SENATE BILL 242

ENROLLED BILL
— Finance/Health and Government Operations —

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

Read and Examined by Proofreaders:

_______________________________________________
Proofreader.

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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

Maryland Department of Health – System for Newborn Screening –
Requirements

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

BY repealing and reenacting, with amendments,

Article – Health – General
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.
SENATE BILL 242

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

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

Article - Health - General


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

(B) "ADVISORY COUNCIL" MEANS THE STATE ADVISORY COUNCIL ON
HEREDITARY AND CONGENITAL DISORDERS.

(C) "Commission" means the State Commission on Hereditary and
Congenital Disorders.

(D) (1) "Congenital disorder" means a significant structural or
functional abnormality of the body that is present at birth.

(2) "Congenital disorder" does not include a condition that results from:

(i) An intrauterine infection; or

(ii) A birth injury.

(E) "Hereditary disorder" means any disorder that:

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

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

13–111.

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

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

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

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

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

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

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

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

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

   (ii) Locating newborn infants with abnormal test results;

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

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

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

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

   (i) Performing newborn screening tests;

   (ii) Coordinating the reporting, follow-up, and treatment activities 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) (1) **NOTWITHSTANDING SUBJECT TO THE APPROVAL OF THE SECRETARY AND THE ADVISORY COUNCIL UNDER SUBPARAGRAPH (II) OF THIS PARAGRAPH 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:**


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

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

(g) (1) The Secretary shall pay all fees collected under the provisions of this subtitle to the Comptroller.

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

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