Department of Legislative Services

Maryland General Assembly
2024 Session

FISCAL AND POLICY NOTE
Third Reader - Revised

Senate Bill 117 (Senator Bailey)
Finance Health and Government Operations

Health - Newborn Screening Program - Implementation of Testing

This emergency bill repeals the requirement that the Secretary of Health and the State Advisory Council on Hereditary and Congenital Disorders (1) determine whether to approve the inclusion of a core condition in the State's Newborn Screening Program within one year after the condition is added to the U.S. Department of Health and Human Services' (HHS) Recommended Uniform Screening Panel (RUSP) and (2) implement testing for any condition within one year after approval. The bill also repeals related provisions regarding the disapproval of conditions by the Advisory Council. Instead, the Maryland Department of Health (MDH) must implement testing for a core condition listed in RUSP within 18 months after the core condition is added to RUSP. Uncodified language requires MDH to implement testing for infantile Krabbe disease within one year after HHS issues its final newborn screening recommendation regarding the disease.

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 2026. Special fund revenues increase correspondingly from fees beginning as early as FY 2026. Medicaid expenditures (50% general funds, 50% federal funds) may increase beginning as early as FY 2026, to pay its share of fees. Federal fund revenues increase accordingly.

Local Effect: None.

Small Business Effect: None.

Analysis

Current Law:

Newborn Screening Program

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 Maryland regulations (COMAR 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 Advisory Council, 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 that is administered by the Secretary of Health to cover costs associated with performing newborn screening tests.

Recommended Uniform Screening Panel

Pursuant to Chapters 265 and 266 of 2022, the Newborn Screening Program is required, subject to the approval of the Secretary and the Advisory Council, to screen for each core condition listed in the RUSP. 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. If inclusion for a condition is approved, MDH must implement testing for the condition within one year. If, however, the Secretary or Advisory Council do not approve the inclusion of a condition, MDH must publicly post and submit to the General Assembly a report that includes the Secretary's justification for not approving the inclusion of the condition and the Advisory Council's final vote regarding its inclusion.

On January 30, 2024, the U.S. Advisory Committee on Heritable Disorders in Newborns and Children voted to recommend adding infantile Krabbe disease to HHS's RUSP.

State Fiscal Effect:

According to MDH's Laboratories Administration, all core conditions listed in RUSP are either currently included in the State's Newborn Screening Program or testing for those conditions is in the process of being implemented (with full implementation anticipated by the end of calendar 2024).

The bill eliminates the current approval process for adding core conditions to the State's screening panel and instead requires implementation of testing for a core condition within 18 months after the condition is added to RUSP.

Testing for infantile Krabbe disease must be implemented within one year after HHS issues its final newborn screening recommendation regarding the disease. While the U.S. Advisory Committee on Heritable Disorders in Newborns and Children voted to *recommend* adding Krabbe disease to RUSP, the date of final action by HHS is unknown at this time.

Special Fund Expenditures

The bill results in a 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 2026. 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. 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.

For context, to implement testing for infantile Krabbe disease, special fund expenditures increase by an estimated $850,000 for one-time equipment costs and approximately $750,000 in annual ongoing costs ($150,000 for equipment maintenance, $300,000 for supplies and reagents, and $300,000 for additional staff). These costs may have been incurred otherwise but are likely accelerated under the bill.

Special Fund Revenues

MDH is statutorily mandated to establish fees to recoup costs to provide newborn screening. Such fees may not exceed the administrative, laboratory, and follow-up costs associated with newborn screening testing in the State. Thus, to the extent that special fund expenditures increase, special fund revenues increase correspondingly from fee increases beginning as early as fiscal 2026. 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.

The Laboratories Administration advises that the State's newborn screening fee – currently set at $106 per baby – has not been adjusted since 2015. Since that time, the Laboratories Administration has implemented new tests for five conditions, and it is currently implementing testing for additional conditions. The Laboratories Administration advises that it has submitted proposals to MDH to increase the newborn screening fee and that those proposals are currently under review. According to the Laboratories Administration, based on current revenues, it may lack sufficient funds to properly implement testing for infantile Krabbe disease or other conditions that are added to RUSP.

Impact on Medicaid

Medicaid covers approximately half of all births in Maryland. Thus, with the implementation of any increase in the newborn screening fee, Medicaid expenditures (50% general funds, 50% federal funds) increase. In fiscal 2025, Medicaid is projected to cover approximately 32,175 births. Medicaid may also incur minimal additional expenditures as a result of any follow-up testing (repeat Tier 1 testing and Tier 2 and 3 testing, as needed) for infantile Krabbe disease beginning as early as fiscal 2026.

Additional Comments: Krabbe leukodystrophy disease, also known as Krabbe disease or globoid cell leukodystrophy, is a severe neurological condition that results from the nervous system's loss of myelin – the protective covering around nerve cells that ensures nerve signals are transmitted rapidly – and the presence of abnormal cells in the brain. Affecting approximately 1 in 100,000 individuals in the United States, Krabbe disease is most prevalent among infants. Infantile Krabbe disease is particularly severe; infants with the disease rarely survive beyond age 2. Hunter's Hope Foundation, an advocacy and research organization for Krabbe disease and related leukodystrophies, advises that the disease's progression in infants and young children can be slowed through treatment.

Eleven states currently screen newborns for Krabbe disease; however, that number is slated to rise with infantile Krabbe disease now recommended to be added to HHS's RUSP. Approximately 12 states, including Maryland as discussed earlier in this analysis, have an RUSP alignment policy under state law. Many of those states may add Krabbe disease to their newborn screening programs in the coming months or years.

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within the last three years.

Designated Cross File: HB 96 (Delegate T. Morgan) - Health and Government Operations.

Information Source(s): Maryland Department of Health; Department of Legislative Services

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