Chapter 178

**(Senate Bill 117)**

AN ACT concerning

**Health – Newborn Screening Program – ~~Krabbe Leukodystrophy~~ Implementation of Testing**

FOR the purpose of repealing the requirement that the Secretary of Health and the State Advisory Council on Hereditary and Congenital Disorders determine whether to approve the inclusion of a core condition in the system for newborn screening within a certain time period after the addition of the condition to the Recommended Uniform Screening Panel; requiring the Maryland Department of Health to implement testing for a core condition listed in the Recommended Uniform Screening Panel within a certain time period after the core condition is added to the Panel; *authorizing the Department to screen for any condition recommended by the Advisory Council and approved by the Secretary;* requiring ~~that~~ the ~~Maryland~~ Department ~~of Health's newborn screening system include screening~~ ~~Health~~ to implement testing for Krabbe leukodystrophy within a certain period of time after the U.S. Department of Health and Human Services issues a certain recommendation; and generally relating to newborn screening.

BY repealing and reenacting, with amendments,
Article – Health – General
Section 13–111
Annotated Code of Maryland
(2023 Replacement Volume)

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

**Article – Health – General**

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~~; AND~~

~~(3) SCREENING FOR KRABBE LEUKODYSTROPHY~~.

(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) (i) ~~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~~ **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 Secretary and the Advisory Council shall determine whether to approve the inclusion of a condition in the system for newborn screening within 1 year after the addition of the condition~~ ~~THE~~ ***SUBJECT TO SUBPARAGRAPH (III) OF THIS PARAGRAPH, THE*** **DEPARTMENT SHALL IMPLEMENT TESTING FOR A CORE CONDITION WITHIN 1 YEAR AND 6 MONTHS AFTER THE CORE CONDITION IS ADDED** to the Recommended Uniform Screening Panel.

***(III) 1. IF THE DEPARTMENT IS UNABLE TO IMPLEMENT TESTING WITHIN 1 YEAR AND 6 MONTHS AFTER A CORE CONDITION IS ADDED TO THE RECOMMENDED UNIFORM SCREENING PANEL DUE TO A DELAY IN THE PROCUREMENT OF EQUIPMENT OR SUPPLIES NEEDED TO IMPLEMENT THE TESTING, THE DEPARTMENT SHALL REPORT TO THE SENATE FINANCE COMMITTEE AND THE HOUSE HEALTH AND GOVERNMENT OPERATIONS COMMITTEE, IN ACCORDANCE WITH § 2–1257 OF THE STATE GOVERNMENT ARTICLE, WITHIN 1 YEAR AND 3 MONTHS AFTER THE ADDITION OF THE CORE CONDITION TO THE RECOMMENDED UNIFORM SCREENING PANEL AND EVERY 3 MONTHS THEREAFTER UNTIL THE TESTING FOR THE CORE CONDITION IS IMPLEMENTED.***

***2. A REPORT REQUIRED UNDER SUBSUBPARAGRAPH 1 OF THIS SUBPARAGRAPH SHALL INCLUDE THE REASON FOR THE DELAY AND THE ANTICIPATED TIMELINE FOR IMPLEMENTATION.***

~~(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.~~

(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.

***(3) THE DEPARTMENT MAY SCREEN FOR ANY CONDITION RECOMMENDED BY THE ADVISORY COUNCIL AND APPROVED BY THE SECRETARY.***

~~(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)~~ **(F)** (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, 2024.~~

SECTION 2. AND BE IT FURTHER ENACTED, That~~,~~*:*

*(a) Subject to subsection (b) of this section and* notwithstanding § 13–111(e)(1)(ii) of the Health – General Article, as enacted by Section 1 of this Act, the Maryland Department of Health shall implement testing for infantile Krabbe disease within 1 year after the U.S. Department of Health and Human Services issues ~~the final newborn screening recommendation regarding the disease~~ *a final recommendation to add screening of the condition to the federal Recommended Uniform Screening Panel*.

*(b) (1) If the Department is unable to implement testing for infantile Krabbe disease within the time period required under subsection (a) of this section due to a delay in the procurement of equipment or supplies needed to implement the testing, the Department shall report to the Senate Finance Committee and the House Health and Government Operations Committee, in accordance with § 2–1257 of the State Government Article, within 9 months after the addition of the final recommendation to add screening of infantile Krabbe disease to the federal Recommended Uniform Screening Panel and every 3 months thereafter until testing for infantile Krabbe disease is implemented.*

*(2) The report required under paragraph (1) of this subsection shall include information on the equipment or supplies needed, the reason for the delay, and the anticipated timeline for implementation.*

SECTION 3. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has been passed by a yea and nay vote supported by three–fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.

**Approved by the Governor, April 25, 2024.**