STATE OF NORTH CAROLINA
DEPARTMENT OF HEALTH AND HUMAN SERVICES

ROY COOPER
GOVERNOR

KODY H. KINSLEY
SECRETARY

September 12, 2024

SENT VIA ELECTRONIC MAIL

The Honorable Joyce Krawiec, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 308, Legislative Office Building
Raleigh, NC 27603

The Honorable Donny Lambeth, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 303, Legislative Office Building
Raleigh, NC 27603

The Honorable Larry Potts, Chair
Joint Legislative Oversight Committee on
Health and Human Services
North Carolina General Assembly
Room 307B1, Legislative Office Building
Raleigh, NC 27603

Dear Chairmen:

North Carolina General State 130A-125(b) requires the Department of Health and Human Services to provide a report to the Joint Legislative Oversight Committee on Health and Human Services 18 months after a condition is added to the Recommended Uniform Screening Panel (RUSP), as part of the Newborn Screening Program. Pursuant to the provisions of law, the Department is pleased to submit the attached report.

Should you have any questions regarding this report, please contact Karen Wade, Director of Policy, at Karen.Wade@dhhs.nc.gov.

Sincerely,

DocuSigned by:
Mark T. Gordon
65A1EF320AD6419...
on behalf of Kody H. Kinsley

Kody H. Kinsley
Secretary

Additions to the Recommended Uniform Screening Panel Report

GS 130A-125(b)

Report to the

Joint Legislative Oversight Committee on Health and Human Services

by

North Carolina Department of Health and Human Services

September 12, 2024

Background

The Recommended Uniform Screening Panel (RUSP) is a list of biochemical and genetic disorders developed by the Secretary of the United States Department of Health and Human Services and their Advisory Committee on Heritable Disorders of Newborns and Children. The RUSP serves as a guide for state newborn screening programs when adding conditions to their mandated screening panels. General Statute 130A-125(b) directs the North Carolina Department of Health and Human Services (DHHS) to include screening for conditions added to the RUSP within three years of the addition. Additionally, Session Law 2021-180, Section 9G.6A.(a) amended NCGS 130A-125(b), to require DHHS to submit a report to the Joint Legislative Oversight Committee on Health and Human Services 18 months after a condition is added to the RUSP.

Newborn screening (NBS) is a comprehensive, coordinated system consisting of education, screening, follow-up contact, diagnosis, treatment and management, and program evaluation designed to identify newborns at risk for rare and potentially fatal conditions that aren't otherwise apparent at birth. NBS for biochemical and genetic disorders involves a small heel prick to collect a few drops of blood on a filter paper card within the first 24-48 hours of life. This card is sent to a laboratory where scientists look for signs of these serious conditions.

In North Carolina, the newborn screening program began in 1966 as a voluntary effort, testing for only one disorder, phenylketonuria (PKU). The state's program became a legislative mandate in 1991 with the passage of "An Act to Establish a Newborn Screening Program."

Through the screening test and subsequent diagnostic evaluation, physicians can determine whether newborns have certain conditions or disorders that eventually could cause health problems. Although these conditions are rare, and most babies have normal screening results, early diagnosis and proper treatment can make the difference between life-long impairment and healthy development.

Implementation

The following conditions have recently been added to the RUSP:

- Mucopolysaccharidosis Type II (MPS-II) added on August 2, 2022
- Guanidinoacetate Methyltransferase (GAMT) deficiency added on January 4, 2023

The Commission for Public Health amended their rules so that any conditions added to the RUSP would automatically be added to the NBS, effective January 1, 2021. In accordance with Section 9G.6A.(a) of Session Law 2021-180, North Carolina's NBS Program is actively working towards a 2025 implementation of these newest RUSP conditions for which DHHS does not currently screen. The process to onboard screening for additional disorders is complex, as newborn screening is more than a simple test. The public health laboratory testing is a critical, core component, but it is just one piece of a broader public health system working for families. Every state newborn screening program has six essential parts: screening, follow-up, diagnosis, management, evaluation, and education, and the Department must still ensure that the full system is in place before screening can begin.

A needs assessment performed by the NBS Program revealed that implementation of screening for MPS-II and GAMT Deficiency will require additional laboratory and follow-up staffing, development of new educational material, IT upgrades, new laboratory equipment, expanded testing supplies, and renovation of the laboratory facility. An increase in the NBS fee will not be needed to support the addition of these conditions. Thus, the NBS Program has initiated the necessary hiring and procurement actions to achieve implementation within the timeline set forth by Section 9G.6A.(a) of Session Law 2021-180. Moreover, the laboratory will begin renovations in fall 2024 to accommodate the additional equipment and staff required for successful implementation of screening for the new disorders.