

# SENATE BILL 117

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EMERGENCY BILL  
(PRE-FILED)

4lr0938  
CF HB 96

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By: **Senator Bailey**

Requested: October 12, 2023

Introduced and read first time: January 10, 2024

Assigned to: Finance

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Committee Report: Favorable with amendments

Senate action: Adopted

Read second time: March 4, 2024

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## CHAPTER \_\_\_\_\_

1 AN ACT concerning

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

4 FOR the purpose of repealing the requirement that the Secretary of Health and the State  
5 Advisory Council on Hereditary and Congenital Disorders determine whether to  
6 approve the inclusion of a core condition in the system for newborn screening within  
7 a certain time period after the addition of the condition to the Recommended Uniform  
8 Screening Panel; requiring the Maryland Department of Health to implement  
9 testing for a core condition listed in the Recommended Uniform Screening Panel  
10 within a certain time period after the core condition is added to the Panel; requiring  
11 that the Maryland Department of ~~Health's newborn screening system include~~  
12 screening Health to implement testing for Krabbe leukodystrophy within a certain  
13 period of time after the U.S. Department of Health and Human Services issues a  
14 certain recommendation; and generally relating to newborn screening.

15 BY repealing and reenacting, with amendments,  
16 Article – Health – General  
17 Section 13–111  
18 Annotated Code of Maryland  
19 (2023 Replacement Volume)

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

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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 **Article – Health – General**

2 13–111.

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

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

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

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

13 (2) Follow-up activities to facilitate the rapid identification and treatment  
14 of an affected child; ~~AND~~

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

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

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

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

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

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

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

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

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

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

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

8 (i) Performing newborn screening tests;

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

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

14 (e) (1) (i) ~~Subject to the approval of the Secretary and the Advisory Council~~  
15 ~~under subparagraph (ii) of this paragraph and notwithstanding any other provision of law,~~  
16 ~~the~~ **THE** Department shall screen for each core condition listed in the U.S. Department of  
17 Health and Human Services' Recommended Uniform Screening Panel.

18 (ii) ~~On or after January 1, 2023, the Secretary and the Advisory~~  
19 ~~Council shall determine whether to approve the inclusion of a condition in the system for~~  
20 ~~newborn screening within 1 year after the addition of the condition.~~ **THE DEPARTMENT**  
21 **SHALL IMPLEMENT TESTING FOR A CORE CONDITION WITHIN 1 YEAR AND 6 MONTHS**  
22 **AFTER THE CORE CONDITION IS ADDED** to the Recommended Uniform Screening Panel.

23 (iii) ~~If the Secretary or Advisory Council does not approve the~~  
24 ~~inclusion of a core condition in the system for newborn screening under subparagraph (i) of~~  
25 ~~this paragraph:~~

26 ~~1. Within 1 year after the addition of the condition to the~~  
27 ~~Recommended Uniform Screening Panel, the Department shall publicly post and submit to~~  
28 ~~the General Assembly, in accordance with § 2-1257 of the State Government Article, a~~  
29 ~~report that includes, as applicable, the Secretary's justification for not approving the~~  
30 ~~inclusion and the final vote of the Advisory Council regarding the inclusion of the condition;~~  
31 ~~and~~

32 ~~2. Each year after the initial disapproval, the Advisory~~  
33 ~~Council shall:~~

34 ~~A. Review the medical literature published on the condition~~  
35 ~~since the initial evaluation and determine whether substantive updates have occurred that~~  
36 ~~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)~~ **(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, 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.

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 ye 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:

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Governor.

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President of the Senate.

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Speaker of the House of Delegates.