

HOUSE BILL 216

J1

(8lr0113)

ENROLLED BILL

—Health and Government Operations/Finance—

Introduced by **Chair, Health and Government Operations Committee (By Request – Departmental – Health and Mental Hygiene)**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

Speaker.

CHAPTER _____

1 AN ACT concerning

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

3 FOR the purpose of establishing in the Department of Health and Mental Hygiene a
4 certain system for screening newborn infants for hereditary and congenital
5 disorders; establishing the Department’s public health laboratory as the sole
6 laboratory authorized to perform the screening tests; requiring the Department
7 to establish protocols for obtaining specimens for testing; requiring the
8 Department to determine the screening tests to be performed; authorizing
9 postscreening testing by certain licensed laboratories under certain
10 circumstances; authorizing the Secretary of Health and Mental Hygiene to
11 delegate certain newborn screening under certain circumstances; requiring the
12 Department to adopt certain regulations; requiring the Department to conduct a
13 certain study; requiring the Department to submit a certain report to certain
14 committees of the General Assembly on or before a certain date; providing for a

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Italics indicate opposite chamber / conference committee amendments.



1 delayed effective date of this Act; and generally relating to the screening and
2 evaluation of newborn infants for hereditary and congenital disorders.

3 BY adding to

4 Article – Health – General

5 Section 13–111 and 13–112

6 Annotated Code of Maryland

7 (2005 Replacement Volume and 2007 Supplement)

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

10 **Article – Health – General**

11 **13–111.**

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

17 (B) EXCEPT AS PROVIDED IN § 13–112 OF THIS SUBTITLE, THE
18 DEPARTMENT’S PUBLIC HEALTH LABORATORY IS THE SOLE LABORATORY
19 AUTHORIZED TO PERFORM TESTS ON SPECIMENS FROM NEWBORN INFANTS
20 COLLECTED TO SCREEN FOR HEREDITARY AND CONGENITAL DISORDERS AS
21 DETERMINED UNDER SUBSECTION (D)(2) OF THIS SECTION.

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

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

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

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

29 (1) ESTABLISH PROTOCOLS FOR A HEALTH CARE PROVIDER TO
30 OBTAIN AND DELIVER TEST SPECIMENS TO THE DEPARTMENT’S PUBLIC
31 HEALTH LABORATORY;

32 (2) DETERMINE THE SCREENING TESTS THAT THE
33 DEPARTMENT’S PUBLIC HEALTH LABORATORY IS REQUIRED TO PERFORM;

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

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

6 (II) LOCATING NEWBORN INFANTS WITH ABNORMAL TEST
7 RESULTS;

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

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

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

18 (I) PERFORMING NEWBORN SCREENING TESTS;

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

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

26 **13-112.**

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

31 (B) SUBJECT TO SUBSECTION (C) OF THIS SECTION, A LABORATORY
32 OTHER THAN THE DEPARTMENT'S PUBLIC HEALTH LABORATORY MAY PERFORM

1 **POSTSCREENING ~~COMPLEMENTARY~~ CONFIRMATORY OR DIAGNOSTIC TESTS ON**
 2 **NEWBORN INFANTS FOR HEREDITARY AND CONGENITAL DISORDERS.**

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

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

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

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

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

16 (b) The Department shall report, in accordance with § 2-1246 of the State
 17 Government Article, to the Senate Finance Committee and the House Health and
 18 Government Operations Committee on the conclusions from the study required under
 19 subsection (a) of this section on or before December 1, 2008.

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

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.