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Sequence Number: 12-12-12  
 Rule ID(s): 5350  
 File Date: 12/13/12  
 Effective Date: 5/31/13

## Proposed Rule(s) Filing Form

*Proposed rules are submitted pursuant to T.C.A. §§ 4-5-202, 4-5-207 in lieu of a rulemaking hearing. It is the intent of the Agency to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State. To be effective, the petition must be filed with the Agency and be signed by twenty-five (25) persons who will be affected by the amendments, or submitted by a municipality which will be affected by the amendments, or an association of twenty-five (25) or more members, or any standing committee of the General Assembly. The agency shall forward such petition to the Secretary of State.*

<b>Agency/Board/Commission:</b>	Department of Health
<b>Division:</b>	Health Services Administration
	Maternal & Child Health/Newborn Screening
<b>Contact Person:</b>	Margaret Major
<b>Address:</b>	Cordell Hull Building, 5 <sup>th</sup> Floor 425 Fifth Avenue Nashville, Tennessee
<b>Zip:</b>	37243
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**Revision Type (check all that apply):**

- Amendment  
 New  
 Repeal

**Rule(s) Revised** (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	Chapter Title
1200-15-01	Phenylketonuria, Hypothyroidism and Other Metabolic/Genetic Defects
Rule Number	Rule Title
1200-15-01-.01	Tests
1200-15-01-.02	Institutions Responsible for Tests for Newborn Infants
1200-15-01-.03	Metabolic/Genetic Newborn Screening Pamphlet Provided to Parents
1200-15-01-.04	Local Health Departments Must Assist the Department of Health
1200-15-01-.05	Fee for Testing
1200-15-01-.06	Department of Education and Department of Health Responsibilities
1200-15-01-.07	Repealed

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to <http://state.tn.us/sos/rules/1360/1360.htm>)

The name of the division of the Department of Health in the Rule title is being changed from Health Services Administration to Family Health and Wellness.

The title of the chapter of 1200-15-01 Phenylketonuria, Hypothyroidism and Other Metabolic/Genetic Defects is being changed to Newborn Hearing Testing, Screening for Metabolic/Genetic Disorders and Critical Congenital Heart Disease.

#### Family Health and Wellness

##### 1200-15-01

Newborn Hearing Testing, Screening for Metabolic/Genetic Disorders and Critical Congenital Heart Disease.

1200-15-01-.01 Tests

1200-15-01-.02 Persons and/or Institutions Responsible for Tests for Newborn Infants

1200-15-01-.03 Newborn Screening Pamphlet Provided to Parents

1200-15-01-.04 Medical Providers and Local Health Departments Must Assist the Department of Health

1200-15-01-.05 Fee for Testing

1200-15-01-.06 Department of Education and Department of Health Responsibilities

1200-15-01-.07 Repealed

Rule 1200-15-01-.01 Tests is amended by deleting the introductory language as well as paragraphs (1) and (2) in their entirety and substituting instead the following, so that as amended, the rule shall read:

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.

Rule 1200-15-01-.02 Institutions Responsible for Test for Newborn Infants is amended by changing the title of the rule to Persons and/or Institutions Responsible for Tests for Newborn Infants and is further amended by deleting the introductory language in its entirety and substituting instead the following, so that as amended the new title and introductory language shall read:

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.

Rule 1200-15-01-.02 Persons and/or Institutions Responsible for Tests for Newborn Infants is further amended by deleting the paragraphs (1), (2), (3), (4), (5) and (6) in their entirety and substituting instead the following, so

that as amended, the new paragraphs shall read:

- (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 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 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.

Rule 1200-15-01-.03 Metabolic/Genetic Newborn Screening, Pamphlet Provided to Parents is amended by changing the title of the rule to Newborn Screening Pamphlet Provided to Parents and is further amended by deleting the introductory language and substituting instead the following:

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.

Rule 1200-15-01-.04 Local Health Departments Must Assist the Department of Health is amended by changing the title of the rule to Medical Providers and Local Health Departments Must Assist the Department of Health and is further amended by deleting the rule in its entirety and substituting instead the following language, so that as amended the new rule shall read:

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.
- (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.

Rule 1200-15-01-.05 Fee for Testing is amended by deleting the language of the rule in its entirety and substituting instead the following, so that as amended, the new rule shall read:

- (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 15<sup>th</sup> of each year, and this new fee shall become effective starting January 1<sup>st</sup> 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.

Rule 1200-15-01-.06 Department of Education and Department of Health Responsibilities is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the rule shall read:

- (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.
- (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.

\* If a roll-call vote was necessary, the vote by the Agency on these rules was as follows:

Board Member	Aye	No	Abstain	Absent	Signature (if required)
N/A					

I certify that this is an accurate and complete copy of proposed rules, lawfully promulgated and adopted by the Commissioner of Health on 8/15/2012, and is in compliance with the provisions of T.C.A. § 4-5-222. The Secretary of State is hereby instructed that, in the absence of a petition for proposed rules being filed under the conditions set out herein and in the locations described, he is to treat the proposed rules as being placed on file in his office as rules at the expiration of sixty (60) days of the first day of the month subsequent to the filing of the proposed rule with the Secretary of State.

Date: 8/15/12

Signature: Mary K Kennedy

Name of Officer: Mary K Kennedy

Title of Officer: Deputy General Counsel

Subscribed and sworn to before me on: 08/15/2012

Notary Public Signature: Barbara E West

My commission expires on: 05/05/2015



MY COMMISSION EXPIRES: May 5, 2015

All proposed rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.

Robert E. Cooper, Jr.  
 Robert E. Cooper, Jr.  
 Attorney General and Reporter  
12-9-12  
 Date

**Department of State Use Only**

Filed with the Department of State on: 12/13/12

Effective on: 5/31/13

Tre Hargett  
 Tre Hargett  
 Secretary of State

RECEIVED  
 2012 DEC 13 PM 3:52  
 SECRETARY OF STATE  
 REGISTRATIONS

**Regulatory Flexibility Addendum**

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

These rules only affect state government and no small businesses will be impacted by their promulgation.

## **Impact on Local Governments**

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 “any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments.” (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

These rule amendments only affect state government and will not have an impact on local governments.

**Additional Information Required by Joint Government Operations Committee**

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

- (A) A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rules sets forth the health conditions for which newborns shall be screened at birth. The significant change is the addition of pulse oximetry screening for critical cyanotic congenital heart disease.

- (B) A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

Public Chapter No. 556, T.C.A. § 68-5-507

- (C) Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

Hospitals, birthing centers, and families of neonates will be most affected.

- (D) Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None

- (E) An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

None

- (F) Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Margaret Major, Maternal & Child Health and Mary Kennedy, Deputy General Counsel, Tennessee Department of Health possess substantial knowledge and understanding of the rule.

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Margaret Major, Maternal & Child Health and Mary Kennedy, Deputy General Counsel, Tennessee Department of Health will explain the rule at a scheduled meeting of the committees.

- (H) Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Margaret Major, Maternal & Child Health, 4<sup>th</sup> Floor Cordell Hull Building, 425 5<sup>th</sup> Avenue North, Nashville TN 37243, (615) 741-0377, [Margaret.Major@tn.gov](mailto:Margaret.Major@tn.gov) ; Mary Kennedy, Deputy General Counsel, 3<sup>rd</sup> Floor Cordell Hull Building, 425 5<sup>th</sup> Avenue North, Nashville TN 37243, (615) 253-4878, [Mary.Kennedy@tn.gov](mailto:Mary.Kennedy@tn.gov)

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

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

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

Newborn Hearing Testing, Screening for Metabolic/Genetic Disorders  
and Critical Congenital Heart Disease.

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1200-15-1-.04	<del>Local Health Departments must Assist the Department of Health, Medical Providers and Local Health Departments Must Assist the Department of Health</del>		

~~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.~~

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 and retained in the medical record for the period of time defined by the hospital or provider policy.~~

(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.

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

- ~~(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.~~
- (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., and 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.*

~~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:~~

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 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.~~
- (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 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) 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-screened for Biotinidase Deficiency, Congenital Adrenal Hyperplasia (CAH), Congenital~~

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

~~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.~~

(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.

~~(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.~~

(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.

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

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

~~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.~~

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., and 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.

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

~~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.~~

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.
- (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., and 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.

**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.~~

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

- ~~(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.~~
- (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 15<sup>th</sup> of each year, and this new fee shall become effective starting January 1<sup>st</sup> 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.*

**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.~~
- (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 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.~~
- (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.

(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.~~

(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.

~~(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.~~

(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., ~~and 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.

**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.