the form designated for newborn screening blood spot collection or a similar form designated by the Department.

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. 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.

1200-15-1-.03 METABOLIC/GENETIC NEWBORN SCREENING, PAMPHLET PROVIDED TO PARENTS.

The chief administrative officer of each hospital shall order the distribution of a pamphlet on Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism, Galactosemia, Hemoglobinopathies, Homocystinuria, Maple Syrup Urine Disease (MSUD), Medium-Chain Acyl CoA Dehydrogenase (MCAD) Deficiency, Phenylketonuria (PKU), and other metabolic/genetic tests as designated by the Department of Health, to every parent, guardian or custodian of an infant screened for these conditions. The pamphlet, distributed by the Department of Health, educates and prepares the family for newborn testing on their infant. If an infant's screen was collected earlier than twenty-four (24) hours after birth and the patient is discharged home, the health care facility must review the information on the back of the pamphlet with the family, which requires them to present the infant to the hospital, physician or health department within 24-48 hours for a repeat screen. 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.

(Rule 1200-15-1-.03, continued)

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. 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.

1200-15-1-.04 LOCAL HEALTH DEPARTMENTS MUST ASSIST THE DEPARTMENT OF HEALTH.

Each local health department shall assist the Department of Health in contacting all cases suspected of having Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism, Galactosemia, Hemoglobinopathies, Homocystinuria, Maple Syrup Urine Disease (MSUD), Medium-Chain Acyl CoA Dehydrogenase (MCAD) Deficiency, Phenylketonuria (PKU), and other metabolic/genetic tests as designated by the Department of Health 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., 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. 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.

1200-15-1-.05 FEE FOR TESTING.

- (1) Fee. A fee of seventy-five dollars and zero cents (\$75.00) shall be due and payable to the Department of Health for conducting any one or all of the following tests on a patient blood sample submitted to the Department for such testing: Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital Hypothyroidism, Galactosemia, Hemoglobinopathies, Homocystinuria, Maple Syrup Urine Disease (MSUD), Medium Chain Acyl CoA Dehydrogenase (MCAD) Deficiency, Phenylketonuria (PKU), and other metabolic/genetic tests as designated by the Department of Health.
- (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 Department of Health State Laboratory.
- (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.

1200-15-1-.06 DEPARTMENT OF EDUCATION AND DEPARTMENT OF HEALTH RESPONSIBILITIES.

- (1) In compliance with 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 all newborns identified by hearing screening to be in need of further hearing testing.
- (2) The Department of Education, IDEA Part C, Tennessee Early Intervention System (TEIS), shall contact the health care 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.

(Rule 1200-15-1-.06, continued)

- (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.
- (4) Reporting shall be coordinated with the Tennessee Early Intervention System (TEIS), Newborn Hearing Screening, and Children's Information Tennessee data systems. Tennessee Early Intervention System (TEIS) will submit follow-up data as outlined in policy developed in cooperation between the programs.

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 filed December 30, 1999; effective March 14, 2000. New rule filed September 26, 2003; effective January 28, 2004.

1200-15-1-.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.