

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

A BILL ENTITLED

1 AN ACT concerning

2 **Newborn Infant Screening – Testing by Nonpublic Laboratories – Authorization**

3 FOR the purpose of authorizing certain laboratories to perform certain screening tests for
4 hereditary and congenital disorders under certain circumstances; authorizing a
5 parent or guardian of a newborn infant to request that a certain laboratory perform
6 certain initial tests to screen for hereditary and congenital disorders; requiring a
7 health care provider to obtain and deliver certain test specimens to screen for
8 hereditary and congenital disorders to certain laboratories under certain
9 circumstances; requiring the Department of Health and Mental Hygiene, in
10 consultation with a certain council, to establish protocols for health care providers to
11 obtain and deliver certain test specimens to certain laboratories; and generally
12 relating to newborn infant screening for hereditary and congenital disorders.

13 BY repealing and reenacting, without amendments,

14 Article – Health – General
15 Section 13–111(a) through (c)
16 Annotated Code of Maryland
17 (2015 Replacement Volume)

18 BY repealing and reenacting, with amendments,

19 Article – Health – General
20 Section 13–111(d) and 13–112
21 Annotated Code of Maryland
22 (2015 Replacement Volume)

23 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

24 That the Laws of Maryland read as follows:

25 **Article – Health – General**

26 13–111.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

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

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

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

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

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

15 (1) Establish protocols for a health care provider to obtain and deliver test
16 specimens to [the]:

17 (I) **THE Department’s public health laboratory; AND**

18 (II) **OTHER LABORATORIES AUTHORIZED TO PERFORM INITIAL**
19 **TESTS ON SPECIMENS UNDER § 13–112(B)(1) OF THIS SUBTITLE;**

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

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

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

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

27 (iii) Sharing newborn screening information between hospitals,
28 health care providers, treatment centers, and laboratory personnel; and

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

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

4 (i) Performing newborn screening tests;

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

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

10 13–112.

11 (a) The Secretary may contract or delegate the screening required under §
12 13–111 of this subtitle to another entity with the approval of the State Advisory Council on
13 Hereditary and Congenital Disorders.

14 (b) Subject to subsection (c) of this section, a laboratory other than the
15 Department's public health laboratory may [perform]:

16 **(1) AT THE REQUEST OF THE PARENT OR GUARDIAN OF A NEWBORN**
17 **INFANT, PERFORM THE INITIAL TESTS ON SPECIMENS COLLECTED TO SCREEN FOR**
18 **HEREDITARY AND CONGENITAL DISORDERS, INCLUDING THE TESTS THE**
19 **DEPARTMENT'S PUBLIC HEALTH LABORATORY OTHERWISE WOULD PERFORM**
20 **UNDER § 13–111 OF THIS SUBTITLE; AND**

21 **(2) PERFORM** postscreening confirmatory or diagnostic tests on newborn
22 infants for hereditary and congenital disorders.

23 (c) Before offering or performing a **SCREENING OR** postscreening test on a
24 newborn infant for hereditary and congenital disorders under subsection (b) of this section,
25 a laboratory shall:

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

28 (2) Meet all the standards and requirements for a laboratory to perform
29 tests on newborn infants for hereditary and congenital disorders that are established by
30 the Secretary.

31 **(D) (1) A PARENT OR GUARDIAN OF A NEWBORN INFANT MAY REQUEST**
32 **THAT A LABORATORY OTHER THAN THE DEPARTMENT'S PUBLIC HEALTH**
33 **LABORATORY PERFORM THE INITIAL TESTS ON SPECIMENS COLLECTED TO SCREEN**
34 **FOR HEREDITARY AND CONGENITAL DISORDERS, INCLUDING THE TESTS THE**

1 DEPARTMENT'S PUBLIC HEALTH LABORATORY OTHERWISE WOULD PERFORM
2 UNDER § 13-111 OF THIS SUBTITLE.

3 (2) AT THE REQUEST OF THE PARENT OR GUARDIAN OF A NEWBORN
4 INFANT, A HEALTH CARE PROVIDER SHALL OBTAIN AND DELIVER TEST SPECIMENS
5 COLLECTED FROM THE NEWBORN INFANT TO SCREEN FOR HEREDITARY AND
6 CONGENITAL DISORDERS TO A LABORATORY:

7 (I) AUTHORIZED TO PERFORM INITIAL SCREENING TESTS
8 UNDER SUBSECTION (B)(1) OF THIS SECTION; AND

9 (II) SELECTED BY THE PARENT OR GUARDIAN TO PERFORM THE
10 SCREENING TESTS.

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