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(PRE-FILED)

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By: Delegate Shetty

Requested: October 7, 2021

Introduced and read first time: January 12, 2022 Assigned to: Health and Government Operations

## A BILL ENTITLED

I AN AC	T concerning	Ø

2	Maryland Department of Health – System for Newborn Screening –
3	Requirements

- FOR the purpose of requiring the system for newborn screening in the Maryland Department of Health to include screening for each condition listed in the U.S.
- Department of Health and Human Services' Recommended Uniform Screening Panel; and generally relating to the system for newborn screening.
- 8 BY repealing and reenacting, with amendments,
- 9 Article Health General
- 10 Section 13–111
- 11 Annotated Code of Maryland
- 12 (2019 Replacement Volume and 2021 Supplement)
- 13 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,
- 14 That the Laws of Maryland read as follows:

## 15 Article - Health - General

- 16 13–111.
- 17 (a) The Department shall establish a coordinated statewide system for screening 18 all newborn infants in the State for certain hereditary and congenital disorders associated 19 with severe problems of health or development, except when the parent or guardian of the 20 newborn infant objects.
- 21 (b) Except as provided in § 13–112 of this subtitle, the Department's public health 22 laboratory is the sole laboratory authorized to perform tests on specimens from newborn 23 infants collected to screen for hereditary and congenital disorders as determined under 24 subsection (d)(2) of this section.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1	(c) The sy	stem for newborn screening shall include:
2	(1)	Laboratory testing and the reporting of test results; and
3 4	(2) of an affected child.	Follow–up activities to facilitate the rapid identification and treatment
5 6	(d) In cons Disorders, the Depart	sultation with the State Advisory Council on Hereditary and Congenital artment shall:
7 8		Establish protocols for a health care provider to obtain and deliver test epartment's public health laboratory;
9 10	(2) laboratory is requir	Determine the screening tests that the Department's public health ed to perform;
11 12	` '	Maintain a coordinated statewide system for newborn screening that bose described in subsection (c) of this section that includes:
13 14	provider of the new	(i) Communicating the results of screening tests to the health care born infant;
15		(ii) Locating newborn infants with abnormal test results;
16 17		(iii) Sharing newborn screening information between hospitals, rs, treatment centers, and laboratory personnel;
18 19		(iv) Delivering needed clinical, diagnostic, and treatment th care providers, parents, and caregivers; and
20 21 22 23	laboratories other	(v) Notifying parents and guardians of newborn infants that than the Department's public health laboratory are authorized to ing confirmatory or diagnostic tests on newborn infants for hereditary rders; and
24 25 26		Adopt regulations that set forth the standards and requirements for for hereditary and congenital disorders that are required under this
27		(i) Performing newborn screening tests;
28 29		(ii) Coordinating the reporting, follow-up, and treatment activities ivers, 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 ANY OTHER PROVISION OF LAW, THE 5 DEPARTMENT SHALL SCREEN FOR EACH CONDITION LISTED IN THE U.S. 6 DEPARTMENT OF HEALTH AND HUMAN SERVICES' RECOMMENDED UNIFORM 7 SCREENING PANEL.
- 8 (II) ON OR AFTER JANUARY 1, 2023, THE DEPARTMENT SHALL 9 INCLUDE IN THE SYSTEM FOR NEWBORN SCREENING ANY CORE OR SECONDARY 10 CONDITION ADDED TO THE RECOMMENDED UNIFORM SCREENING PANEL WITHIN 2 YEARS AFTER THE ADDITION OF THE CONDITION TO THE PANEL.
- 12 **(2)** Notwithstanding any other provision of law, if the Secretary of Health 13 and Human Services issues federal recommendations on critical congenital heart disease 14 screening of newborns, the Department shall adopt the federal screening recommendations.
- 15 (f) (1) The Secretary shall pay all fees collected under the provisions of this subtitle to the Comptroller.
- 17 (2) The Comptroller shall distribute the fees to the Newborn Screening 18 Program Fund established under § 13–113 of this subtitle.
- SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect 20 October 1, 2022.