

HOUSE BILL 109

J1

(2lr0689)

ENROLLED BILL

— *Health and Government Operations/Finance* —

Introduced by **Delegate Shetty**

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 **Maryland Department of Health – System for Newborn Screening –**
3 **Requirements**

4 FOR the purpose of requiring the system for newborn screening in the Maryland
5 Department of Health to include screening for each condition listed in the U.S.
6 Department of Health and Human Services' Recommended Uniform Screening
7 Panel, subject to the approval of the State Advisory Council on Hereditary and
8 Congenital Disorders and the Secretary of Health; establishing certain requirements
9 related to the approval or disapproval of the inclusion of a condition and the
10 implementation of testing for a condition approved for inclusion in the system for
11 newborn screening; and generally relating to the system for newborn screening.

12 BY repealing and reenacting, with amendments,

13 Article – Health – General
14 Section 13–101 and 13–111

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 Annotated Code of Maryland
2 (2019 Replacement Volume and 2021 Supplement)

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

5 **Article – Health – General**

6 13–101.

7 (a) In this subtitle the following words have the meanings indicated.

8 **(B) “ADVISORY COUNCIL” MEANS THE STATE ADVISORY COUNCIL ON**
9 **HEREDITARY AND CONGENITAL DISORDERS.**

10 **[(b)] (C) “Commission” means the State Commission on Hereditary and**
11 **Congenital Disorders.**

12 **[(c)] (D) (1) “Congenital disorder” means a significant structural or**
13 **functional abnormality of the body that is present at birth.**

14 (2) “Congenital disorder” does not include a condition that results from:

15 (i) An intrauterine infection; or

16 (ii) A birth injury.

17 **[(d)] (E) “Hereditary disorder” means any disorder that:**

18 (1) Is transmitted through the genetic material deoxyribonucleic acid
19 (DNA); or

20 (2) Arises through the improper processing of the information in the
21 genetic material.

22 13–111.

23 ~~**(A) (1) IN THIS SECTION, “SPECIALIZED TESTING EQUIPMENT” MEANS**~~
24 ~~**EQUIPMENT NECESSARY TO RUN A TEST APPROVED BY THE U.S. FOOD AND DRUG**~~
25 ~~**ADMINISTRATION OR A LABORATORY DEVELOPED TEST.**~~

26 ~~**(2) “SPECIALIZED TESTING EQUIPMENT” DOES NOT INCLUDE:**~~

27 ~~**(i) TESTING REAGENTS; OR**~~

28 ~~**(ii) DISPOSABLE LABORATORY EQUIPMENT.**~~

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

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

9 ~~(c)~~ ~~(D)~~ (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)~~ ~~(E)~~ (d) In consultation with the State Advisory Council on Hereditary and
14 Congenital Disorders, the Department shall:

15 (1) Establish protocols for a health care provider to obtain and deliver test
16 specimens to the Department’s public health laboratory;

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

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

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

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

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

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

28 (v) Notifying parents and guardians of newborn infants that
29 laboratories other than the Department’s public health laboratory are authorized to
30 perform postscreening confirmatory or diagnostic tests on newborn infants for hereditary
31 and congenital disorders; 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 ~~(e) (F) (e)~~ **(1) (I) NOTWITHSTANDING SUBJECT TO THE APPROVAL OF**
 11 **THE SECRETARY AND THE ADVISORY COUNCIL UNDER PARAGRAPH (2) OF THIS**
 12 **SUBSECTION AND NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE**
 13 **DEPARTMENT SHALL SCREEN FOR EACH CORE CONDITION LISTED IN THE U.S.**
 14 **DEPARTMENT OF HEALTH AND HUMAN SERVICES' RECOMMENDED UNIFORM**
 15 **SCREENING PANEL.**

16 **(II) ON OR AFTER JANUARY 1, 2023, THE DEPARTMENT SHALL**
 17 **INCLUDE IN THE SYSTEM FOR NEWBORN SCREENING ANY CORE OR SECONDARY**
 18 **CONDITION ADDED TO THE RECOMMENDED UNIFORM SCREENING PANEL**
 19 **SECRETARY AND THE ADVISORY COUNCIL SHALL DETERMINE WHETHER TO**
 20 **APPROVE THE INCLUSION OF A CONDITION IN THE SYSTEM FOR NEWBORN**
 21 **SCREENING WITHIN ~~2 YEARS~~ 1 YEAR AFTER THE ADDITION OF THE CONDITION TO**
 22 **THE ~~PANEL~~ RECOMMENDED UNIFORM SCREENING PANEL.**

23 **(III) IF THE SECRETARY OR ADVISORY COUNCIL DOES NOT**
 24 **APPROVE THE INCLUSION OF A CORE CONDITION IN THE SYSTEM FOR NEWBORN**
 25 **SCREENING UNDER SUBPARAGRAPH (I) OF THIS PARAGRAPH:**

26 **1. WITHIN 1 YEAR AFTER THE ADDITION OF THE**
 27 **CONDITION TO THE RECOMMENDED UNIFORM SCREENING PANEL, THE**
 28 **DEPARTMENT SHALL PUBLICLY POST AND SUBMIT TO THE GENERAL ASSEMBLY, IN**
 29 **ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT ARTICLE, A REPORT**
 30 **THAT INCLUDES, AS APPLICABLE, THE SECRETARY'S JUSTIFICATION FOR NOT**
 31 **APPROVING THE INCLUSION AND THE FINAL VOTE OF THE ADVISORY COUNCIL**
 32 **REGARDING THE INCLUSION OF THE CONDITION; AND**

33 **2. EACH YEAR AFTER THE INITIAL DISAPPROVAL, THE**
 34 **ADVISORY COUNCIL SHALL:**

1 A. REVIEW THE MEDICAL LITERATURE PUBLISHED ON
2 THE CONDITION SINCE THE INITIAL EVALUATION AND DETERMINE WHETHER
3 SUBSTANTIVE UPDATES HAVE OCCURRED THAT WOULD MERIT FORMAL
4 REEVALUATION OF THE INCLUSION OF THE CONDITION; AND

5 B. IF THE ADVISORY COUNCIL UPHOLDS ITS
6 DISAPPROVAL OF THE CONDITION, PUBLICLY PUBLISH AND SUBMIT TO THE
7 GENERAL ASSEMBLY, IN ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT
8 ARTICLE, A REPORT ON THE REASON FOR THE DISAPPROVAL.

9 (2) Notwithstanding any other provision of law, if the Secretary of Health
10 and Human Services issues federal recommendations on critical congenital heart disease
11 screening of newborns, the Department shall adopt the federal screening recommendations.

12 (F) IF THE SECRETARY AND THE ADVISORY COUNCIL APPROVE THE
13 INCLUSION OF A CONDITION IN THE SYSTEM FOR NEWBORN SCREENING UNDER
14 SUBSECTION (E) OF THIS SECTION, THE DEPARTMENT SHALL IMPLEMENT TESTING
15 FOR THE CONDITION WITHIN 1 YEAR AFTER THE DATE OF THE APPROVAL.

16 ~~(G) (1) IF THE SECRETARY AND THE ADVISORY COUNCIL APPROVE THE~~
17 ~~INCLUSION OF A CONDITION IN THE SYSTEM FOR NEWBORN SCREENING UNDER~~
18 ~~SUBSECTION (F) OF THIS SECTION, WITHIN 1 YEAR AFTER THE DATE OF THE~~
19 ~~APPROVAL, THE DEPARTMENT SHALL:~~

20 ~~(I) IF TESTING FOR THE CONDITION CAN BE IMPLEMENTED~~
21 ~~WITHOUT THE PROCUREMENT OF SPECIALIZED TESTING EQUIPMENT, IMPLEMENT~~
22 ~~TESTING FOR THE CONDITION; OR~~

23 ~~(H) IF THE IMPLEMENTATION OF TESTING REQUIRES THE~~
24 ~~PROCUREMENT OF SPECIALIZED TESTING EQUIPMENT, SIGN A FINAL~~
25 ~~PROCUREMENT CONTRACT WITH A VENDOR FOR ALL EQUIPMENT NECESSARY TO~~
26 ~~IMPLEMENT TESTING.~~

27 ~~(2) FOR PROCUREMENTS REQUIRED UNDER PARAGRAPH (1)(H) OF~~
28 ~~THIS SUBSECTION:~~

29 ~~(I) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE~~
30 ~~DEPARTMENT MAY USE EXPEDITED PROCUREMENT UNDER § 13-108 OF THE STATE~~
31 ~~FINANCE AND PROCUREMENT ARTICLE; AND~~

32 ~~(H) THE PROCUREMENT CONTRACT SHALL INCLUDE A CLAUSE~~
33 ~~AUTHORIZING THE STATE TO TERMINATE THE CONTRACT IF THE VENDOR HAS NOT~~
34 ~~FULFILLED THE CONTRACT WITHIN 6 MONTHS.~~

1 ~~(H)~~ ~~(G)~~ (1) The Secretary shall pay all fees collected under the
2 provisions of this subtitle to the Comptroller.

3 (2) The Comptroller shall distribute the fees to the Newborn Screening
4 Program Fund established under § 13–113 of this subtitle.

5 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
6 October 1, 2022.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.