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THE MARYLAND HOUSE OF DELEGATES
ANNAPOLIS, MARYLAND 21401

HB 109
Maryland Department of Health – System for Newborn Screening – Requirements
Statement in SUPPORT

Chair Kelley, Vice-Chair Feldman and esteemed members of the Senate Finance Committee, thank you for the opportunity to testify today in support of House Bill 109, which will help improve the process by which Maryland screens newborn babies for treatable rare disorders, saving lives as well as money to our healthcare system in the process. HB109 passed the House of Delegates nearly unanimously, with a vote of 130-1. This bill is cross-filed with Senate Bill 242, which your Committee - in addition to the entire Senate - passed unanimously. The House adopted a couple of amendments in coordination with, and with the support of, the Senate sponsor, MDH, patient advocates, and the State Advisory Council on Hereditary and Congenital Disorders.

Currently in Maryland, when babies are born, unless the parents choose to opt-out, they receive the benefit of a newborn screening test as part of the state's universal newborn screening (NBS) program. The Newborn Screen is a special test that is used to test babies for certain serious medical conditions in order to identify babies who have specific disorders before they get sick, helping them to get treatment as soon as possible. It is the very first test administered to all babies born in Maryland and frequently identifies babies who are sick who have no prior family history of rare disorders. It does not test for everything – only 50 conditions including cystic fibrosis, severe immunodeficiency disorders, the presence of abnormal red blood cells or sickle cell disease and more.

Maryland develops its list of disorders screened from the federal Recommended Uniform Screening Panel (RUSP) that is developed by the US Health and Human Services Department. RUSP is a list of disorders that HHS recommends for states to screen as part of their NBS; however each state utilizes its own discretion on what to screen for. As such, some states screen for a majority but not all disorders recommended by RUSP, while others screen for additional disorders. The disorders on RUSP are chosen based on evidence that supports the potential net

benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments.[1]

HB109 will require that newborn screening in Maryland includes screening for each of the conditions listed in the U.S. Department of Health and Human Services' Recommended Uniform Screening Panel (RUSP) within two years of the condition being added to the Panel. Specifically, the Secretary of Health and the State Advisory Council on Hereditary and Congenital Disorders have one year to determine whether to approve the inclusion of a condition in the system for newborn screening after the condition is added to RUSP. Following this, the Department must implement the testing or - if necessary - sign a final procurement contract with a vendor for all equipment necessary to implement the testing within one year. This timeline was created in collaboration with the Department of Health, the State Advisory Council, and advocates to ensure that conditions are screened for as soon as possible while also respecting the external limitations the Department might potentially face in the procurement process. With this, we will ensure that all newborns in Maryland receive the most updated, comprehensive medical attention they deserve from the very beginning of their lives.

Maryland recently added four additional conditions to our state's NBS program including Spinal Muscular Atrophy (SMA), Pomp, Mucopolysaccharidoses Type I and Fabry Disease. These diseases began to be screened for in 2019 and screen for disorders that cause progressive muscle weakness, breathing and heart problems, cell enlargement and dysfunction, and abnormal deposits of lipids in the kidneys, heart and brain. Maryland is also preparing to soon add X-linked Adrenoleukodystrophy (X-ALD or ALD), a condition that primarily impacts the nervous system and adrenal glands.[2] It is unclear when this will occur, however, it is important to note that RUSP has included ALD on its recommendations for 8 years.[3] However, only five states actively test their newborns for this disease.[4] Given that one in every 21,000 males born is at risk for ALD and about half of female babies born with the condition may develop symptoms, early adoption of this disorder as part of the NBS panel is critical and could save countless babies' lives.

Through early detection and treatment, many of these conditions can be treated early and prevent future healthcare expenses, as well as unnecessary trauma to babies and their families. For

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[1] Health Resources & Services Administration, Federal Advisory Committees, Recommended Uniform Screening Panel: https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html
[2] Maryland Department of Health, Genetics, Newborn Metabolic Screening: https://health.maryland.gov/phpa/genetics/Pages/NBS_Program.aspx
[3] HRSA, Executive Summary, X-linked Adrenoleukodystrophy: https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/rusp/previous-nominations/x-ald-exsum.pdf
[4] Per ALDConnect, only California, New York, Connecticut, Pennsylvania, and Minnesota currently test for ALD: https://aldconnect.org/recommended-uniform-screening-panel-rusp/

example, treating patients with Phenylketonuria costs between $1-2 billion annually in the United States, while the annual costs of screening and treating Phenylketonuria from birth is around $342 million.[5] Furthermore, treating an infant with Severe Combined Immunodeficiency (SCID) can cost Medicaid as much as $2 million if not diagnosed at birth. However, if diagnosed at birth, SCID can be cured with a bone marrow transplant costing around $100,000.[6]

I respectfully request a favorable report on HB109. Thank you.

[5] March of Dimes, Issue Brief, "Newborn Screening Saves Lives and Money": https://www.marchofdimes.org/materials/Issue-Brief-newborn-screening-november-2014.pdf
[6] March of Dimes, Issue Brief, Newborn Screening: https://www.marchofdimes.org/materials/20201105%20Newborn%20Screening%20101.pdf

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March 30, 2022

HB 109 - SUPPORT

Maryland Department of Health – System for Newborn Screening – Requirements

Dear Chair Kelley, Vice-Chair Feldman, and Members of the Finance Committee,

The Recommended Uniform Screening Panel (RUSP) is a list of disorders that the Secretary of the Department of Health and Human Services (HHS) recommends for states to screen as part of their state universal newborn screening (NBS) programs. According to HHS, disorders on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments. It is recommended that every newborn be screened for all disorders on the RUSP. The RUSP currently consists of 35 core conditions and 26 secondary conditions. Secondary conditions screening is recommended when the screening of the core conditions indicated a risk for the secondary condition.

This bill requires our state to adopt RUSP. Maryland currently screens newborns for 50 conditions. There are 34 conditions in the RUSP that Maryland currently fails to screen [Carbamoyl Phosphate Synthetase I Deficiency, Congenital Toxoplasmosis, , Gaucher, Glucose-6-Phosphate Dehydrogenase Deficiency, Guanidinoacetate Methyltransferase Deficiency, Human Immunodeficiency Virus, Hyperornithine with Gyrate Deficiency, Hyperornithinemia-Hyperammonemia-Homocitrullinuria Syndrome , Krabbe , Mucopolysaccharidosis Type-II, Niemann-Pick Disease, Nonketotic Hyperglycinemia , Ornithine Transcarbamylase Deficiency, Prolinemia, Pyroglutamic Acidemia, T-cell Related Lymphocyte Deficiencies]. Most states screen for the majority of disorders on the RUSP. Some states also screen for additional disorders.

Secular Maryland advocates for state laws and policies to follow the consensus recommendations of the experts as closely as possibly. Accordingly we favor passage of this bill.

Respectfully,
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2022 EveryLife HB 109 Senate Side.pdf
Uploaded by: Scott Tiffin
Position: FAV

Committee:	**Health and Government Operations Committee**
Bill Number:	**House Bill 109**
Title:	**Maryland Department of Health – System for Newborn Screening – Requirements**
Hearing Date:	**March 30, 2022**
Position:	**Support**

EveryLife Foundation for Rare Diseases supports *Senate Bill 242 – Home- and Community-Based Services Waiver - Participation and Applications*. This bill seeks ensure that all Maryland children are able to access the best available screening.

Newborn screening programs save lives and reduce healthcare costs by identifying children with rare diseases before they become symptomatic. This allows children to be quickly connected to treatment. Nationwide there have been growing delays in implementing new recommended testing. House Bill 109 seeks to address this issue by streamlining the process so Maryland can begin screening new disorders within 2 years of the United States Department of Health and Human Services issuing a recommendation.

We ask for a favorable report. If we can provide any further information, please contact Scott Tiffin at stiffin@policypartners.net.