

HOUSE BILL 216

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8lr0113

By: **Chair, Health and Government Operations Committee (By Request -
Departmental - Health and Mental Hygiene)**

Introduced and read first time: January 23, 2008

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: February 28, 2008

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; and generally relating to the
13 screening and evaluation of newborn infants for hereditary and congenital
14 disorders.

15 BY adding to

16 Article - Health - General

17 Section 13-111 and 13-112

18 Annotated Code of Maryland

19 (2005 Replacement Volume and 2007 Supplement)

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

22 **Article - Health - General**

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.



1 **13-111.**

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

7 (B) EXCEPT AS PROVIDED IN § 13-112 OF THIS SUBTITLE, THE
8 DEPARTMENT'S PUBLIC HEALTH LABORATORY IS THE SOLE LABORATORY
9 AUTHORIZED TO PERFORM TESTS ON SPECIMENS FROM NEWBORN INFANTS
10 COLLECTED TO SCREEN FOR HEREDITARY AND CONGENITAL DISORDERS AS
11 DETERMINED UNDER SUBSECTION (D)(2) OF THIS SECTION.

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

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

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

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

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

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

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

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

29 (II) LOCATING NEWBORN INFANTS WITH ABNORMAL TEST
30 RESULTS;

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

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

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

11 (I) PERFORMING NEWBORN SCREENING TESTS;

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

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

19 **13-112.**

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

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

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

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

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

4 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
5 October 1, 2008.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.