

SENATE BILL 117

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(PRE-FILED)

4r0938
CF HB 96

By: **Senator Bailey**

Requested: October 12, 2023

Introduced and read first time: January 10, 2024

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning

2 **Health – Newborn Screening Program – Krabbe Leukodystrophy**

3 FOR the purpose of requiring that the Maryland Department of Health’s newborn
4 screening system include screening for Krabbe leukodystrophy; and generally
5 relating to newborn screening.

6 BY repealing and reenacting, with amendments,

7 Article – Health – General

8 Section 13–111

9 Annotated Code of Maryland

10 (2023 Replacement Volume)

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

13 **Article – Health – General**

14 13–111.

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

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

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

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

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

4 **(3) SCREENING FOR KRABBE LEUKODYSTROPHY.**

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

30 (iii) Establishing fees for newborn screening that do not exceed an
31 amount sufficient to cover the administrative, laboratory, and follow-up costs associated

1 with the performance of screening tests under this subtitle.

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

6 (ii) On or after January 1, 2023, the Secretary and the Advisory
7 Council shall determine whether to approve the inclusion of a condition in the system for
8 newborn screening within 1 year after the addition of the condition to the Recommended
9 Uniform Screening Panel.

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

13 1. Within 1 year after the addition of the condition to the
14 Recommended Uniform Screening Panel, the Department shall publicly post and submit to
15 the General Assembly, in accordance with § 2–1257 of the State Government Article, a
16 report that includes, as applicable, the Secretary's justification for not approving the
17 inclusion and the final vote of the Advisory Council regarding the inclusion of the condition;
18 and

19 2. Each year after the initial disapproval, the Advisory
20 Council shall:

21 A. Review the medical literature published on the condition
22 since the initial evaluation and determine whether substantive updates have occurred that
23 would merit formal reevaluation of the inclusion of the condition; and

24 B. If the Advisory Council upholds its disapproval of the
25 condition, publicly publish and submit to the General Assembly, in accordance with §
26 2–1257 of the State Government Article, a report on the reason for the disapproval.

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

30 (f) If the Secretary and the Advisory Council approve the inclusion of a condition
31 in the system for the newborn screening under subsection (e) of this section, the
32 Department shall implement testing for the condition within 1 year after the date of the
33 approval.

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

36 (2) The Comptroller shall distribute the fees to the Newborn Screening

1 Program Fund established under § 13–113 of this subtitle.

2 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
3 October 1, 2024.