

# HOUSE BILL 109

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(PRE-FILED)

2lr0689  
CF SB 242

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By: **Delegate Shetty**

Requested: October 7, 2021

Introduced and read first time: January 12, 2022

Assigned to: Health and Government Operations

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Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 12, 2022

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## 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  
15 Annotated Code of Maryland  
16 (2019 Replacement Volume and 2021 Supplement)

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

19 **Article – Health – General**

20 13–101.

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

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

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

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

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

9 **(i) An intrauterine infection; or**

10 **(ii) A birth injury.**

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

12 **(1) Is transmitted through the genetic material deoxyribonucleic acid**  
 13 **(DNA); or**

14 **(2) Arises through the improper processing of the information in the**  
 15 **genetic material.**

16 13–111.

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

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

21 **(I) TESTING REAGENTS; OR**

22 **(II) DISPOSABLE LABORATORY EQUIPMENT.**

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

27 ~~(b)~~ **(C)** Except as provided in § 13–112 of this subtitle, the Department’s public  
 28 health laboratory is the sole laboratory authorized to perform tests on specimens from

1 newborn infants collected to screen for hereditary and congenital disorders as determined  
2 under subsection ~~(d)(2)~~ **(E)(2)** of this section.

3 ~~(e)~~ **(D)** The system for newborn screening shall include:

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

5 (2) Follow-up activities to facilitate the rapid identification and treatment  
6 of an affected child.

7 ~~(d)~~ **(E)** In consultation with the State Advisory Council on Hereditary and  
8 Congenital Disorders, the Department shall:

9 (1) Establish protocols for a health care provider to obtain and deliver test  
10 specimens to the Department's public health laboratory;

11 (2) Determine the screening tests that the Department's public health  
12 laboratory is required to perform;

13 (3) Maintain a coordinated statewide system for newborn screening that  
14 carries out the purpose described in subsection ~~(e)~~ **(D)** of this section that includes:

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

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

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

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

22 (v) Notifying parents and guardians of newborn infants that  
23 laboratories other than the Department's public health laboratory are authorized to  
24 perform postscreening confirmatory or diagnostic tests on newborn infants for hereditary  
25 and congenital disorders; and

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

29 (i) Performing newborn screening tests;

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

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

~~(e)~~ **(F) (1) (I) NOTWITHSTANDING SUBJECT TO THE APPROVAL OF THE SECRETARY AND THE ADVISORY COUNCIL UNDER PARAGRAPH (2) OF THIS SUBSECTION AND NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE DEPARTMENT SHALL SCREEN FOR EACH CORE CONDITION LISTED IN THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES' RECOMMENDED UNIFORM SCREENING PANEL.**

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

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

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

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

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

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

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

4           **(G) (1) IF THE SECRETARY AND THE ADVISORY COUNCIL APPROVE THE**  
5 **INCLUSION OF A CONDITION IN THE SYSTEM FOR NEWBORN SCREENING UNDER**  
6 **SUBSECTION (F) OF THIS SECTION, WITHIN 1 YEAR AFTER THE DATE OF THE**  
7 **APPROVAL, THE DEPARTMENT SHALL:**

8                   **(I) IF TESTING FOR THE CONDITION CAN BE IMPLEMENTED**  
9 **WITHOUT THE PROCUREMENT OF SPECIALIZED TESTING EQUIPMENT, IMPLEMENT**  
10 **TESTING FOR THE CONDITION; OR**

11                   **(II) IF THE IMPLEMENTATION OF TESTING REQUIRES THE**  
12 **PROCUREMENT OF SPECIALIZED TESTING EQUIPMENT, SIGN A FINAL**  
13 **PROCUREMENT CONTRACT WITH A VENDOR FOR ALL EQUIPMENT NECESSARY TO**  
14 **IMPLEMENT TESTING.**

15           **(2) FOR PROCUREMENTS REQUIRED UNDER PARAGRAPH (1)(II) OF**  
16 **THIS SUBSECTION:**

17                   **(I) NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE**  
18 **DEPARTMENT MAY USE EXPEDITED PROCUREMENT UNDER § 13-108 OF THE STATE**  
19 **FINANCE AND PROCUREMENT ARTICLE; AND**

20                   **(II) THE PROCUREMENT CONTRACT SHALL INCLUDE A CLAUSE**  
21 **AUTHORIZING THE STATE TO TERMINATE THE CONTRACT IF THE VENDOR HAS NOT**  
22 **FULFILLED THE CONTRACT WITHIN 6 MONTHS.**

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

25           (2) The Comptroller shall distribute the fees to the Newborn Screening  
26 Program Fund established under § 13-113 of this subtitle.

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