# 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

## March 24, 2025

## 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 Recommended Universal Screening Panel (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 are not 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 is available online and distributed by birthing facilities.

- *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 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 (Methymalonyl-CoA Mutase Deficiency)
- Propionic Acidemia

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

***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 a 2025 implementation of the following core conditions on the RUSP for which DHHS does not currently screen:
- Mucopolysaccharidosis Type II (MPS-II)
  - added to RUSP on August 2, 2022
- Guanidinoacetate Methyltransferase (GAMT) deficiency
  - added to RUSP on January 4, 2023
- Infantile Krabbe Disease
  - added to RUSP on July 1, 2024

The process of onboard screening for additional disorders is complex as newborn screening is more than a lab 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 2023-24 | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | State Lab/IT | | Follow up Program Children | | Equipment Fund | | Indirect Cost | | Total Newborn Screen Program | |
| **Expenditure Description** | **Budget** | **Expended** | **Budget** | **Expended** | **Budget** | **Expended** | **Budget** | **Expended** | **Budget** | **Expended** |
| Personal Services* | $ 3,189,463.00 | $ 2,663,479.83 | $ 484,760.00 | $ 402,940.75 | | | | | $ 3,674,223.00 | $ 3,066,420.58 |
| Purchased Services** | $ 3,370,219.00 | $ 2,145,878.89 | $ 13,189.00 | $ 3,894.56 | | | | | $ 3,383,408.00 | $ 2,149,773.45 |
| Supplies | $ 2,554,778.00 | $ 3,373,115.30 | $ 1,759.00 | $ - | | | | | $ 2,556,537.00 | $ 3,373,115.30 |
| Property, Plant & Equipment | $ 29,964.00 | $ 109,497.75 | $ 361.00 | $ - | $ 3,700,000.00 | $ 323,827.60 | | | $ 3,730,325.00 | $ 433,325.35 |
| Other Expenses & Adj | $ - | $ - | | | | | | | $ - | $ - |
| Aid & Public Assistance | $ - | $ - | $ 237,943.00 | $ 163,933.00 | | | | | $ 237,943.00 | $ 163,933.00 |
| **Total Expenditures** | **$ 9,144,424.00** | **$ 8,291,971.77** | **$ 738,012.00** | **$ 570,768.31** | **$ 3,700,000.00** | **$ 323,827.60** | **$ -** | **$ -** | **$ 13,582,436.00** | **$ 9,022,634.68** |
| | | | | | | | | | | |
| **Revenue Decription** | **Budget** | **Collected** | **Budget** | **Collected** | **Budget** | **Collected** | **Budget** | **Collected** | **Budget** | **Collected** |
| Other License, Fees/Permits**** | $ 24,424.00 | $ 68,680.00 | | | | | | | $ 24,424.00 | $ 68,680.00 |
| Newborn Screening Fees***** | $ 8,581,582.00 | $ 11,988,561.92 | $ 656,382.00 | $ - | $ 3,700,000.00 | $ 3,718,416.00 | | | $ 12,937,964.00 | $ 15,706,977.92 |
| Accts Receivable Interest | $ - | $ 42,079.14 | | | | | | | $ - | $ 42,079.14 |
| Accts Receivable Penalty | $ - | $ 4,618.40 | | | | | | | $ - | $ 4,618.40 |
| DMA Medicaid Title X****** | $ 538,418.00 | $ 27,352.77 | $ 66,548.00 | $ - | | | | | $ 604,966.00 | $ 27,352.77 |
| **Total Revenues** | **$ 9,144,424.00** | **$ 12,131,292.23** | **$ 722,930.00** | **$ -** | **$ 3,700,000.00** | **$ 3,718,416.00** | **$ -** | **$ -** | **$ 13,567,354.00** | **$ 15,849,708.23** |
| *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 2023-2024.

| 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 |
| 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 | $64,763 |
| Laboratory Specialist | $62,877 |
| Laboratory Specialist | $79,152 |
| Medical Laboratory Supervisor I | $74,273 |
| Medical Laboratory Supervisor I | $74,273 |
| Medical Laboratory Technician | $37,577 |
| Medical Laboratory Technologist I | $56,640 |
| Medical Laboratory Technologist I | $55,823 |
| Medical Laboratory Technologist I | $55,823 |
| Medical Laboratory Technologist I | $56,640 |
| Medical Laboratory Technologist II | $59,443 |

| | |
|---|---|
| Medical Laboratory Technologist II | $59,443 |
| Medical Laboratory Technologist II | $59,443 |
| Medical Laboratory Technologist II | $85,846 |
| 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 | $85,000 |
| 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 2024-25 Fees & Other Receipts Received Year-to-Date (as of February 3, 2025) | Estimated SFY 2024-25 Fees & Other Receipts | Projected SFY 2025-26 Fees & Other Receipts |
|---|---|---|---|
| **NBS** | **$5,499,138.27** | **$10,998,276** | **$12,120,000** |
| **NBS Equipment Replacement and Acquisition Fund** | **$1,685,749.00** | **$3,371,498** | **$3,720,000** |
| **Total** | **$7,184,887.27** | **$14,369,774** | **$15,840,000** |

Receipts reflect the change in the 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. The 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 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,
- 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 assure the wellbeing of babies born in the state. In addition to maintaining screening for the conditions mandated by state law, the NC NBS Program is preparing for the addition of screening for three new conditions added to the RUSP in 2022-2024: MPS-II, GAMT Deficiency, and Infantile Krabbe Disease.

The needs assessment performed last year as part of the planning process for the addition of the new disorders provided important information to guide the implementation process for the three new conditions. Implementation of screening for MPS-II, GAMT Deficiency, and Infantile Krabbe Disease requires 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. All of this preparation and implementation work is being performed without an increase in the NBS fee. Therefore, onboarding the testing for these additional 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.

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 their ongoing MPS-II pilot study 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) Health Resources and Services Administration (HRSA) Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) is currently reviewing the evidence to support population-based screening for Metachromatic Leukodystrophy (MLD). DHHS anticipates a recommendation by the end of 2025. If the ACHDNC recommends the addition of MLD to the RUSP, the NC NBS Program will conduct a needs assessment in 2026 to determine the instrumentation, equipment, and staffing required to add screening for the disorder.

## (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, 2024, was $16,433,194.68. 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.

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

As of January 30, 2024, the amount credited to the Newborn Screening Equipment Replacement and Acquisition Fund for SFY 2024-25 is $1,685,749.

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

For SFY 2024, $323,827.60 was expended or encumbered on items in the following chart:

| | |
|---|---|
| Instrument maintenance to support screening for required conditions | $22,876.29 |
| Small equipment to support screening for biochemical and genetic disorders | $223,325.21 |
| IT equipment and maintenance needed to support screening and for data analysis | $77,626.10 |
| **TOTAL** | **$323,827.60** |

For SFY 2025, as of February 3, 2025**, $1,603,390.89** has been either expended or encumbered on items in the following chart:

| | |
|---|---|
| Laboratory equipment to support screening for biochemical and genetic disorders | $974,420.81 |
| Laboratory equipment maintenance and service contracts | $508,176.21 |
| Information technology support and maintenance | $76,549.38 |
| Information technology equipment | $44,244.49 |
| **TOTAL** | **$1,603,390.89** |

## (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 $17,500,000 from the NBS Equipment Replacement and Acquisition Fund over the current and subsequent state fiscal years (see below).

**SFY 2025**

| | |
|---|---|
| Analytical Chemistry Instrumentation in support of screening for new RUSP conditions | $3,135,774.33 |
| Laboratory Equipment Maintenance and Support | $3,284,414.00 |
| **TOTAL PROPOSED Remaining SFY 2024 EXPENDITURES** | **$6,420,188.33** |

**SFY 2026**

| | |
|---|---|
| New Nitrogen Generation System to supply Analytical Chemistry Instrumentation in support of screening for new RUSP conditions | $500,000 |
| Laboratory instrumentation to support identification of hemoglobinopathies, including Sickle Cell | $50,000 |
| Upgraded liquid handling instrumentation in support of screening for Severe Combined Immunodeficiency (SCID), Spinal Muscular Atrophy (SMA), and Cystic Fibrosis | $600,000 |
| Information Technology upgrades to support new disorder expansion | $200,000 |
| Facility infrastructure upgrades to support new instrumentation | $895,000 |
| IT Maintenance and Support | $250,000 |
| Laboratory Equipment Maintenance and Support | $1,500,000 |
| New information management system to support laboratory and follow-up activities | $1,750,000 |
| **TOTAL PROPOSED SFY 2026 EXPENDITURES** | **$5,745,000** |

**SFY 2027**

| | |
|---|---|
| New molecular instrumentation in support of screening for Severe Combined Immunodeficiency (SCID) and Spinal Muscular Atrophy (SMA) | $850,000 |
| Facility infrastructure upgrades to support new instrumentation for molecular testing | $785,000 |
| New information management system to support laboratory and follow-up activities | $1,750,000 |
| IT Maintenance and Support | $250,000 |
| Laboratory Equipment Maintenance and Support | $1,700,000 |
| **TOTAL PROPOSED SFY 2027 EXPENDITURES** | **$5,335,000** |

## (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 figure out how to establish care protocols, networks, and reimbursement mechanisms so they can meet the ethical obligation to treat every baby identified through newborn screening.
- Considerations 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 are assessing the 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 emerge. 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" will publish a report on the current landscape of newborn screening systems, processes, and research in the United States. This document will provide 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 selected for this committee to share his expertise and the successful experiences of the NC NBS Program.