

Department of Legislative Services
Maryland General Assembly
2022 Session

FISCAL AND POLICY NOTE
Enrolled - Revised

House Bill 109

(Delegate Shetty)

Health and Government Operations

Finance

**Maryland Department of Health – System for Newborn Screening –
Requirements**

This bill requires the Maryland Department of Health’s (MDH) Newborn Screening Program, subject to the approval of the Secretary of Health and the State Advisory Council on Hereditary and Congenital Disorders, to screen for each core condition listed in the U.S. Department of Health and Human Services’ (HHS) Recommended Uniform Screening Panel (RUSP). On or after January 1, 2023, the Secretary and the advisory council must determine whether to approve the inclusion of a condition in the State’s newborn screening panel within one year of any condition being added to RUSP. The bill (1) establishes reporting and other requirements if the Secretary or advisory council *do not* approve the inclusion of a core condition and (2) requires MDH to implement testing for a condition within one year after the date the condition is approved for inclusion in the State’s program.

Fiscal Summary

State Effect: Potential significant increase in special fund expenditures for MDH’s Laboratories Administration to screen for additional conditions beginning as early as FY 2023. Special fund revenues increase correspondingly from fees beginning as early as FY 2023.

Local Effect: None.

Small Business Effect: None.

Analysis

Bill Summary:

Disapproval of Inclusion of a Core Condition

If the Secretary or the advisory council does not approve the inclusion of a core condition in the State's newborn screening panel, MDH must, within one year after the addition of the condition to RUSP, publicly post and submit to the General Assembly a report that includes, as applicable, the Secretary's justification for not approving the condition for inclusion and the final vote of the advisory council regarding the inclusion of the condition.

Each year after the initial disapproval, the advisory council must review applicable medical literature on the condition to determine whether substantive updates have occurred that would merit formal reevaluation of the inclusion of the condition. If the advisory council upholds its disapproval of the condition, the advisory council must publicly publish and submit to the General Assembly a report on the reason for the continued disapproval.

Approval of Inclusion of a Core Condition

If the Secretary and the advisory council approve – regardless of whether at first review or subsequent review after a disapproval – the inclusion of a core condition in the State's newborn screening panel, MDH must, within one year after the date of approval, implement testing for the condition.

Current Law: MDH's Newborn Screening Program is a statewide system for screening all newborn infants in Maryland for certain hereditary and congenital disorders associated with severe problems of health or development (except when the parent or guardian of the newborn objects). The program was codified and centralized by Chapter 256 of 2008, which established the MDH public health laboratory as the sole laboratory in Maryland allowed to perform the screening tests. The system for newborn screening includes laboratory testing, reporting of test results, and follow-up activities to facilitate the rapid identification and treatment of an affected child. The laboratory is required to screen for 58 first-tier metabolic hereditary disorders on all screening specimens collected. These conditions are listed in the Code of Maryland Regulations (10.10.13.12). Second-tier tests can only be performed when requested by an individual authorized to request a medical laboratory test.

MDH is required, in consultation with the State Advisory Council on Hereditary and Congenital Disorders, to establish 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. Fees are deposited into the Newborn Screening Program

Fund, a special fund which is administered by the Secretary of Health to cover costs associated with performing newborn screening tests.

The Maryland Advisory Council on Hereditary and Congenital Disorders was established to ensure the policies and programs of the State for hereditary and congenital disorders comply with the principles established in Subtitle 1 of Title 13 of the Health-General Article, which governs hereditary and congenital disorders programs. The council makes recommendations to the Secretary of Health about which conditions are tested for as part of Maryland's newborn screening panel.

RUSP is a list of disorders that the Secretary of HHS recommends for states to screen as part of their state universal newborn screening programs. Conditions included on RUSP have also been supported by the federal Advisory Committee on Heritable Disorders in Newborns and Children. Additionally, conditions listed on RUSP are part of the comprehensive preventative health guidelines supported by HHS' Health Resources and Services Administration under § 2713 of the Public Health Service Act. There are 35 core conditions and 26 secondary conditions.

State Expenditures: Potential significant increase in special fund expenditures for MDH in any year in which additional core conditions must be added to the State's screening panel that otherwise would not have been added, beginning as early as fiscal 2023. However, any impact depends on several factors including whether the condition would have been added absent the bill, the type of condition and the equipment and staff time necessary to test for the condition, and how commonly the condition is detected. For example, some conditions will be rarely detected, but others might be routinely detected and require additional time to provide follow-up services for additional abnormal newborn screening results. The timing of any increase in special fund expenditures depends on when conditions are added to RUSP and subsequently added to the State's screening panel.

MDH advises that the department currently screens for all conditions on RUSP except for X-linked adrenoleukodystrophy (X-ALD). X-ALD was recently recommended to be included by the Maryland Advisory Council on Hereditary Congenital Disorders and was approved for inclusion by the Secretary. MDH is in the process of implementing testing for X-ALD and anticipates being able to screen for the condition within a few months of obtaining the required equipment. For context, MDH estimates that the initial cost to add X-ALD to the State's screening panel is \$1.0 million, which includes \$708,000 to purchase equipment and ongoing annual costs of at least \$243,640 for reagents and supplies and \$48,360 for additional staff. On the other hand, MDH notes that some conditions can be added with existing resources and staff.

State Revenues: MDH is statutorily mandated to establish fees to recoup costs to provide newborn screening. Thus, to the extent that special fund expenditures increase, special fund

revenues increase correspondingly from fee increases beginning as early as fiscal 2023. The program is entirely special funded and, since at least fiscal 2019, fee revenues have fully funded program expenditures. The timing and magnitude of any such potential fee increase would depend on when conditions are added, actual costs to implement additional screening, and whether then-current fee levels are sufficient to cover any increased expenditures.

Additional Information

Prior Introductions: None.

Designated Cross File: SB 242 (Senator Hershey, *et al.*) - Finance.

Information Source(s): Maryland Department of Health; Maryland State Advisory Council on Hereditary and Congenital Disorders; U.S. Department of Health and Human Services; Department of Legislative Services

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