

Newborn Screening Program Annual Report

G.S. 130A-125(e)



Report to the

**House Appropriations Committee on Health and Human
Services**

**Senate Appropriations Committee on Health and Human
Services**

Fiscal Research Division

By

North Carolina Department of Health and Human Services

April 14, 2026

Reporting Requirement

North Carolina General Statute 130A-125(e) requires the Department of Health and Human Services (DHHS) to annually report on March 1 to the House Appropriations Committee on Health and Human Services, the Senate Appropriations Committee on Health and Human Services, and the Fiscal Research Division on the DHHS Newborn Screening Program.

The report shall include the following information for the preceding fiscal year:

- (1) A description of the services funded by the Newborn Screening Program, including a description of the Department's activities with respect to each of the services listed in GS § 130A-125(a).
- (2) A detailed budget and list of expenditures for the Newborn Screening Program, including all positions funded.
- (3) Fees and other receipts collected for the Newborn Screening Program.
- (4) Projected fees and other receipts for the Newborn Screening Program for the current and upcoming fiscal year.
- (5) Any condition the Department anticipates will be listed on the RUSP within the current or upcoming fiscal year and a description of the following:
 - a. Any laboratory instruments or equipment the Department will need to purchase in order to perform screening for that condition.
 - b. Any additional positions the Department will need to establish in order to perform screening for that condition.
- (6) The balance in the Newborn Screening Equipment Replacement and Acquisition Fund as of the preceding June 30.
- (7) Amounts credited to the Fund.
- (8) Amounts expended from the Fund and the purposes of the expenditures.
- (9) Proposed expenditures of the monies in the Fund for the current and upcoming fiscal year.
- (10) Any other information the Department deems relevant to maintaining the Newborn Screening Program as a fee-supported program.

Introduction and Background

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.

(1) Services Funded by the Newborn Screening (NBS) Program

The following are services funded by the NBS Program and activities completed by the DHHS Division of Public Health (DPH) and Division of Child and Family Well-Being (DCFW) for each program component listed in G.S. 130A-125(a):

- *Development and distribution of educational materials regarding the availability and benefits of newborn screening*
 - The brochure “A Test to Save Your Baby’s Life” describes the newborn metabolic screening program, and is translated into English, Spanish, Hmong, Mandarin, and Arabic. It is available online and is distributed at the time of birth.
 - The flyer “North Carolina Newborn Screening Program” describes the NBS program. It is available online and is disseminated via targeted distribution to obstetric/prenatal practices.
 - Syndrome-specific information is provided in conjunction with the reporting of abnormal results to parents and providers. Examples include education pamphlets for Cystic Fibrosis and Severe Combined Immunodeficiency (SCID).
 - The brochure “My Baby’s Hearing Screening” describes what to expect from newborn hearing screening, and is translated into English, Spanish, Arabic, Chinese, French, Hmong, Korean and Vietnamese. It, too, is available online and distributed by birthing facilities.
 - Web resources about Newborn Screening Services on the NCDHHS Child and Family Well-Being Website and the State Laboratory of Public Health Website.

- *Provision of laboratory testing*

The State Laboratory of Public Health (SLPH) provides all laboratory services for the newborn screening (NBS) program for conditions on the North Carolina Newborn Screening Program Panel, in accordance with the Recommended Universal Screening Panel (RUSP) from the Secretary of the United States Department of Health and Human Services.

As of this report, SLPH provides screening for the following core conditions on the RUSP:

Amino Acid Disorders

- Argininosuccinic Aciduria
- Citrullinemia, Type I
- Classic Phenylketonuria
- Homocystinuria
- Maple Syrup Urine Disease
- Tyrosinemia, Type I

Endocrine Disorders

- Congenital Adrenal Hyperplasia
- Primary Congenital Hypothyroidism

Fatty Acid Oxidation Disorders

- Carnitine Uptake Defect
- Long-Chain L-3 Hydroxyacyl-CoA Dehydrogenase Deficiency
- Medium-Chain Acyl-CoA Dehydrogenase Deficiency
- Trifunctional Protein Deficiency
- Very Long-Chain Acyl-CoA Dehydrogenase Deficiency

Hemoglobin Disorders

- S, Beta-Thalassemia
- S, C Disease
- Sickle Cell Anemia

Organic Acid Conditions

- 3-Hydroxy-3-Methylglutaric Aciduria
- 3-Methylcrotonyl-CoA Carboxylase Deficiency
- Beta-Ketothiolase Deficiency
- Glutaric Acidemia, Type I
- Holocarboxylase Synthetase Deficiency
- Isovaleric Acidemia
- Methylmalonic Acidemia (Cobalamin Disorders)
- Methylmalonic Acidemia (Methylmalonyl-CoA Mutase Deficiency)
- Propionic Acidemia

Lysosomal Storage Disorders

- Glycogen Storage Disease Type II (Pompe)
- Mucopolysaccharidosis Type I (MPS-I)
- Mucopolysaccharidosis Type II (MPS-II)

Other Disorders

- Biotinidase Deficiency
- Classic Galactosemia
- Cystic Fibrosis
- Severe Combined Immunodeficiency
- Spinal Muscular Atrophy due to homozygous deletion of exon 7 in SMN1
- X-linked Adrenoleukodystrophy

As of this report, SLPH provides screening for the following secondary conditions on the RUSP:

Amino Acid Disorders

- Argininemia
- Benign Hyperphenylalaninemia
- Biopterin defect in cofactor biosynthesis
- Biopterin defect in cofactor regeneration
- Citrullinemia, type II
- Hypermethioninemia
- Tyrosinemia, Type II
- Tyrosinemia, Type III

Fatty Acid Oxidation Disorders

- Carnitine Acylcarnitine Translocase Deficiency
- Carnitine Palmitoyltransferase Type I Deficiency
- Carnitine Palmitoyltransferase Type II Deficiency
- Glutaric Acidemia, Type II
- Short-Chain Acyl-CoA Dehydrogenase Deficiency
- Medium-chain ketoacyl-CoA Thiolase Deficiency
- Medium/short-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency

Hemoglobin Disorders

- Various other hemoglobinopathies

Organic Acid Conditions

- 2-Methylbutyrylglycinuria
- 2-Methyl-3-hydroxybutyric aciduria
- 3-Methylglutaconic aciduria
- Isobutyrylglycinuria
- Malonic acidemia
- Methylmalonic Acidemia with Homocystinuria

Other Disorders

- Galactoepimerase deficiency
- Galactokinase deficiency
- T-cell related lymphocyte deficiencies

In accordance with G.S. 130A-125(b), North Carolina's NBS Program is actively working towards implementation of the following core conditions on the RUSP for which DHHS does not currently screen:

- Guanidinoacetate Methyltransferase (GAMT) deficiency
 - added to RUSP on January 4, 2023
- Infantile Krabbe Disease
 - added to RUSP on July 1, 2024
- Duchenne Muscular Dystrophy (DMD)
 - added to RUSP on December 16, 2025
- Metachromatic Leukodystrophy (MLD)
 - added to RUSP on December 16, 2025

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.

- *Development of follow-up protocols to assure early treatment for identified children, and the provision of genetic counseling and support services for the families of identified children*
 - As disorders are added to the NC NBS panel, follow-up protocols are developed from a literature review with subspecialist input and are approved by the NC NBS Advisory Committee.
 - Subspecialist and genetics resource lists are faxed to the provider at the time of an abnormal result report and include test results and recommendations.

- *Provision of necessary dietary treatment products or medications for identified children as medically indicated and when not otherwise available*
 - Orders for specialized metabolic formulas are initiated by a tertiary care center in North Carolina caring for individuals without third-party coverage of these products and sent to the DHHS Division of Child and Family Well-Being, Community Nutrition Services Section.
 - Specialized metabolic formulas are ordered by Community Nutrition Services Section directly from the manufacturer, shipped to local Special Supplemental Nutrition Program for Women Infants and Children (WIC) agencies, and picked up by families or individuals for whom the products were ordered.

- *For each newborn, provision of physiological screening in each ear for the presence of permanent hearing loss*
 - Medical facilities that provide birthing or inpatient neonatal services are required to physiologically screen each newborn in each ear for the presence of permanent hearing loss before the infant is discharged from the medical facility unless medical complications prevent screening.
 - Any physician that attends a newborn within 30 days of birth and determines that the newborn has not been physiologically screened in each ear for the presence of permanent hearing loss is required to refer the patient for such screening within 30 days of birth or as soon as is practical.
 - All persons performing physiologic hearing screenings for infants less than six months of age and/or diagnostic auditory evaluations and amplification selections for infants less than twelve months of age are required to report the results of these screenings, evaluations, or selections to DHHS within five days.
 - Infants who do not pass the initial newborn hearing screening should receive an outpatient re-screening by one month of age, unless there are known risk factors for permanent hearing loss, and they are referred directly for a diagnostic auditory evaluation.
 - Infants who do not pass the outpatient re-screening should be referred to a pediatric audiologist for diagnostic auditory evaluation no later than three months of age.
 - Infants who are diagnosed with permanent hearing loss should be fitted with amplification devices (if appropriate) and referred to early intervention services no later than six months of age.

- *For each newborn, provision of pulse oximetry screening to detect congenital heart defects*
 - Critical Congenital Heart Defect screening and evaluation of positive or abnormal screens are required before discharge from the care of the attending provider of the neonate or infant.

- All medical facilities and attending providers of the neonate or infant are required to have and implement a written protocol for evaluation and follow up of positive screenings.
- Evaluation and follow up should occur as soon as possible (but no later than 24 hours after obtaining a positive screening) and should follow most current published recommendations from the American Academy of Pediatrics and the American Heart Association.

(2) Detailed budget and list of expenditures for the Newborn Screening Program, including all positions funded

Newborn Screening SFY 2024-25										
Expenditure Description	State Lab/IT		Follow up Program Children		Equipment Fund		Indirect Cost		Total Newborn Screen Program	
	Budget	Expended	Budget	Expended	Budget	Expended	Budget	Expended	Budget	Expended
Personal Services*	\$ 3,380,016.00	\$ 2,933,738.77	\$ 490,866.00	\$ 459,891.30					\$ 3,870,882.00	\$ 3,393,630.07
Purchased Services**	\$ 3,065,294.00	\$ 966,920.78	\$ 3,532.00	\$ 5,875.16					\$ 3,068,826.00	\$ 972,795.94
Supplies	\$ 4,634,977.00	\$ 4,839,592.85	\$ 436.00	\$ -					\$ 4,635,413.00	\$ 4,839,592.85
Property, Plant & Equipment	\$ 46,736.00		\$ 1,083.00	\$ 677.97	\$ 3,700,000.00	\$ 1,893,992.91			\$ 3,747,819.00	\$ 1,894,670.88
Other Expenses & Adj	\$ 718,026.00	\$ 47,024.38							\$ 718,026.00	\$ 47,024.38
Aid & Public Assistance	\$ -	\$ -	\$ 222,108.00	\$ 163,847.04					\$ 222,108.00	\$ 163,847.04
Total Expenditures	\$ 11,845,049.00	\$ 8,787,276.78	\$ 718,025.00	\$ 630,291.47	\$ 3,700,000.00	\$ 1,893,992.91	\$ -	\$ -	\$ 16,263,074.00	\$ 11,147,714.12
Revenue Description	Budget	Collected	Budget	Collected	Budget	Collected	Budget	Collected	Budget	Collected
Other License, Fees/Permits****	\$ 24,424.00	\$ 178,770.00				\$ 54,870.00			\$ 24,424.00	\$ 233,640.00
Newborn Screening Fees*****	\$ 11,282,207.00	\$ 11,372,188.07	\$ 718,025.00	\$ 630,426.54	\$ 3,700,000.00	\$ 3,499,497.00			\$ 15,700,232.00	\$ 15,502,111.61
Accts Receivable Interest	\$ -	\$ 23,798.65							\$ -	\$ 23,798.65
Accts Receivable Penalty	\$ -	\$ 196.40							\$ -	\$ 196.40
DMA Medicaid Title X*****	\$ 538,418.00	\$ 107,427.57		\$ -					\$ 538,418.00	\$ 107,427.57
Total Revenues	\$ 11,845,049.00	\$ 11,682,380.69	\$ 718,025.00	\$ 630,426.54	\$ 3,700,000.00	\$ 3,554,367.00	\$ -	\$ -	\$ 16,263,074.00	\$ 15,867,174.23
*Expenditures Incurred for services rendered by permanent employees and the related fringe benefits										
**Expenditures incurred for services required to ensure the ongoing operation of State government facilities and government services, ie. Operational services, maintenance agreements, travel,										
****Fees form workshops										
*****Collected per NC General Statute 147-86.23										
*****Medicaid receipts from non-hospital repeat NBS samples										

There are 39 positions supporting the NBS Program funded in SFY 2024-2025.

Positions Funded SFY 2023-2024	
DPH (State Laboratory)	Budgeted Salary
Administrative Supervisor	\$45,311
Chemist I	\$65,667
Chemist I	\$56,650
Chemist I	\$59,029
Chemist II	\$73,076
Chemist II	\$73,000
Chemistry Manager II	\$95,843
Chemistry Supervisor II	\$84,796
Chemistry Technician II	\$46,165
Laboratory Improvement Consultant	\$65,962
Laboratory Improvement Consultant	\$61,800
Laboratory Specialist	\$67,914
Laboratory Specialist	\$71,763
Laboratory Specialist	\$72,000
Laboratory Specialist	\$79,152

Medical Laboratory Supervisor I	\$74,273
Medical Laboratory Supervisor I	\$74,273
Medical Laboratory Technician	\$37,966
Medical Laboratory Technologist I	\$56,640
Medical Laboratory Technologist I	\$56,094
Medical Laboratory Technologist I	\$56,094
Medical Laboratory Technologist I	\$56,640
Medical Laboratory Technologist II	\$59,732
Medical Laboratory Technologist II	\$59,732
Medical Laboratory Technologist II	\$59,732
Medical Laboratory Technologist II	\$60,000
Medical Laboratory Technologist II	\$61,888
Medical Laboratory Technologist II	\$62,594
Medical Laboratory Technologist II	\$65,280
Medical Laboratory Technologist II	\$68,680
Medical Laboratory Technologist II	\$68,680
Public Health Scientist	\$78,000
Public Health Scientist	\$87,971
Public Health Scientist	\$98,320
DCFW (Follow-up)	Budgeted Salary
Public Health Genetic Counselor	\$74,231
Public Health Educator II	\$72,090
Social Worker	\$60,141
Social Worker	\$57,064
Social Worker	\$60,571
Information Technology	Budgeted Salary
Application Systems Specialist	\$117,114

**(3) Fees and other receipts collected for the Newborn Screening Program, and
(4) projected fees and other receipts for the Newborn Screening Program for
the current and upcoming fiscal year**

Fund	SFY 2025-26 Fees & Other Receipts Received Year-to-Date (as of December 31, 2025)	Estimated SFY 2025-26 Fees & Other Receipts	Projected SFY 2026-27 Fees & Other Receipts
NBS	\$6,267,591.38	\$ 12,535,182	\$12,120,000
NBS Equipment Replacement and Acquisition Fund	\$ 1,942,755	\$ 3,885,510	\$3,720,000
Total	\$ 8,210,346.38	\$ 16,420,692	\$15,840,000

Receipts reflect the current NBS fee approved by the General Assembly and increased by the Commission for Public Health at 10A NCAC 42B .0108 to keep the Newborn Screening

Program receipt supported. Authorized fee increases in advance of new disorder implementation are critical to build the infrastructure to initiate and ultimately support screening for new conditions. The Department uses these funds to:

- Hire and sustain essential staff
 - In the SLPH to develop, validate, and implement testing strategies and provide operation support to identify new disorders,
 - In the follow-up program to enhance follow-up services for existing disorders and provide additional services for new disorders, and
 - On the information technology (IT) team to configure the program's information management system to include new disorders, enable electronic reporting, and support improvements to the Laboratory Information Management Software,
- Procure laboratory supplies to test for new disorders,
- Acquire, support, and maintain laboratory and IT instrumentation that will support new disorder testing, and
- Upgrade software, equipment, and infrastructure for program quality and process improvement initiatives.

Since the last report to these Committees, the NC NBS Program has continued to provide critical public health services to ensure the well-being of babies born in the state. In August 2025, the NC NBS Program implemented screening for MPS-II, the fifth new condition added to the state's newborn screening panel in less than four and a half years. In addition to program expansion, the NC NBS Laboratory was renovated to upgrade the testing space. These upgrades were critical as the NC NBS Program is preparing for the addition of screening for four new RUSP conditions over the next three years: GAMT Deficiency, Infantile Krabbe Disease, DMD, and MLD.

Implementation of screening for GAMT Deficiency and Infantile Krabbe Disease is already in process and has required additional laboratory and follow-up staffing, development of new educational material, IT upgrades, new laboratory equipment, expanded testing supplies, and significant renovation of the laboratory facility. The addition of screening for GAMT is delayed beyond the three-year requirement due to challenges executing contracts needed to procure the aforementioned equipment and testing supplies. The preparation and implementation work for GAMT Deficiency and Infantile Krabbe Disease did not require an increase in the NBS fee. Onboarding the testing for these two RUSP conditions will utilize the bulk of the projected receipts that are greater than prior year expenditures for the NBS Program and a substantial portion of the balance of the NBS Equipment Replacement and Acquisition Fund.

In preparation for the implementation of screening for DMD and MLD, the NC NBS Program will complete a needs assessment for the addition of these two conditions. This assessment will consider the need for additional laboratory and follow-up staffing, educational material, IT upgrades, laboratory equipment, and testing supplies as well as the potential need to increase the NBS fee to offset costs. In consultation with the Secretary of NCDHHS, if a fee increase is determined to be needed, the NBS Program will request that the Commission for Public Health commence rulemaking to amend 10A NCAC 42B .0108 and prepare a fiscal note to address required costs.

NC DHHS is coordinating with colleagues in other states and using national resources like those available from the Association of Public Health Laboratories (APHL) to learn from those states who have already implemented screening for these conditions. In addition, the NC NBS Program is collaborating with RTI International on lessons learned from prior pilot studies to more quickly develop educational materials and follow-up protocols to expedite mandated screening.

(5) Conditions the Department anticipates will be listed on the RUSP within the current or upcoming fiscal year

The US Department of Health and Human Services (US HHS) disbanded the federal Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC), which oversees the RUSP, in March 2025. All committee work related to reviewing new conditions for the RUSP was suspended. However, US HHS continues to assess new conditions for the RUSP and on December 16, 2025, the Secretary of US HHS added Duchenne Muscular Dystrophy (DMD) and Metachromatic Leukodystrophy (MLD). Currently, the NC NBS Program is working on implementation activities for core conditions on the RUSP for which DHHS does not currently screen and will continue to monitor developments at the federal level.

(6) Balance in the Newborn Screening Equipment Replacement and Acquisition Fund as of the preceding June 30

The beginning balance in the Fund from June 30, 2025, was \$18,093,568.77. In 2023, G.S. 130-125(d) was amended to allow use of this fund to also support and maintain the equipment procured for the NBS Program. This change will allow a more balanced budget approach and reduce the balance of the fund. Planned expenditures for most of the balance in the Fund are described in subsequent sections.

(7) Amount Credited to the Newborn Screening Equipment Replacement and Acquisition Fund

As of December 31, 2025, the amount credited to the Newborn Screening Equipment Replacement and Acquisition Fund for SFY 2025-26 is \$1,942,755.

(8) Amounts expended from the Fund and the purposes of the expenditures

For SFY 24-25, **\$1,675,510.26** was expended on items in the following chart:

Laboratory equipment to support screening for required conditions	\$837,778.41
Laboratory equipment service, support, and maintenance	\$654,374.53
Information technology equipment and services to support screening and data analysis for required conditions	\$99,024.51
Information technology equipment service, support, and maintenance	\$84,332.81
TOTAL	\$1,675,510.26

For SFY 25-26, as of December 30, 2025, **\$2,461,189.30** has been either expended or encumbered on items in the following chart:

Laboratory equipment to support screening for required conditions	\$1,463,440.40
Laboratory equipment service, support, and maintenance	\$915,551.50
Information technology equipment service, support, and maintenance	\$82,197.40
TOTAL	\$2,461,189.30

(9) Proposed expenditures of the monies in the Fund for the current and upcoming fiscal year

The SLPH anticipates the following expenditures and approximate costs totaling **\$12,952,000** from the NBS Equipment Replacement and Acquisition Fund over the current and next state fiscal years (see below). In addition, the program anticipates an additional \$7,100,000 in new information system costs over the three subsequent fiscal years, which will further utilize the balance in the Fund.

SFY 25-26

Laboratory equipment to support screening for required conditions	\$3,064,000
Laboratory equipment service, support, and maintenance	\$1,254,000
Information technology equipment and services to support screening and data analysis for required conditions	\$1,074,000
Information technology equipment service, support, and maintenance	\$80,000
TOTAL PROPOSED Remaining SFY 25-26 EXPENDITURES	\$5,472,726

SFY 26-27

Laboratory equipment to support screening for required conditions	\$910,000
Laboratory equipment service, support, and maintenance	\$1,500,000
Information technology equipment and services to support screening and data analysis for required conditions	\$200,000
Information technology equipment service, support, and maintenance	\$250,000
New information management system project to support laboratory and follow-up activities	\$4,620,000
TOTAL PROPOSED SFY 26-27 EXPENDITURES	\$7,480,000

10) Other information relevant to maintaining the Newborn Screening Program as a fee-supported program

Newborn screening resides in an ever-changing and complicated environment that requires states to constantly adapt to new circumstances, ranging from advances in technology and treatments to new socio-political, economic, or ethical developments. The challenges NC and other states are facing in newborn screening are well documented and may be summarized as follows:

- New technologies will radically change our ability to cost-effectively screen for many conditions at once. Basic science discoveries will continue to identify markers of new

disorders. These advances could further add to the list of thousands of known and potentially screen-able disorders.

- Disorder therapies will continue to evolve, transforming previously “untreatable” disorders into conditions that can be treated or cured. New treatments are likely to be highly effective, but very expensive, raising fundamental cost-benefit and cost-efficacy questions. States will have to determine how to establish care protocols, networks, and reimbursement mechanisms so they can meet the ethical obligation to treat every baby identified through newborn screening.
- Bioethical and medicolegal issues associated with the retention and use of dried blood spots presents risks to the maintenance of a regulatory compliant, high-quality, and efficient screening program that provides accurate results for the newborns in the jurisdiction. Programs need to ensure that statutory language exists to permit appropriate and necessary use of these biospecimens for the long-term growth and stability of this critical public health service.

Newborn screening is a highly successful public health program. However, despite this success, many challenges are emerging that will require systems to adapt. Fortunately, North Carolina has a wealth of public and private partners committed to advancing newborn screening policy and practice; an objective that will require systematic collaboration with the goal of maximizing the health of young children and the well-being of families. In May 2025, the National Academies of Sciences, Engineering, and Medicine committee on “Newborn Screening: Current Landscape and Future Directions” published a report on the current landscape of newborn screening systems, processes, and research in the United States. This document provides national guidance on the sustainable adoption of screening for new conditions using new technologies. The Director of the North Carolina State Laboratory of Public Health was a member of this committee and brings his expertise to the successful experiences of the NC NBS Program.