

HOUSE BILL 827

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By: **Delegate O'Donnell**

Introduced and read first time: February 8, 2016

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 13, 2016

CHAPTER _____

1 AN ACT concerning

2 **Newborn Infant Screening – Testing by Nonpublic Laboratories – ~~Authorization~~**
3 **Notification**

4 FOR the purpose of ~~authorizing certain laboratories to perform certain screening tests for~~
5 ~~hereditary and congenital disorders under certain circumstances; authorizing a~~
6 ~~parent or guardian of a newborn infant to request that a certain laboratory perform~~
7 ~~certain initial tests to screen for hereditary and congenital disorders; requiring a~~
8 ~~health care provider to obtain and deliver certain test specimens to screen for~~
9 ~~hereditary and congenital disorders to certain laboratories under certain~~
10 ~~circumstances; requiring the Department of Health and Mental Hygiene, in~~
11 ~~consultation with a certain council, to establish protocols for health care providers to~~
12 ~~obtain and deliver certain test specimens to certain laboratories; requiring that the~~
13 coordinated statewide system for newborn screening that the Department of Health
14 and Mental Hygiene is required to maintain include notifying parents and guardians
15 of newborn infants that laboratories other than the Department's public health
16 laboratory are authorized to perform postscreening confirmatory or diagnostic tests
17 on newborn infants for hereditary and congenital disorders; and generally relating
18 to newborn infant screening for hereditary and congenital disorders.

19 BY repealing and reenacting, without amendments,
20 Article – Health – General
21 Section 13–111(a) through (c)
22 Annotated Code of Maryland
23 (2015 Replacement Volume)

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 BY repealing and reenacting, with amendments,
 2 Article – Health – General
 3 Section 13–111(d) ~~and 13–112~~
 4 Annotated Code of Maryland
 5 (2015 Replacement Volume)

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

8 **Article – Health – General**

9 13–111.

10 (a) The Department shall establish a coordinated statewide system for screening
 11 all newborn infants in the State for certain hereditary and congenital disorders associated
 12 with severe problems of health or development, except when the parent or guardian of the
 13 newborn infant objects.

14 (b) Except as provided in § 13–112 of this subtitle, the Department’s public health
 15 laboratory is the sole laboratory authorized to perform tests on specimens from newborn
 16 infants collected to screen for hereditary and congenital disorders as determined under
 17 subsection (d)(2) of this section.

18 (c) The system for newborn screening shall include:

19 (1) Laboratory testing and the reporting of test results; and

20 (2) Follow–up activities to facilitate the rapid identification and treatment
 21 of an affected child.

22 (d) In consultation with the State Advisory Council on Hereditary and Congenital
 23 Disorders, the Department shall:

24 (1) Establish protocols for a health care provider to obtain and deliver test
 25 specimens to ~~the~~

26 ~~(I) THE~~ Department’s public health laboratory; ~~AND~~

27 ~~(II) OTHER LABORATORIES AUTHORIZED TO PERFORM INITIAL~~
 28 ~~TESTS ON SPECIMENS UNDER § 13–112(B)(1) OF THIS SUBTITLE;~~

29 (2) Determine the screening tests that the Department’s public health
 30 laboratory is required to perform;

31 (3) Maintain a coordinated statewide system for newborn screening that
 32 carries out the purpose described in subsection (c) of this section that includes:

1 (i) Communicating the results of screening tests to the health care
2 provider of the newborn infant;

3 (ii) Locating newborn infants with abnormal test results;

4 (iii) Sharing newborn screening information between hospitals,
5 health care providers, treatment centers, and laboratory personnel; ~~and~~

6 (iv) Delivering needed clinical, diagnostic, and treatment
7 information to health care providers, parents, and caregivers; and

8 **(V) NOTIFYING PARENTS AND GUARDIANS OF NEWBORN**
9 **INFANTS THAT LABORATORIES OTHER THAN THE DEPARTMENT'S PUBLIC HEALTH**
10 **LABORATORY ARE AUTHORIZED TO PERFORM POSTSCREENING CONFIRMATORY OR**
11 **DIAGNOSTIC TESTS ON NEWBORN INFANTS FOR HEREDITARY AND CONGENITAL**
12 **DISORDERS; AND**

13 (4) Adopt regulations that set forth the standards and requirements for
14 newborn screening for hereditary and congenital disorders that are required under this
15 subtitle, including:

16 (i) Performing newborn screening tests;

17 (ii) Coordinating the reporting, follow-up, and treatment activities
18 with parents, caregivers, and health care providers; and

19 (iii) Establishing fees for newborn screening that do not exceed an
20 amount sufficient to cover the administrative, laboratory, and follow-up costs associated
21 with the performance of screening tests under this subtitle.

22 ~~13-112.~~

23 ~~(a) The Secretary may contract or delegate the screening required under §~~
24 ~~13-111 of this subtitle to another entity with the approval of the State Advisory Council on~~
25 ~~Hereditary and Congenital Disorders.~~

26 ~~(b) Subject to subsection (c) of this section, a laboratory other than the~~
27 ~~Department's public health laboratory may [perform].~~

28 **(1) AT THE REQUEST OF THE PARENT OR GUARDIAN OF A NEWBORN**
29 **INFANT, PERFORM THE INITIAL TESTS ON SPECIMENS COLLECTED TO SCREEN FOR**
30 **HEREDITARY AND CONGENITAL DISORDERS, INCLUDING THE TESTS THE**
31 **DEPARTMENT'S PUBLIC HEALTH LABORATORY OTHERWISE WOULD PERFORM**
32 **UNDER § 13-111 OF THIS SUBTITLE; AND**

1 ~~(2) PERFORM postscreening confirmatory or diagnostic tests on newborn~~
2 ~~infants for hereditary and congenital disorders.~~

3 ~~(e) Before offering or performing a SCREENING OR postscreening test on a~~
4 ~~newborn infant for hereditary and congenital disorders under subsection (b) of this section,~~
5 ~~a laboratory shall:~~

6 ~~(1) Obtain and maintain a license issued by the Secretary as required by~~
7 ~~Title 17 of this article; and~~

8 ~~(2) Meet all the standards and requirements for a laboratory to perform~~
9 ~~tests on newborn infants for hereditary and congenital disorders that are established by~~
10 ~~the Secretary.~~

11 ~~(D) (1) A PARENT OR GUARDIAN OF A NEWBORN INFANT MAY REQUEST~~
12 ~~THAT A LABORATORY OTHER THAN THE DEPARTMENT'S PUBLIC HEALTH~~
13 ~~LABORATORY PERFORM THE INITIAL TESTS ON SPECIMENS COLLECTED TO SCREEN~~
14 ~~FOR HEREDITARY AND CONGENITAL DISORDERS, INCLUDING THE TESTS THE~~
15 ~~DEPARTMENT'S PUBLIC HEALTH LABORATORY OTHERWISE WOULD PERFORM~~
16 ~~UNDER § 13-111 OF THIS SUBTITLE.~~

17 ~~(2) AT THE REQUEST OF THE PARENT OR GUARDIAN OF A NEWBORN~~
18 ~~INFANT, A HEALTH CARE PROVIDER SHALL OBTAIN AND DELIVER TEST SPECIMENS~~
19 ~~COLLECTED FROM THE NEWBORN INFANT TO SCREEN FOR HEREDITARY AND~~
20 ~~CONGENITAL DISORDERS TO A LABORATORY;~~

21 ~~(I) AUTHORIZED TO PERFORM INITIAL SCREENING TESTS~~
22 ~~UNDER SUBSECTION (B)(1) OF THIS SECTION; AND~~

23 ~~(II) SELECTED BY THE PARENT OR GUARDIAN TO PERFORM THE~~
24 ~~SCREENING TESTS.~~

25 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
26 October 1, 2016.