

## CHAPTER 256

(House Bill 216)

AN ACT concerning

### **Hereditary and Congenital Disorders – Newborn Screening**

FOR the purpose of establishing in the Department of Health and Mental Hygiene a certain system for screening newborn infants for hereditary and congenital disorders; establishing the Department's public health laboratory as the sole laboratory authorized to perform the screening tests; requiring the Department to establish protocols for obtaining specimens for testing; requiring the Department to determine the screening tests to be performed; authorizing postscreening testing by certain licensed laboratories under certain circumstances; authorizing the Secretary of Health and Mental Hygiene to delegate certain newborn screening under certain circumstances; requiring the Department to adopt certain regulations; requiring the Department to conduct a certain study; requiring the Department to submit a certain report to certain committees of the General Assembly on or before a certain date; providing for a delayed effective date of this Act; and generally relating to the screening and evaluation of newborn infants for hereditary and congenital disorders.

BY adding to

Article – Health – General  
Section 13–111 and 13–112  
Annotated Code of Maryland  
(2005 Replacement Volume and 2007 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

#### **Article – Health – General**

#### **13–111.**

(A) **THE DEPARTMENT SHALL ESTABLISH A COORDINATED STATEWIDE SYSTEM FOR SCREENING ALL NEWBORN INFANTS IN THE STATE FOR CERTAIN HEREDITARY AND CONGENITAL DISORDERS ASSOCIATED WITH SEVERE PROBLEMS OF HEALTH OR DEVELOPMENT, EXCEPT WHEN THE PARENT OR GUARDIAN OF THE NEWBORN INFANT OBJECTS.**

(B) **EXCEPT AS PROVIDED IN § 13–112 OF THIS SUBTITLE, THE DEPARTMENT'S PUBLIC HEALTH LABORATORY IS THE SOLE LABORATORY AUTHORIZED TO PERFORM TESTS ON SPECIMENS FROM NEWBORN INFANTS**

**COLLECTED TO SCREEN FOR HEREDITARY AND CONGENITAL DISORDERS AS DETERMINED UNDER SUBSECTION (D)(2) OF THIS SECTION.**

**(C) THE SYSTEM FOR NEWBORN SCREENING SHALL INCLUDE:**

**(1) LABORATORY TESTING AND THE REPORTING OF TEST RESULTS; AND**

**(2) FOLLOW-UP ACTIVITIES TO FACILITATE THE RAPID IDENTIFICATION AND TREATMENT OF AN AFFECTED CHILD.**

**(D) IN CONSULTATION WITH THE STATE ADVISORY COUNCIL ON HEREDITARY AND CONGENITAL DISORDERS, THE DEPARTMENT SHALL:**

**(1) ESTABLISH PROTOCOLS FOR A HEALTH CARE PROVIDER TO OBTAIN AND DELIVER TEST SPECIMENS TO THE DEPARTMENT'S PUBLIC HEALTH LABORATORY;**

**(2) DETERMINE THE SCREENING TESTS THAT THE DEPARTMENT'S PUBLIC HEALTH LABORATORY IS REQUIRED TO PERFORM;**

**(3) MAINTAIN A COORDINATED STATEWIDE SYSTEM FOR NEWBORN SCREENING THAT CARRIES OUT THE PURPOSE DESCRIBED IN SUBSECTION (C) OF THIS SECTION THAT INCLUDES:**

**(I) COMMUNICATING THE RESULTS OF SCREENING TESTS TO THE HEALTH CARE PROVIDER OF THE ~~NEW-BORN~~ NEWBORN INFANT;**

**(II) LOCATING NEWBORN INFANTS WITH ABNORMAL TEST RESULTS;**

**(III) SHARING NEWBORN SCREENING INFORMATION BETWEEN HOSPITALS, HEALTH CARE PROVIDERS, TREATMENT CENTERS, AND LABORATORY PERSONNEL; AND**

**(IV) DELIVERING NEEDED CLINICAL, DIAGNOSTIC, AND TREATMENT INFORMATION TO HEALTH CARE PROVIDERS, PARENTS, AND CAREGIVERS; AND**

**(4) ADOPT REGULATIONS THAT SET FORTH THE STANDARDS AND REQUIREMENTS FOR NEWBORN SCREENING FOR HEREDITARY AND CONGENITAL DISORDERS THAT ARE REQUIRED UNDER THIS SUBTITLE, INCLUDING:**

(I) **PERFORMING NEWBORN SCREENING TESTS;**

(II) **COORDINATING THE REPORTING, FOLLOW-UP, AND TREATMENT ACTIVITIES WITH PARENTS, CAREGIVERS, AND HEALTH CARE PROVIDERS; AND**

(III) **ESTABLISHING FEES FOR NEWBORN SCREENING THAT DO NOT EXCEED AN AMOUNT SUFFICIENT TO COVER THE ADMINISTRATIVE, LABORATORY, AND FOLLOW-UP COSTS ASSOCIATED WITH THE PERFORMANCE OF SCREENING TESTS UNDER THIS SUBTITLE.**

**13-112.**

(A) **THE SECRETARY MAY CONTRACT OR DELEGATE THE SCREENING REQUIRED UNDER § 13-111 OF THIS SUBTITLE TO ANOTHER ENTITY WITH THE APPROVAL OF THE STATE ADVISORY COUNCIL ON HEREDITARY AND CONGENITAL DISORDERS.**

(B) **SUBJECT TO SUBSECTION (C) OF THIS SECTION, A LABORATORY OTHER THAN THE DEPARTMENT'S PUBLIC HEALTH LABORATORY MAY PERFORM POSTSCREENING ~~COMPLEMENTARY~~ CONFIRMATORY OR DIAGNOSTIC TESTS ON NEWBORN INFANTS FOR HEREDITARY AND CONGENITAL DISORDERS.**

(C) **BEFORE OFFERING OR PERFORMING A POSTSCREENING TEST ON A NEWBORN INFANT FOR HEREDITARY AND CONGENITAL DISORDERS UNDER SUBSECTION (A) OF THIS SECTION, A LABORATORY SHALL:**

(1) **OBTAIN AND MAINTAIN A LICENSE ISSUED BY THE SECRETARY AS REQUIRED BY TITLE 17 OF THIS ARTICLE; AND**

(2) **MEET ALL THE STANDARDS AND REQUIREMENTS FOR A LABORATORY TO PERFORM TESTS ON NEWBORN INFANTS FOR HEREDITARY AND CONGENITAL DISORDERS THAT ARE ESTABLISHED BY THE SECRETARY.**

**SECTION 2. AND BE IT FURTHER ENACTED, That:**

**(a) The Department of Health and Mental Hygiene shall study whether a coordinated statewide system for screening newborn infants in the State for certain hereditary and congenital disorders should be applied to all newborn infants in the State.**

**(b) The Department shall report, in accordance with § 2-1246 of the State Government Article, to the Senate Finance Committee and the House Health and**

Government Operations Committee on the conclusions from the study required under subsection (a) of this section on or before December 1, 2008.

SECTION 3. AND BE IT FURTHER ENACTED, That Section 1 of this Act shall take effect January 1, 2009.

SECTION ~~2.~~ 4. AND BE IT FURTHER ENACTED, That, except as provided in Section 3 of this Act, this Act shall take effect ~~October 1, 2008~~ June 1, 2009.

**Approved by the Governor, April 24, 2008.**