

Proposed Rules
of the
Tennessee Department of Health
Bureau of Health Services Administration
Women's Health and Genetics/Newborn Screening

Chapter 1200-15-01
Phenylketonuria, Hypothyroidism and Other Metabolic/Genetic Defects

Presented herein are proposed amendments of the Department of Health, Bureau of Health Services Administration, submitted pursuant to Tennessee Code Annotated § 4-5-202 in lieu of a rulemaking hearing. It is the intent of the Department of Health, Bureau of Health Services Administration, to promulgate these rules without a rulemaking hearing unless a petition requesting such hearing is filed within thirty (30) days of the publication date of the issue of the Tennessee Administrative Register in which the proposed amendments are published. Such petition to be effective must be filed with the Bureau of Health Services Administration on the 4th Floor of the Cordell Hull Building located at 425 Fifth Avenue North, Nashville, Tennessee, 37243, and in the Administrative Procedures Division of the Department of State, Eighth Floor, William R. Snodgrass Tennessee Tower, 312 Eighth Avenue North, Nashville, Tennessee, 37243, and must 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.

For copies of the entire text of the proposed amendments, contact:

Margaret Major, WHG
Department of Health
Fifth Floor, Cordell Hull Building
425 Fifth Avenue, North
Nashville, Tennessee 37243
(615) 741-0377
email: Margaret.Major@state.tn.us

The text of the proposed amendments is as follows:

Amendments

Rule 1200-15-01-.05, Fee For Testing, paragraph (1), is amended by deleting the entire paragraph and substituting instead the following language, so that as amended, the paragraph shall read:

- (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.

Authority: T.C.A. §§ 4-5-202, 68-5-401 et seq., and 68-5-501 et seq.

The proposed rules set out herein were properly filed in the Department of State on the 9th day of August, 2007, and pursuant to the instructions set out above, and in the absence of the filing of an

appropriate petition calling for a rulemaking hearing, will become effective on the 28th day of December, 2007. (FS 08-10-07; DBID 2653)

REGULATORY FLEXIBILITY ANALYSIS
OF RULES BEING CONSIDERED FOR AUTHORIZATION
TO HAVE A RULEMAKING HEARING
Genetics and Newborn Screening

The Department of Health must consider whether the rules being proposed are such that in relation to small businesses (businesses with 50 or fewer full time employees) the proposed language of the rules meets all of the following requirements:

- (1) That they do not overlap, duplicate, or conflict with other federal, state, and local governmental rules; and
- (2) That they exhibit clarity, conciseness, and lack of ambiguity; and
- (3) That they establish flexible compliance and/or reporting requirements for small businesses; and
- (4) That they establish friendly schedules or deadlines for compliance and/or reporting requirements for small businesses; and
- (5) That they consolidate or simplify compliance or reporting requirements for small businesses; and
- (6) That they establish performance standards for small businesses as opposed to design or operational standards; and
- (7) That they do not create unnecessary entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

The Women's Health/Genetics Section of the Tennessee Department of Health has conducted this analysis and concluded that as to small businesses the proposed rules or rule amendments substantially meet all of the required objectives.

Any specific issues applicable to the rules or amendments under consideration raised by the analysis are as follows:

- (3) The proposed rules are not written with special consideration for flexible compliance and/or reporting requirements because the mission of newborn screening is to test all infants at birth, report results as soon as possible, and follow-up appropriately for the best interest of the infant's health. The proposed rules change only the amount of the fee charged by the State Laboratory for the testing and follow-up services.
- (4) The schedules and deadlines throughout the proposed rules have been determined to be those in the best interests of the newborn infant and allowing for appropriate intervention upon any laboratory findings as a result of the newborn screening test.
- (6) Rules for the newborn screening services are based on current and accepted medical standards for screening infants for metabolic and genetics disorders; therefore, these rules apply to all facilities providing birthing services in Tennessee.
- (7) The proposed rules increase the fee charged for the newborn screening testing and follow-up

services. This increase is necessary to maintain the services which are provided to all infants born in Tennessee. The proposed rules do not create any barriers to entrepreneurial activity or curb innovation. They are necessary for the protection of the health, safety and welfare of Tennesseans.

**ECONOMIC IMPACT STATEMENT
PROPOSED RULES – Genetics and Newborn Screening**

1. Type(s) and number of small businesses subject to the proposed rule:

All hospitals with obstetric/delivery services (77); there is no practical way to determine if any of these are considered small businesses.

All birthing centers (3); all three would most likely be considered small businesses.

2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule: The proposed rule increases the fee charged by the State for newborn screening at the State Laboratory. There would be no additional reporting or recordkeeping required, as the State already charges for this service. The reporting, recordkeeping and administrative costs should not change because of the change in the fees charged.

3. Probable effect on impacted small businesses and consumers: Birthing hospitals and other birthing facilities currently pay the State Laboratory for the newborn screening tests submitted on babies born at their facilities. This will not change with the proposed change in the rule.

4. Description of any alternate methods of achieving the purpose of the proposed rule: Increasing the fee charged for newborn screening by the State is necessary to maintain the service and to cover the costs for testing. There is no other alternative source of funding available to the Department other than increasing the fee. Requesting an appropriation from the State Legislature was not considered to be a viable alternative. There were no known sources of grant funding available for this purpose.

5. Comparison of proposed rule with any federal or state counterparts: Newborn screening is handled by the states, not at the federal level. States use a variety of sources of funds to provide the screening services, including state appropriations and charging fees.

6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule: T.C.A. 68-5-401 requires that every newborn infant be tested for phenylketonuria, hypothyroidism, galactosemia and other metabolic/genetic defects that would result in mental retardation or physical dysfunction as determined by the Department of Health. Exemptions under the law are for religious beliefs of the family. There are no exemptions made for any facility. Any person violating the provisions of this chapter or the rules relative to testing of newborn infants commits a Class C misdemeanor.