

SENATE BILL 242

J1

(2lr0690)

ENROLLED BILL

— Finance/Health and Government Operations —

Introduced by ~~Senator Hershey~~ Senators Hershey, Beidle, Benson, and Klausmeier

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.

President.

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 ~~core~~ 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 genetic
21 material.

22 13–111.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

27 (i) Performing newborn screening tests;

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

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

4 (e) (1) (i) ~~NOTWITHSTANDING~~ SUBJECT TO THE APPROVAL OF THE
5 SECRETARY AND THE ADVISORY COUNCIL UNDER SUBPARAGRAPH (II) OF THIS
6 PARAGRAPH AND NOTWITHSTANDING ANY OTHER PROVISION OF LAW, THE
7 DEPARTMENT SHALL SCREEN FOR EACH CORE CONDITION LISTED IN THE U.S.
8 DEPARTMENT OF HEALTH AND HUMAN SERVICES' RECOMMENDED UNIFORM
9 SCREENING PANEL.

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

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

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

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

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

33 B. IF THE ADVISORY COUNCIL UPHOLDS ITS
34 DISAPPROVAL OF THE CONDITION, PUBLICLY PUBLISH AND SUBMIT TO THE
35 GENERAL ASSEMBLY, IN ACCORDANCE WITH § 2-1257 OF THE STATE GOVERNMENT
36 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 **(F) IF THE SECRETARY AND THE ADVISORY COUNCIL APPROVE THE**
5 **INCLUSION OF A CONDITION IN THE SYSTEM FOR THE NEWBORN SCREENING UNDER**
6 **SUBSECTION (E) OF THIS SECTION, THE DEPARTMENT SHALL IMPLEMENT TESTING**
7 **FOR THE CONDITION WITHIN 1 YEAR AFTER THE DATE OF THE APPROVAL.**

8 ~~(F)~~ **(G)** (1) The Secretary shall pay all fees collected under the provisions of
9 this subtitle to the Comptroller.

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

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

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.