



DEPARTMENT OF HEALTH

Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

March 27, 2024

The Honorable Joseline A. Peña-Melnyk
Chair, House Health and Government Operations Committee
Room 241, House Office Building
Annapolis, Maryland 21401

RE: Senate Bill 117 – Health - Newborn Screening Program - Implementation of Testing – Letter of Information with Amendments

Dear Chair Peña-Melnyk and Committee Members:

The Maryland Department of Health (Department) respectfully submits this letter of information with amendments for SB 117 – Health - Newborn Screening Program - Implementation of Testing. SB 117 as amended repeals the requirement for the Secretary of Health and the State Advisory Council on Hereditary and Congenital Disorders (Council) to determine whether to approve the inclusion of a core condition in the system for newborn screening within a certain time period after the addition of the condition to the Recommended Uniform Screening Panel (RUSP). As amended, SB 117 requires the Department to implement testing within 18 months of a core condition's addition to the RUSP, and requires the Department to implement testing for Krabbe leukodystrophy within one year after the U.S. Department of Health and Human Services issues the final newborn screening recommendation regarding the disease.

Currently, the Council has the authority to recommend to the Secretary whether to add a condition to Maryland's newborn screening panel. This process allows for the consideration of state-specific factors such as the impacted population, as compared to Maryland's demographics, the available resources in the state for diagnostic testing and treatment, and the capacity of the Maryland Newborn Screening Program to provide the screening tests and nurses to follow up with the results. The Council also coordinates with Genetic Centers such as Children National Medical Center, University of Maryland, Kennedy Krieger, and Johns Hopkins University who often provide confirmatory testing and treatment to make sure the Centers are prepared for new tests and referral. To ensure that the Department retains the capability to test for conditions specific to the state, which might not be encompassed in the RUSP, the Department suggests an amendment to explicitly provide this authority.

While recognizing the urgent need to implement newborn screening tests for new conditions, the Department faces several barriers that may hinder adherence to the 18-month deadline specified in the legislation. Some conditions necessitate costly and sophisticated laboratory instruments, and the state's procurement timelines for acquiring these instruments alone may extend beyond

the allotted 18 months. To address this challenge, the Department proposes an amendment to SB 117 to require the Department to report on the status of our efforts to implement testing, if the Department has not met the 18-month deadline. Additionally, the Department requests clarification on the requirements for implementation of testing for infantile Krabbe leukodystrophy. As amended, the requirement is based on the issuance of a final recommendation, regardless of whether or not the recommendation is to add the disease to the RUSP.

SB 117 will require the Department to obtain additional staff, equipment, and supplies. To address this impact, the Department intends to increase the Newborn Screening Fee via the regulatory process. This increase aims to generate sufficient revenue to cover the majority of the costs to implement and sustain testing operations for new conditions. Although the specific conditions to be added to the RUSP in the future remain uncertain, advancements in technology and science suggest rapid growth to the RUSP in the coming years. With each condition added there is the potential need for costly new laboratory equipment and additional staff.

If you would like to discuss this further, please do not hesitate to contact Sarah Case-Herron, Director of Governmental Affairs at sarah.case-herron@maryland.gov.

Sincerely,



Laura Herrera Scott, M.D., M.P.H.
Secretary