U.S. Department of Health and Human Services
Health Resources and Services Administration

REPORT TO CONGRESS

Newborn Screening Activities
Fiscal Year 2017 and Fiscal Year 2018

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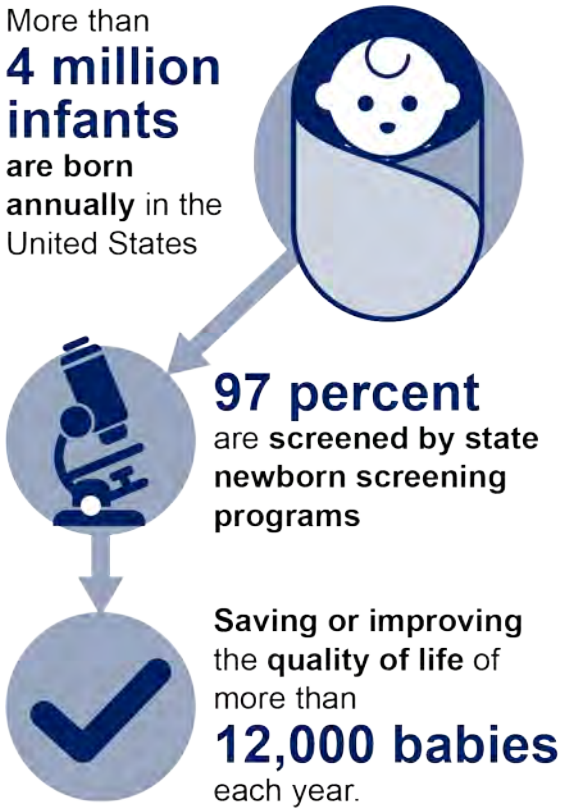
Executive Summary

Newborn screening is a vital public health program that identifies newborns with disorders and conditions that may not be apparent at birth but that require immediate intervention.

Screening practices and the disorders and conditions included in newborn screening vary by state. The Recommended Uniform Screening Panel (RUSP) is a standardized list of disorders and conditions for which screening is beneficial based on rigorous evidence. Conditions on the RUSP are chosen based on the net benefits of screening, the accessibility of proven diagnostic tests, and the availability of treatments if a disorder is identified in a newborn (See Appendix A for information on RUSP and Appendix B for information state screening practices).



Source: Newborn Screening Technical assistance and Evaluation Program (NewSTEPs), *www.newsteps.org*

Federal agencies, including the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC), provide support to newborn screening programs and the newborn screening community to ensure proper and timely screening and intervention. This report is required by the Newborn Screening Saves Lives Reauthorization Act of 2014 and provides information on activities authorized by Sections 1109, 1110, and 1112 through 1115 of Title XI of the Public Health Service Act (the Act) and builds on previous reports from fiscal years (FY) 2015 and 2016.

The programs and activities authorized by the Act were established to enhance, improve, or expand the ability of state and local public health agencies to provide screening, counseling, and health care services to newborns and children with or at risk for heritable disorders. Results from FY 2017 and FY 2018 activities include:

- **Promptness of time-critical results:** The percentage of results for time-critical disorders[1] reported within 5 days of birth increased from 40 percent in 2016 to 58 percent in 2018 under the *Improving the Timeliness of Newborn Screening Diagnosis Initiative.* The purpose of this initiative was to improve the time to diagnosis and treatment for

[1] Time-critical disorders are conditions that may manifest with acute symptoms in the first days of life and require immediate treatment to reduce risk of morbidity and mortality. Advisory Committee on Heritable Disorders in Newborns and Children, "Newborn Screening Timeliness Goals," 2015, Accessed June 4, 2019, https://www.hrsa.gov/advisory-committees/heritable-disorders/newborn-screening-timeliness.html.

infants undergoing newborn screening who receive a presumptive positive result. Timely reporting leads to early diagnosis and intervention so that more newborns receive treatment for time-critical disorders earlier in life.

- **Widespread use of the Newborn Screening Data Repository (NewSTEPS):** Forty-six newborn screening programs in states representing 84 percent of births in the United States signed Memorandums of Understanding outlining the data security and data sharing parameters of the repository and signifying their intentions to participate in NewSTEPs data aggregation.
- **Additional state funding to implement screening for new disorders**: Twelve additional states were selected to receive funding for new disorder newborn screening implementation, including California with over 471,000 births in 2017.[2] With the additional states, there are now 16 funded states implementing testing for Pompe disease, Mucopolysaccharidosis I, and X-linked Adrenoleukodystrophy.
- **Increased number of states screening for Severe Combined Immunodeficiency (SCID):** 50 states, Washington, DC, Puerto Rico, and Guam now universally screen for SCID, an increase from 44 states in FY 2016. HRSA added SCID to the RUSP in 2010. SCID affects approximately 1 in 58,000 infants and is treatable if detected early.[3] While newborns with SCID appear healthy, they are extremely vulnerable to infection and can die without treatment.[4]

The newborn screening programs and activities administered by HRSA and the CDC ensure proper screening of infants born in the United States and that those identified receive early intervention to achieve the best possible health outcomes. HRSA and the CDC are committed to ensuring the identification, sharing, and implementation of best practices to improve the health of all infants and children in the United States.

[2] Association of Public Health Laboratories, "California State Profile," 2019, Accessed April 8, 2019, https://data.newsteps.org/newsteps-web/stateProfile/viewProfile.action?fromMap=true&stateName=California.
[3] Association of Public Health Laboratories, "Severe Combined Immunodeficiency (SCID)," 2019, Accessed March 21, 2019, https://www.newsteps.org/disorders/scid.
[4] Ibid.

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Acronym List

ACHDNC	Advisory Committee on Heritable Disorders in Newborns and Children
APHL	Association of Public Health Laboratories
CDC	Centers for Disease Control and Prevention
FY	Fiscal Year
HIT	Health Information Technology
HRSA	Health Resources and Services Administration
ICC	Interagency Coordinating Committee
MPS I	Mucopolysaccharidosis I
NewSTEPs	Newborn Screening Technical Assistance and Evaluation Program
RGN	Regional Genetics Network
RUSP	Recommended Uniform Screening Panel
SCID	Severe Combined Immunodeficiency
SMA	Spinal muscular atrophy
X-ALD	X-linked Adrenoleukodystrophy

Legislative Language

Section 11(b) of the Newborn Screening Saves Lives Reauthorization Act of 2014 [Public Law 113-240], which added 42 U.S.C. 300b-17, requires that:

> *(b) REPORT BY SECRETARY.— (1) IN GENERAL.—The Secretary of Health and Human Services shall— (A) not later than 1 year after the date of enactment of this Act, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on activities related to— (i) newborn screening; and (ii) screening children who have or are at risk for heritable disorders; and (B) not less than every 2 years, submit to such committees an updated version of such report. (2) CONTENTS. —The report submitted under this subsection shall contain a description of— (A) the ongoing activities under sections 1109, 1110, and 1112 through 1115 of the Public Health Service Act; and (B) the amounts expended on such activities.*

Introduction and Overview

This report discusses the newborn screening activities and associated expenditures of funds authorized by the Newborn Screening Saves Lives Act of 2007 (P.L. 110-204) and reauthorized by the Newborn Screening Saves Lives Reauthorization Act of 2014 (P.L. 113-240). The Newborn Screening Saves Lives Reauthorization Act of 2014 requires a report on activities conducted under Sections 1109, 1110, and 1112 through 1115 of Title XI of the Public Health Service Act (Act) (42 U.S.C. §§ 300b-8, 300b-9, and 300b-11 through 300b-14). Other Department of Health and Human Services activities supporting newborn screening funded under other authorities are not addressed in this report.

The Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC) administer these sections of the Public Health Service Act:

- **Section 1109 - Improved Newborn Screening for Heritable Disorders**: authorizes grants to enhance, improve, or expand the ability of state and local public health agencies to provide screening, counseling, or health care services to newborns and children with or at risk for heritable disorders and is administered by HRSA.
- **Section 1110 - Evaluating the Effectiveness of Newborn and Child Screening and Follow-up Programs:** authorizes grants for demonstration programs that evaluate the effectiveness of screening, follow-up, counseling, or health care services in reducing newborn and child morbidity and mortality caused by heritable disorders and is administered by HRSA.[5]
- **Section 1112 - Clearinghouse of Newborn Screening Information**: authorizes the establishment and maintenance of a central, web-based clearinghouse of current newborn

[5] The CDC and HRSA are both authorized to administer programs under this section; however, the CDC does not currently administer any programs under this section.

screening educational and family support and services information, materials, resources, research, and data, and HRSA administers the program.

- **Section 1113 - Laboratory Quality and Surveillance**: authorizes the provision of quality assurance for laboratories involved in screening newborns and children for heritable disorders or conditions, and CDC administers the program. These activities include quality assurance for conducting newborn screening tests, timeliness of processing such tests, performance evaluation services, technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests, and appropriate quality control and other performance test materials to evaluate the performance of new screening tools. This section also authorizes the coordination of laboratory surveillance activities. Surveillance activities include standardizing data collection and reporting, using electronic health records, and promoting newborn screening data sharing with state-based programs related to birth defects and developmental disabilities monitoring.
- **Section 1114 - Interagency Coordinating Committee on Newborn and Child Screening**: authorizes the Interagency Coordinating Committee (ICC) on Newborn and Child Screening to assess existing activities and infrastructure to make recommendations for programs to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC). The ICC includes representatives from the CDC, HRSA, the Agency for Healthcare Research and Quality, the Food and Drug Administration, and the National Institutes of Health (NIH). HRSA and CDC administer the ICC.
- **Section 1115 - National Contingency Plan for Newborn Screening**: the development of a national contingency plan for newborn screening for use by a state, region, or consortium of states in the event of a public health emergency. CDC administers the Newborn Screening Contingency Plan.

This report on ongoing activities authorized by the sections listed above is the third report on newborn screening activities administered by HRSA and CDC. The report covers activities in fiscal years (FY) 2017 and 2018. The agencies structured the report around the sections of the authorizing legislation describing the purpose, goals, and activities for the programs under each section.

Part I: Improved Newborn & Child Screening for Heritable Disorders (Sec. 1109)

Newborn screening is a public health intervention in newborns for critical disorders and conditions that may be asymptomatic at birth. Early detection and treatment are needed to prevent permanent disability or death.[6]

HRSA administers the programs below, under **Section 1109** of the Public Health Service Act. These programs help increase the number of newborns who receive screening, counseling, or health care services and to improve the quality of that care. HRSA also administers grants to support activities that:

- Improve the ability of state and local public health agencies to provide screening, counseling, and health care services to newborns and children with these disorders.
- Provide education and training programs about newborn screening counseling, testing, follow-up, treatment, and specialty services for newborn screening stakeholders, including health care professionals, laboratory personnel, parents, families, and support groups.
- Establish a system to assess and coordinate follow-up and treatment related to congenital,[7,8] genetic,[9] and metabolic conditions.[10]
- Improve the timeliness of newborn screening from specimen collection[11] through diagnosis.

Improving the Timeliness of Newborn Screening Diagnosis Initiative

In September 2015, HRSA awarded a cooperative agreement to the University of Colorado School of Public Health for the *Improving the Timeliness of Newborn Screening Diagnosis Initiative*. Together, the University of Colorado School of Public Health and the Association of Public Health Laboratories (APHL) promote innovative continuous quality improvement

[6] U.S. National Library of Medicine, Genetics Home Reference, "What is Newborn Screening," 2019, Accessed August 27, 2019, https://ghr.nlm.nih.gov/primer/newbornscreening/nbs.

[7] A congenital condition, also known as a birth defect, is defined as "structural or functional abnormalities present at birth that can cause physical disability, intellectual and developmental disability, and other health problems. Some may be fatal, especially if not detected and treated early." (See: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, "About Birth Defects," 2019, Accessed May 15, 2019, https://www.nichd.nih.gov/health/topics/birthdefects/about.)

[8] World Health Organization, "Congenital anomalies," 2016, Accessed on May 15, 2019, http://www.who.int/mediacentre/factsheets/fs370/en/

[9] A genetic condition is defined as "a condition that is caused by changes in genes or chromosomes. Also known as a hereditary disease or an inherited disorder." (See: Baby's First Test, "Glossary," 2019, Accessed May 15, 2019, https://www.babysfirsttest.org/newborn-screening/glossary#letter_g.)

[10] A metabolic condition is defined as "a disorder or defect in the way the body breaks down food or other products (metabolism)." (See: Baby's First Test, "Glossary," 2019, Accessed May 15, 2019, https://www.babysfirsttest.org/newborn-screening/glossary#letter_m.)

[11] Specimen collection in newborn screening is defined as when a few drops of blood are obtained from a heel stick within 24 to 48 hours of a child's birth. These blood spots are sent to a laboratory usually at the state or territorial public health department for testing. (See Centers for Disease Control and Prevention, "Newborn Screening Laboratory Bulletin," 2019, Accessed May 15, 2019, https://www.cdc.gov/nbslabbulletin/bulletin.html.)

processes through a shared learning collaborative of 28 participating state/territorial newborn screening programs. These programs work to identify and overcome barriers to timely newborn screening through technical and financial assistance.

PURPOSE

- **Improve the time for diagnosis and treatment** of infants undergoing newborn screening who receive a presumptive positive result.

OBJECTIVES

- **Increase the number of states that meet the ACHDNC recommendations** on screening timeliness and the number of infants that receive timely diagnosis and treatment for heritable disorders.
- **Coordinate quality improvement projects** that use practice-based strategies to improve timeliness of newborn screening, diagnosis, and treatment.
- **Develop a strategy** to obtain newborn screening timeliness data.
- **Engage public and private partners** to coordinate activities, develop and distribute educational materials, and share best practices and lessons learned.
- **Provide ongoing technical assistance** and facilitate collaboration among stakeholders to address the needs of state newborn screening programs and the impact on health disparities within underserved populations such as rural and tribal communities.

To achieve timely diagnosis and treatment and to avoid associated disability, morbidity, and mortality, the ACHDNC recommends the following time frames to communicate results to the newborn's health care provider:

- Presumptive positive results for time-critical conditions should be communicated immediately but no later than 5 days after birth.
- Presumptive positive results for all other conditions should be communicated as soon as possible but no later than 7 days after birth.
- All newborn screening tests should be completed within 7 days after birth and results reported as soon as possible.[12]

The initiative goal is to achieve timely reporting of results in 95 percent of infants who received a dried-blood spot newborn screening within each state participating in the program.

[12] Joseph A. Bocchini Jr. letter to the Honorable Sylvia Mathews Burwell, *Chair Letter to Secretary: Timely Newborn Screening Goals*, April 16, 2015, https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/heritable-disorders/reports-recommendations/letter-to-sec-timely-newborn%20.pdf.

FY 2017 AND FY 2018 UPDATE[13]

During this period, the *Improving the Timeliness of Newborn Screening Diagnosis Initiative* conducted the following activities to progress toward its goals:

- Educated birthing facility staff about best practices to improve timely specimen collection and transportation by teaching staff the recommended procedures on the collection on specimen and when to send specimens to the laboratory.
- Developed efficient specimen delivery systems by analyzing data on various courier services and the length of time needed for delivery of specimens.
- Evaluated laboratory processes, expansion of operations, and data sharing through Health Information Technology (HIT) by analyzing state specific data on laboratory practices and operations as well as consulting with states that maximize their use of HIT to strengthen newborn screening processes.
- Supported state and territorial newborn screening programs to improve timeliness with a continuous quality improvement framework.
- Used an interactive data repository and a collaborative learning environment.

Part II lists additional activities and accomplishments.

Newborn Screening Data Repository and Technical Assistance Program

In 2014, HRSA awarded a cooperative agreement to the APHL to conduct the Newborn Screening Data Repository and Technical Assistance Program. APHL established Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs) to conduct these activities.

PURPOSE

- **Provide technical assistance** on the implementation of state-based public health newborn screening and other genetics programs.

OBJECTIVES

- **Develop, coordinate, and provide technical assistance** through innovative educational and quality improvement activities related to newborn screening.
- **Develop and disseminate information that addresses gaps in short-term follow-up**[14] identified by providers and public health professionals.
- **Develop a national newborn screening data repository** to standardize, maintain, and analyze quantitative quality measures, case definitions, and other data and information to evaluate the impact of state and territorial newborn screening programs.

[13] In FY 2018, this program was restructured to add additional quality improvement activities and funding and renamed Quality Improvement in Newborn Screening

[14] Short-term follow-up is defined as "the process of ensuring that all newborns are screened, that an appropriate follow-up caregiver is informed of results, that confirmatory testing has been completed, that the newborn has received a diagnosis and, if necessary, treatment." (See: Baby's First Test, "Glossary," 2019, Accessed March 22, 2019, https://www.babysfirsttest.org/newborn-screening/glossary#letter_s.)

- **Support activities that strengthen laboratory performance and quality assurance**, **short- and long-term newborn screening follow-up, and public health interactions** at the community, state, regional, and national levels.
- **Provide a forum for timely interactive communication** between state and public health stakeholders regarding newborn screening and support training opportunities for public health practitioners.

FY 2017 AND FY 2018 UPDATE

During this period, the program implemented the following activities to make progress toward its goals:

- Strengthened the newborn screening system through enhancement of the existing network of stakeholders by creating a culture of trust; providing opportunities for timely, interactive communication; and offering a forum for collaboration among national, regional, and state newborn screening programs. Activities included leading topic specific workgroups with nationally known experts, sharing best practices and challenges with state newborn screening programs and working with informational technology organizations so that states can seamlessly enter data into a central repository for analysis.
- Facilitated continuous quality improvement and data-driven outcome assessments in the newborn screening system by providing a standardized repository and supporting the integration of HIT frameworks.
- Created a dynamic national newborn screening technical assistance resource center that proactively provides training, addresses challenges, and supports program improvement through partnerships with key stakeholders throughout the newborn screening community. NewSTEPs provided technical assistance from July 1, 2017 to June 30, 2018.

Part II lists additional activities and accomplishments during this period.

Regional Genetics Networks Program

Building on the work of the Regional Genetic and Newborn Screening Service Collaboratives Initiative (funded from 2004–2016), HRSA funded seven Regional Genetics Networks (RGNs) for 3 years beginning in 2017. The RGNs include:

- Region 1 – New England Regional Genetics Network (awarded to the University of New Hampshire): Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- Region 2 – New York Mid-Atlantic Regional Genetics Network (awarded to Health Research, Inc. /New York State Department of Health): Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Virginia, and West Virginia.
- Region 3 – Southeast Regional Genetics Network (awarded to Emory University): Alabama, Florida, Georgia, Louisiana, Mississippi, North Carolina, South Carolina, Tennessee, Puerto Rico, and Virgin Islands.

- Region 4 – Midwest Regional Genetics Network (awarded to Michigan Public Health Institute): Indiana, Illinois, Michigan, Minnesota, Ohio, Wisconsin, and Kentucky.
- Region 5 – Heartland Regional Genetics Network (awarded to the University of Arkansas for Medical Sciences): Arkansas, Iowa, Kansas, Missouri, Nebraska, Oklahoma, North Dakota, and South Dakota.
- Region 6 – Mountain States Regional Genetics Network (awarded to Texas Health Institute): Arizona, Colorado, Montana, Nevada, New Mexico, Texas, Utah, and Wyoming.
- Region 7 – Western States Regional Genetics Network (awarded to State of Hawaii Department of Health): Alaska, California, Hawaii, Guam, Idaho, Oregon, and Washington.

PURPOSE

- **Improve health equity and health outcomes** in individuals with genetic conditions, reduce morbidity and mortality caused by genetic conditions (including congenital and metabolic disorders), and improve the quality of coordinated and comprehensive genetic services to children and their families.

OBJECTIVES

- **Link medically underserved populations** (based on poverty, rural geographic location, and/or populations that experience health disparities)[15] to genetic services.
- **Implement quality improvement activities** to increase the connection with genetic services for the medically underserved.
- **Implement evidence-based innovative models of telehealth**[16] with a focus on clinical genetics outreach.
- **Provide resources** to genetic service providers, public health officials, and families.

FY 2017 AND FY 2018 UPDATE

During this period, the RGN program developed a regional infrastructure to identify underserved populations with or at risk for heritable disorders and to connect patients to genetic services. The program provides health professionals with education, training, and other resources within their region. The program also implemented telehealth services to increase access to genetic services and provided education to underserved populations to improve knowledge of genetic conditions.

[15] Medically underserved areas/populations are areas or populations HRSA has designated as having too few primary care providers (i.e., health professional shortage areas), high infant mortality rates, extreme poverty, or a disproportionate elderly population. Health Resources and Services Administration, "Medically Underserved Areas and Populations (MUA/Ps)," Accessed July 1, 2019, https://bhw.hrsa.gov/shortage-designation/muap.

[16] HRSA defines telehealth as the use of electronic information and telecommunications technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration. Health Resources and Services Administration, "Telehealth Programs," Accessed July 1, 2019, https://www.hrsa.gov/rural-health/telehealth/index.html.

Within the first year of the project, the RGNs connected nearly 500 individuals and families with genetic services. The RGNs also supported the implementation of new telegenetics sites across the United States. For example, Colorado and Arizona established telegenetics clinics to provide genetic services to rural populations within their respective states.

Severe Combined Immunodeficiency (SCID) Newborn Screening Implementation Program

SCID is a genetic condition that is the result of an immune system so compromised that it is almost nonexistent. SCID affects 1 in 58,000 infants and is treatable if detected early.[17] Infants born with SCID usually die within one year due to severe recurrent infections unless they have undergone successful stem cell transplantation. In 2010, HRSA added SCID to the Recommended Uniform Screening Panel (RUSP).

To better support states in implementing SCID screening, in FY 2014 HRSA established the SCID Newborn Screening Implementation Program.

PURPOSE

- **Enhance, improve, or expand** the ability of state and local public health agencies (including territories and tribes) to screen for SCID as part of their newborn screening programs, resulting in a greater number of newborns who are screened, identified, and referred for treatment for SCID.

OBJECTIVES

- **Assess needs, develop partnerships, and provide resources** to increase the number of fully implemented programs for SCID newborn screening.
- **Develop, provide, and disseminate education and training materials** on SCID screening and treatment for newborn screening laboratory personnel, health care professionals, patient advocacy and support groups, and parents and families.

FY 2017 AND FY 2018 UPDATE

- All 50 states, Washington, DC, Puerto Rico, and Guam universally screen for SCID.
- The number of states screening newborns increased from 44 states in FY 2016 and 45 states in FY 2017 to 50 states in FY 2018.

Newborn Screening Implementation Program Regarding Conditions Added to the Recommended Uniform Screening Panel

Adding a new condition to a state newborn screening program requires significant time and investment. In FY 2016, HRSA awarded funds to APHL to support screening for Pompe disease, Mucopolysaccharidosis I (MPS I), and X-linked Adrenoleukodystrophy (X-ALD), the

[17] Association of Public Health Laboratories, "Severe Combined Immunodeficiency (SCID)," 2019, Accessed March 21, 2019, https://www.newsteps.org/disorders/scid.

three conditions the Secretary of Health and Human Services had most recently added to the RUSP.

PURPOSE

- **Support states** in increasing the number of newborns screened, identified, and referred for treatment for these conditions.

OBJECTIVES

- **Increase capacity of state newborn screening programs** to screen for conditions recently added to the RUSP.
- **Support implementation, education, and awareness** of newborn screening for conditions recently added to the RUSP.
- **Distribute national, regional, and state education and training resources** for parents, families, and health care providers.

FY 2017 AND FY 2018 UPDATE[18]

During this period, the Newborn Screening Implementation program focused on the following activities to make progress toward its objectives:

- Integrated screening for Pompe disease, MPS I, and/or X-ALD into newborn screening systems by offering technical assistance via a competitive application process to newborn screening programs.
- Assessed the readiness for implementation of screening and provided technical assistance and resources for gaining authority and funding to implement screening for new conditions.
- Assessed needs and provided resources and technical assistance to at least 15 state newborn screening programs to increase the number of states that could achieve full implementation of newborn screening for at least one of the new conditions by September 2018.
- Assembled, developed, and disseminated educational and training materials for laboratory scientists, newborn screening follow-up staff, health care professionals, and families on new condition screening, treatment, and long-term follow-up.

Part II lists activities and accomplishments.

Newborn Screening Family Education Program

The Clearinghouse of Newborn Screening Information (see Part III for more information) ended in FY 2018 and was followed by the funding of a new family focused program in FY 2018 called the Newborn Screening Family Education Program. HRSA awarded funds to the Genetic Alliance to develop and deliver educational programs about newborn screening, counseling, testing, follow-up and treatment, specialty services and support activities that increase awareness, knowledge, and understanding of newborn screening for parents, families, patient

[18] In FY 2018, this program was restructured and was included in the Newborn Screening Data Repository and Technical Assistance Program.

advocacy and support groups. This program began at the end of FY 2018; therefore, HRSA will report activities and accomplishments in the next report to Congress.

Part II: Evaluating the Effectiveness of Newborn & Child Screening & Follow-up Programs (Sec. 1110)

HRSA requires grantees to evaluate the efficacy and progress of state newborn screening programs and to revise their processes in response to evaluation results. Part I of this report described the purpose and objectives of the Improving the Timeliness of Newborn Screening Diagnosis Initiative, Newborn Screening Data Repository and Technical Assistance Program, and Newborn Screening Implementation Program Regarding Conditions Added to the RUSP. Administered by HRSA, **Section 1110** of the Public Health Service Act focuses on evaluating the effectiveness of these programs. Part II of this report highlights the key accomplishments of these programs in FY 2017 and FY 2018.

Because of these programs more newborns received timely screenings during FY 2017 and FY 2018 than previously resulting in the early diagnosis and efficient treatment of more heritable disorders.

Improving the Timeliness of Newborn Screening Diagnosis Initiative

In FY 2017 and FY 2018, the *Improving the Timeliness of Newborn Screening Diagnosis Initiative* made strides on reporting time-critical[19] and non-time-critical disorder results within the recommended time frames, highlighting the importance of continued efforts in this area. Participating states are working with quality improvement experts to improve the time from collection of newborn screening specimens to diagnosis and treatment of infants identified with a possible heritable condition.

KEY ACCOMPLISHMENTS

- The median percent of specimens with a presumptive positive result for time-critical disorders reported within 5 days of birth increased between 2016 and 2018:[20]
    - 40 percent of specimens (18 states reporting) in 2016;
    - 50 percent of specimens (20 states reporting) in 2017; and
    - 58 percent of specimens (17 states reporting) in 2018.
- For both 2017 and 2018, two newborn screening programs reached the 95 percent benchmark for reporting time-critical results within 5 days of birth compared to one state in 2015.

[19] Time-critical disorders are conditions that may manifest with acute symptoms in the first days of life and require immediate treatment to reduce risk of morbidity and mortality. Advisory Committee on Heritable Disorders in Newborns and Children, "Newborn Screening Timeliness Goals," 2015, Accessed June 4, 2019, https://www.hrsa.gov/advisory-committees/heritable-disorders/newborn-screening-timeliness.html.

[20] The states taking part in the Improving the Timeliness of Newborn Screening Diagnosis Initiative varied year-to-year.

- The median percent of specimens with a presumptive positive result for non-time-critical disorders reported within 7 days of birth increased from 2016 to 2018:[21]
    - 68 percent of specimens (18 states reporting) in 2016;
    - 76 percent of specimens (21 states reporting) in 2017; and
    - 80 percent of specimens (17 states reporting) in 2018.
- In 2018, 9 of the 22 (41 percent) state teams submitting data reached the 95 percent benchmark for all results reported within 7 days of birth.

Newborn Screening Data Repository and Technical Assistance Program

The Newborn Screening Data Repository and Technical Assistance Program provides resources to state newborn screening programs to evaluate the effectiveness of their processes and use real-time data to inform quality improvements. In FY 2017 and 2018, this program strengthened engagement with the newborn screening community increasing the data collected on quality indicators and case definitions.

KEY ACCOMPLISHMENTS

- 50 states, Washington, DC, Puerto Rico, and Guam completed state profiles of their newborn screening programs. State profiles are an overview of the state program and include data on the disorders screened, relevant policies, and other crucial information. This information is available on the NewSTEPs website.
- 46 newborn screening programs in states representing 84 percent of births in the United States, signed Memoranda of Understanding with APHL to contribute data to the NewSTEPs data repository.
- 30 newborn screening programs entered more than 15,000 confirmed cases of conditions on the RUSP.
- 7 reviews of newborn screening programs were completed by APHL. These onsite reviews assess components of a newborn screening program including the laboratory system, birth facilities, and follow-up system for quality improvement purposes.
- 29 webinars were conducted focused on HIT, critical congenital heart disease, short-term follow-up, SCID, and new disorders. Work groups of newborn screening stakeholders guided these webinars.
- 100 plus attendees from over 40 states participated in the Short-Term Follow-Up National Meeting on May 17–18, 2018, in Bethesda, MD. The purpose of this meeting was to convene newborn screening personnel from all state newborn screening programs and pertinent partners and stakeholders to share best practices, challenges, and solutions for short and long-term follow-up newborn screening.

[21] The states taking part in the Improving the Timeliness of Newborn Screening Diagnosis Initiative varied year-to-year.

Newborn Screening Implementation Program Regarding Conditions Added to the RUSP

The Newborn Screening Implementation Program conducted a series of activities to support implementation of screening for new disorders on the RUSP, specifically X-ALD, Pompe disease, and MPS I. The program successfully increased the number of children screened for these new disorders during FY 2018. Prior to award, most states had not implemented screening for X-ALD, Pompe disease, and MPS I.

KEY ACCOMPLISHMENTS

- 16 states received funding for new disorder newborn screening implementation.
- 13 states and Washington, DC implemented X-ALD newborn screening during FY 2018.
- 16 states and Washington, DC implemented MPS I newborn screening during FY 2018.
- 17 states and Washington, DC implemented Pompe disease newborn screening during FY 2018.

Part III: Clearinghouse of Newborn Screening Information (Sec. 1112)

The Newborn Screening Clearinghouse, launched in 2009, maintains a central, online repository of current educational information, materials, resources, research, and data on newborn screening, as authorized under **Section 1112** of the Public Health Service Act.

HRSA provided the second cycle of funding for the Clearinghouse through a cooperative agreement awarded from September 1, 2014 – August 31, 2018 to the Genetic Alliance for a website called www.babysfirsttest.org.

PURPOSE

- **Provide education,** engage consumers and stakeholders, and improve the dissemination of newborn screening information to increase awareness, knowledge, and understanding of newborn screening and genetic conditions.

OBJECTIVES

- **Create an interactive, web-based forum** organized in a clear format for multiple audiences. The forum should promote information sharing and dissemination of authoritative and evidence-based lay informational and educational materials. The forum should also include community training initiatives, health care provider educational materials, and newborn screening best practices and guidelines. Finally, the forum should include information and tools that promote culturally sensitive education and decision-making regarding newborn screening for heritable disorders.
- **Conduct activities to increase awareness, knowledge, and understanding** of newborn genetic conditions and screening services parents and family members of newborns,

health care professionals, industry representatives, policy makers, and members of the public.

- **Conduct activities to increase awareness, knowledge, and understanding** of newborn screening policies.
- **Promote and support communities** in their efforts to understand the newborn screening process that is specific to their community, region, and/or state.
- **Promote national and state-level policies and best practices** regarding newborn screening.
- **Form partnerships with stakeholders,** including federal and non-federal organizations and other Department of Health and Human Services-funded organizations to collaborate, coordinate, promote, and support their efforts and to inform innovative methods of dissemination and educational outreach.
- **Develop a robust evaluation plan** that analyzes project activities and results.

FY 2017 AND FY 2018 UPDATE[22]

BABYSFIRSTTEST.ORG

- 5.3 million visits since 2011
- 91,000 visits per month, on average

The program focused on the following activities to make progress toward its objectives:

- Redesigned the BabysFirstTest.org website to improve function and navigation, ensuring responsiveness to mobile users, who make up 61 percent of site visitors. Website engagements resulted in a 55 percent increase in newsletter subscribers (more than 1,500 total).
- Promoted the Newborn Screening Education and Training Resource Center, mailed more than 65,000 educational resources (as of August 2018), and created resources for Alaska, Colorado, and Virginia.
- Developed materials, including impact briefs, a "Newborn Screening for Critical Congenital Heart Disease" brochure in English and Spanish, and fact sheets on "Newborn Screening: More Than a PKU Screen"[23] and "Plain Language Recommendations for Reporting Newborn Screening Results."
- Hosted 5 webinars with more than 200 attendees.
- Developed the "Newborn Screening Education Best Practices Framework"—through the Best Practices Work Group working collaboratively with experts—for use by state newborn screening staff and hospital staff when developing educational programs and materials.
- Improved engagement with the Spanish-language community by enhancing the design and functionality of the Spanish-language site Spanish.BabysFirstTest.org, conducting a survey to better understand users of the Spanish-language site; and creating a program development plan detailing engagement activities with Spanish-speaking families.

[22] In FY 2018, this program was restructured as a contract.
[23] Also known as Phenylketonuria. National Institutes of Health, U.S. National Library of Medicine, Genetics in Home Reference, "Phenylketonuria," 2019, Accessed on July 7, 2019, https://ghr.nlm.nih.gov/condition/phenylketonuria.

Part IV: Laboratory Quality & Surveillance (Sec. 1113)

The CDC, as authorized under **Section 1113** of the Public Health Service Act, operates the nation's only quality assurance program, the Newborn Screening Quality Assurance Program, for ensuring the accuracy of newborn screening blood spot tests conducted by public health laboratories.

PURPOSE

- **Provide unique services directly** to laboratories to improve the detection of newborn disease.

OBJECTIVES

- **Support newborn screening laboratories** by providing quality assurance materials and proficiency testing services for tests that detect more than 50 congenital conditions in newborns, including all the laboratory-identified primary disorders on the RUSP.
- **Prepare, certify, and distribute** more than 800,000 dried-blood spot quality assurance materials that mimic disease samples to participating laboratories each year.
- **Provide training and technical support** to state and territorial laboratories to enhance nationwide laboratory capacity and capability.
- **Develop new methods** for recent and anticipated additions to the RUSP.
- **Help laboratories add new conditions to screening panels** and implement new screening technologies to improve disease detection and severity prediction.
- **Develop, conduct, and host hands-on training workshops** on current and innovative laboratory techniques for state newborn screening programs.
- **Evaluate filter paper used to produce blood collection cards** for newborn screening to ensure the quality of the cards.

FY 2017 AND FY 2018 UPDATE

During this period, the program focused on the following activities to make progress toward its objectives:

- Provided quality assurance services to nearly 700 laboratories, covering all U.S. states and territories as well as 86 countries.
- Expedited nationwide screening of new high-priority conditions by doubling direct support to state programs through a new 2-year cooperative agreement with seven states to provide critical laboratory equipment, staffing, and supplies for population-based testing.
- Expanded CDC's and states' capacity to better evaluate and interpret complex newborn screening test data by modernizing quality assurance systems, implementing advanced technology for data analytics, supporting expert workforce in state newborn screening programs, and partnering with newborn screening stakeholders to identify and disseminate best practices.

- Achieved accreditation to the International Organization for Standardization 17043 standard for proficiency testing providers, supporting state laboratory accreditation, and reinforcing the CDC's high standard of quality for materials and services.
- Developed or improved screening tests for 12 current or anticipated diseases on the RUSP, including guanidinoacetate methyltransferase deficiency, X-ALD, methylmalonic acidemia, propionic acidemia, homocystinuria and cobalamin disorders, Wilson disease, adenosine deaminase deficiency, spinal muscular atrophy (SMA), glucose-6-phosphate dehydrogenase deficiency, congenital adrenal hyperplasia, and cerebrotendinous xanthomatosis.
- Created quality assurance materials for molecular newborn screening tests that identify babies at risk for galactosemia and pilot-tested the materials with seven state newborn screening programs.
- Developed strategies for harmonizing newborn screening cutoff values for biochemical tests among hundreds of newborn screening laboratories worldwide, which enabled comparison among peer laboratories and provided supporting tools to standardize newborn screening data.
- Created dried-blood spot reference materials for SMA and provided the materials, technical assistance, and proficiency testing to support implementation of screening by Massachusetts, Utah, and Minnesota, who screened approximately 100,000 newborns and identified and treated six infants with SMA.

Part V: Interagency Coordinating Committee on Newborn & Child Screening (Sec. 1114)

The ICC, co-chaired by HRSA and CDC, is composed of the HRSA Administrator, CDC Director, the Agency for Healthcare Research and Quality Director, the Food and Drug Administration Commissioner, and the NIH Director, or their designees. **Section 1114** of the Public Health Service Act authorizes the ICC and its activities.

PURPOSE

Coordinate collaborative efforts for newborn and child screening among all Department of Health and Human Services agencies and assess existing newborn screening activities and infrastructure to make recommendations on heritable disorders for newborn screening.

FY 2017 AND FY 2018 UPDATE

The ICC provided information on three conditions, MPS I, X-ALD, and SMA, to assist the Secretary in the decision to include the conditions on the RUSP. The Secretary added MPS I and X-ALD in 2015 and SMA to the RUSP in 2018.

Part VI: National Contingency Plan for Newborn Screening (Sec. 1115)

The Newborn Screening Contingency Plan takes into account the variability of state newborn screening resources and processes and provides guidance on the formation of state-specific plans that need to be in place to continue critically important newborn screening and clinical management operations in the face of emergencies. **Section 1115** of the Public Health Service Act authorized the development of the plan and requires updating the plan as needed or at least every 5 years.[24]

CDC originally published the plan in July 2010 and published a revised version in August 2017. In 2015, the CDC provided funding to the Association of Maternal and Child Health Programs to assess existing plans and professional literature to update and revise the Newborn Screening Contingency Plan as needed. The 2017 version adds point-of-care screening for critical congenital heart defects and newborn hearing and streamlines text into a usable checklist tool for emergency planners at the state and local levels.[25]

Part VII: Funding Amounts

The FY 2017 and FY 2018 funding amounts for HRSA and the CDC newborn screening activities are in the table below.

Funding Amounts

Program/Initiative	FY 2017 Funding	FY 2018 Funding
HRSA		
Improving the Timeliness of Newborn Screening Diagnosis (Quality Improvement in Newborn Screening)[26]	$1,800,000	$3,300,000
Newborn Screening Data Repository and Technical Assistance Program	$950,000	$1,500,000
Regional Genetics Networks Program	$4,200,000	$4,200,000
Severe Combined Immunodeficiency (SCID) Newborn Screening	$2,000,000	$2,700,000

[24] U.S. Department of Health and Human Services, *Newborn Screening Contingency Plan: Version II*, August 2017, https://www.cdc.gov/ncbddd/documents/Screening-Contingency-Plan-Version-II.pdf.
[25] Ibid.
[26] In FY 2018, this program was restructured to add additional quality improvement activities and funding and renamed Quality Improvement in Newborn Screening.

Program/Initiative	FY 2017 Funding	FY 2018 Funding
Newborn Screening Implementation Program Regarding Conditions Added to the Recommended Uniform Screening Panel[27]	$2,000,000	n/a
Clearinghouse of Newborn Screening Information[28]	$725,000	$495,000
Newborn Screening Family Education Program[29]	n/a	$400,000
Total HRSA Funding	**$11,675,000**	**$12,595,000**
CDC		
Laboratory Quality and Surveillance	$8,381,000	$13,400,000
National Contingency Plan for Newborn Screening	n/a	n/a
Total CDC Funding	**$8,381,000**	**$13,400,000**

Part VIII: Summary and Conclusion

The newborn screening programs administered by HRSA and CDC in FY 2017 and 2018, resulted in the screening and treatment of heritable disorders for more infants born in the United States earlier than during previous years, and:

- Increased the number of states reporting results for non-time-critical and time-critical disorders within the recommended time frames.
- Increased the number of states with support to implement screening for Pompe disease, MPS I, and X-ALD, the three newest conditions added to the RUSP.
- Developed resources, including fact sheets, webinars, and interactive infographics, geared toward increasing awareness of the importance of newborn screening.
- Provided continuous quality improvement, coaching, financial support, and educational opportunities to all state and territory newborn screening programs.
- Ensured the accuracy of newborn screening blood spot tests conducted by public health laboratories.
- Funded critical infrastructure and test development in states to reduce barriers to implementing screening for new conditions.
- Expanded CDC and state capacity to interpret complex newborn screening tests for better detection of disease.

Through expert collaboration, information sharing, resource pooling, and targeted intervention, HRSA and CDC ensure the identification, sharing, and implementation of best practices to improve the health of all infants and children in the United States.

[27] In FY 2018, this program was restructured and was included in the Newborn Screening Data Repository and Technical Assistance Program.
[28] In FY 2018, this program was restructured as a contract and a grant program called Newborn Screening Family Education.
[29] Ibid.

Appendix A: Recommended Uniform Screening Panel

The Recommended Uniform Screening Panel (RUSP) is a list of disorders the Secretary of Health and Human Services recommends for screening at birth as part of states' newborn screening programs. The Secretary chooses disorders on the RUSP 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. The Secretary recommends screening of every newborn for all disorders on the RUSP.[30]

Most states screen for the majority of disorders on the RUSP; newer conditions are still in the process of adoption. Some states also screen for additional disorders. Although states determine what disorders their newborn screening program will screen for, the RUSP establishes a standardized list of disorders that have undergone a rigorous evidence review and are supported by the ACHDNC and the Secretary of Health and Human Services.[31]

RUSP Core Conditions

A condition on the newborn screening panel is classified as a "core condition" if there is a specific test available that is sensitive enough to detect the condition, the health outcomes of the condition are well-understood, and there is an available and effective treatment.

RUSP Core Conditions (as of July 2018)[32]

Metabolic Disorder						
Core Condition	Organic acid condition	Fatty acid oxidation disorders	Amino acid disorders	Endocrine Disorders	Hemoglobin Disorders	Other Disorders
Propionic acidemia	X					
Methylmalonic acidemia (methylmalonyl-CoA mutase)	X					
Methylmalonic acidemia (cobalamin disorders)	X					
Isovaleric acidemia	X					
3-Methylcrotonyl-CoA carboxylase deficiency	X					
3-Hydroxy-3-methylglutaric aciduria	X					
Holocarboxylase synthetase deficiency	X					
ß-Ketothiolase deficiency	X					
Glutaric acidemia type I	X					

[30] Health Resources and Services Administration, "Recommended Uniform Screening Panel," February 2019, Accessed March 22, 2019, https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html.
[31] Ibid.
[32] Ibid.

Metabolic Disorder						
Core Condition	Organic acid condition	Fatty acid oxidation disorders	Amino acid disorders	Endocrine Disorders	Hemoglobin Disorders	Other Disorders
Carnitine uptake defect/carnitine transport defect		X				
Medium-chain acyl-CoA dehydrogenase deficiency		X				
Very long-chain acyl-CoA dehydrogenase deficiency		X				
Long-chain L-3 hydroxyacyl-CoA dehydrogenase deficiency		X				
Trifunctional protein deficiency		X				
Argininosuccinic aciduria			X			
Citrullinemia, type I			X			
Maple syrup urine disease			X			
Homocystinuria			X			
Classic phenylketonuria			X			
Tyrosinemia, type I			X			
Primary congenital hypothyroidism				X		
Congenital adrenal hyperplasia				X		
SS disease (Sickle cell anemia)					X	
S, βeta-thalassemia					X	
SC disease					X	
Biotinidase deficiency						X
Critical congenital heart disease						X
Cystic fibrosis						X
Classic galactosemia						X
Glycogen Storage Disease Type II (Pompe)						X
Hearing loss						X
Severe combined immunodeficiencies						X
Mucopolysaccharidosis Type 1						X
X-linked Adrenoleukodystrophy						X
Spinal Muscular Atrophy due to homozygous deletion of exon 7 in SMN1						X

RUSP Secondary Conditions

"Secondary conditions" are conditions that can be identified when screening for a core condition, or because of confirmatory testing following a positive newborn screening result (e.g., a result outside of the normal reference range).

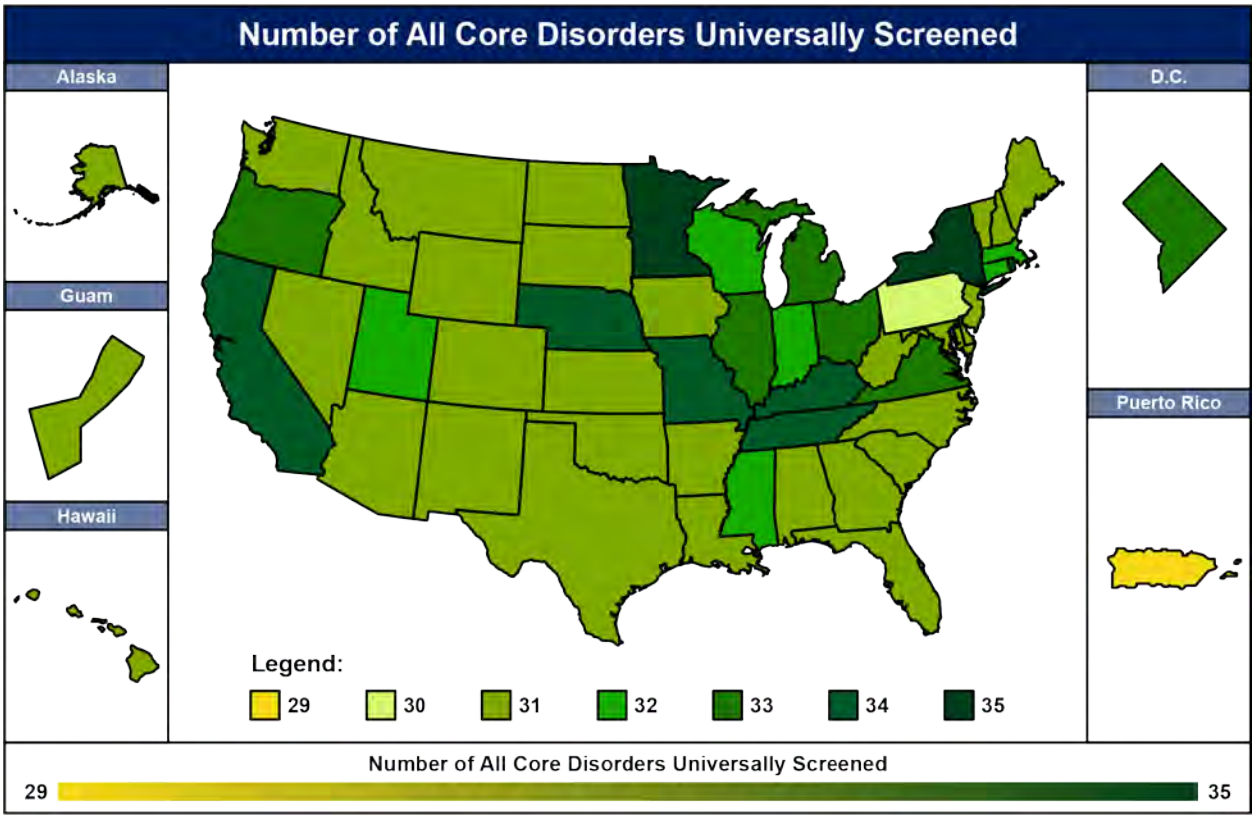
RUSP Secondary Conditions (as of July 2018)[33]

Metabolic Disorder					
Secondary Condition	Organic acid condition	Fatty acid oxidation disorders	Amino acid disorders	Hemoglobin Disorders	Other Disorders
Methylmalonic acidemia with homocystinuria	X				
Malonic acidemia	X				
Isobutyrylglycinuria	X				
2-Methylbutyrylglycinuria	X				
3-Methylglutaconic aciduria	X				
2-Methyl-3-hydroxybutyric aciduria	X				
Short-chain acyl-CoA dehydrogenase deficiency		X			
Medium/short-chain L-3-hydroxyacyl-CoA dehydrogenase deficiency		X			
Glutaric acidemia type II		X			
Medium-chain ketoacyl-CoA thiolase deficiency		X			
2,4 Dienoyl-CoA reductase deficiency		X			
Carnitine palmitoyltransferase type I deficiency		X			
Carnitine palmitoyltransferase type II deficiency		X			
Carnitine acylcarnitine translocase deficiency		X			
Argininemia			X		
Citrullinemia, type II			X		
Hypermethioninemia			X		
Benign hyperphenylalaninemia			X		
Biopterin defect in cofactor biosynthesis			X		
Biopterin defect in cofactor regeneration			X		
Tyrosinemia, type II			X		
Tyrosinemia, type III			X		
Various other hemoglobinopathies				X	
Galactoepimerase deficiency					X
Galactokinase deficiency					X
T-cell related lymphocyte deficiencies					X

[33] Health Resources and Services Administration, "Recommended Uniform Screening Panel," February 2019, Accessed March 22, 2019, https://www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html.

Appendix B: RUSP Conditions Screened by State or Territory

The map and table below show the number of core disorders universally screened per state.



Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

Number of Core Disorders Universally Screened Per State

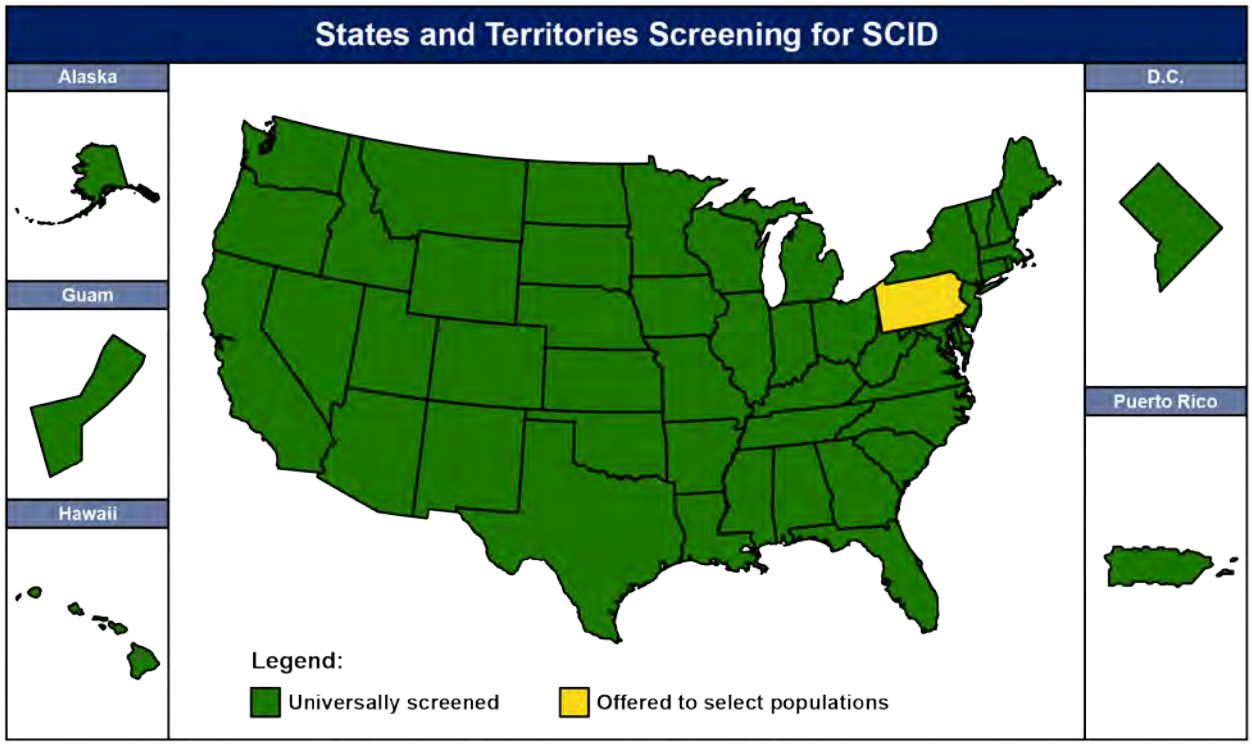
Alabama: 31
Alaska: 31
Arizona: 31
Arkansas: 31
California: 34
Colorado: 31
Connecticut: 32
Delaware: 31
District of Columbia: 33
Florida: 31
Georgia: 31
Guam: 31
Hawaii: 31
Idaho: 31
Illinois: 33
Indiana: 32
Iowa: 31
Kansas: 31
Kentucky: 34
Louisiana: 31
Massachusetts: 32
Maine: 31
Maryland: 31
Michigan: 33
Minnesota: 35
Mississippi: 32
Missouri: 34
Montana: 31
Nebraska: 34
Nevada: 31
New Hampshire: 31
New Jersey: 31
New Mexico: 31
New York: 35
North Carolina: 31
North Dakota: 31
Ohio: 33
Oklahoma: 31
Oregon: 33
Pennsylvania: 30
Puerto Rico: 29
Rhode Island: 34
South Carolina: 31
South Dakota: 31
Tennessee: 34
Texas: 31
Utah: 32
Vermont: 31
Virginia: 33
Washington: 31
West Virginia: 31
Wisconsin: 32
Wyoming: 31

Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

Appendix C: States and Territories Screening for Specific Conditions

The maps and tables below show the states and territories screening for SCID, Pompe disease, MPS I, and X-ALD.

States and Territories Screening for SCID (added to the RUSP in 2010)



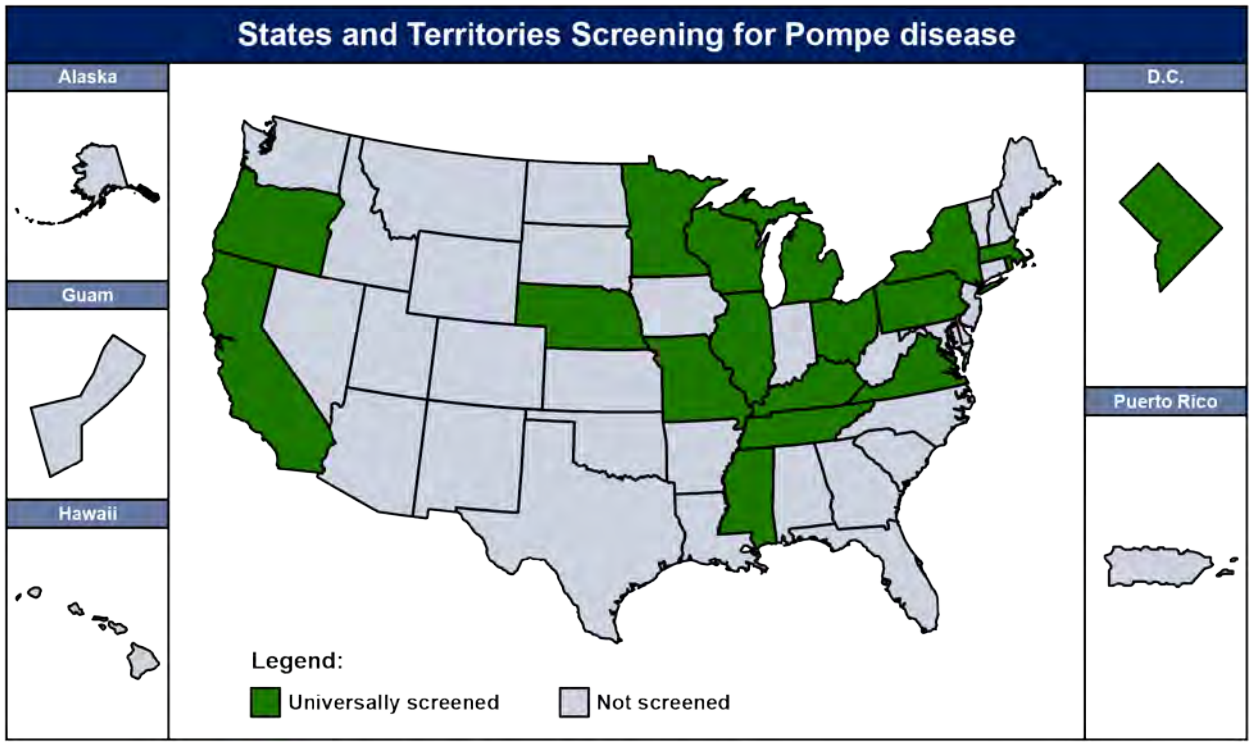
Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Newborn Screening Programs Universally Screening for SCID

Alabama
Alaska
Arizona
Arkansas
California
Colorado
Connecticut
Delaware
District of Columbia
Florida
Georgia
Guam
Hawaii
Idaho
Illinois
Indiana
Iowa
Kansas
Kentucky
Louisiana
Massachusetts
Maine
Maryland
Michigan
Minnesota
Mississippi
Missouri
Montana
Nebraska
Nevada
New Hampshire
New Jersey
New Mexico
New York
North Carolina
North Dakota
Ohio
Oklahoma
Oregon
Puerto Rico
Rhode Island
South Carolina
South Dakota
Tennessee
Texas
Utah
Vermont
Virginia
Washington
West Virginia
Wisconsin
Wyoming
Total: 52 programs

Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Screening for Pompe disease (added to the RUSP 2015)



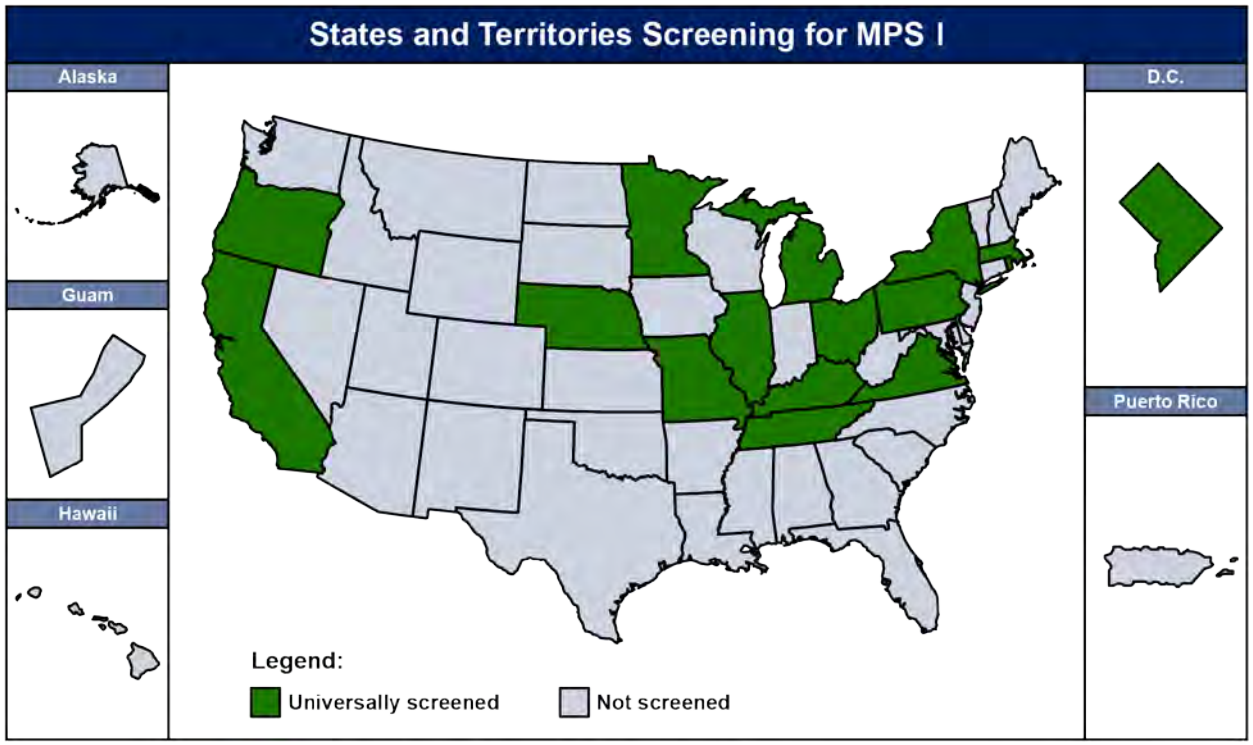
Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Newborn Screening Programs Universally Screening for Pompe disease

California	Michigan	New York	Tennessee
District of Columbia	Minnesota	Ohio	Virginia
Illinois	Mississippi	Oregon	Wisconsin
Kentucky	Missouri	Pennsylvania	**Total: 18 programs**
Massachusetts	Nebraska	Rhode Island	

Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Screening for MPS I (added to the RUSP 2016)



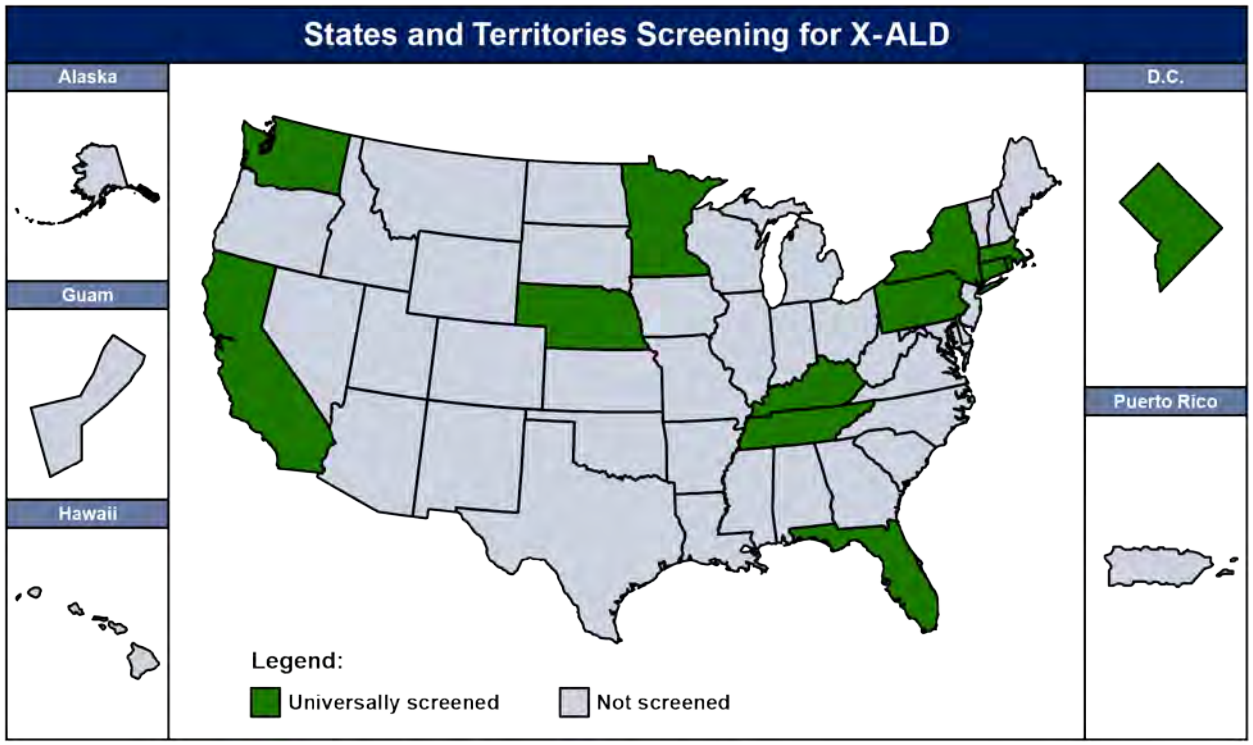
Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Newborn Screening Programs Universally Screening for MPS I

California
District of Columbia
Illinois
Kentucky
Massachusetts
Michigan
Minnesota
Missouri
Nebraska
New York
Ohio
Oregon
Pennsylvania
Rhode Island
Tennessee
Virginia
Total: 16 programs

Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Screening for X-ALD (added to the RUSP 2016)



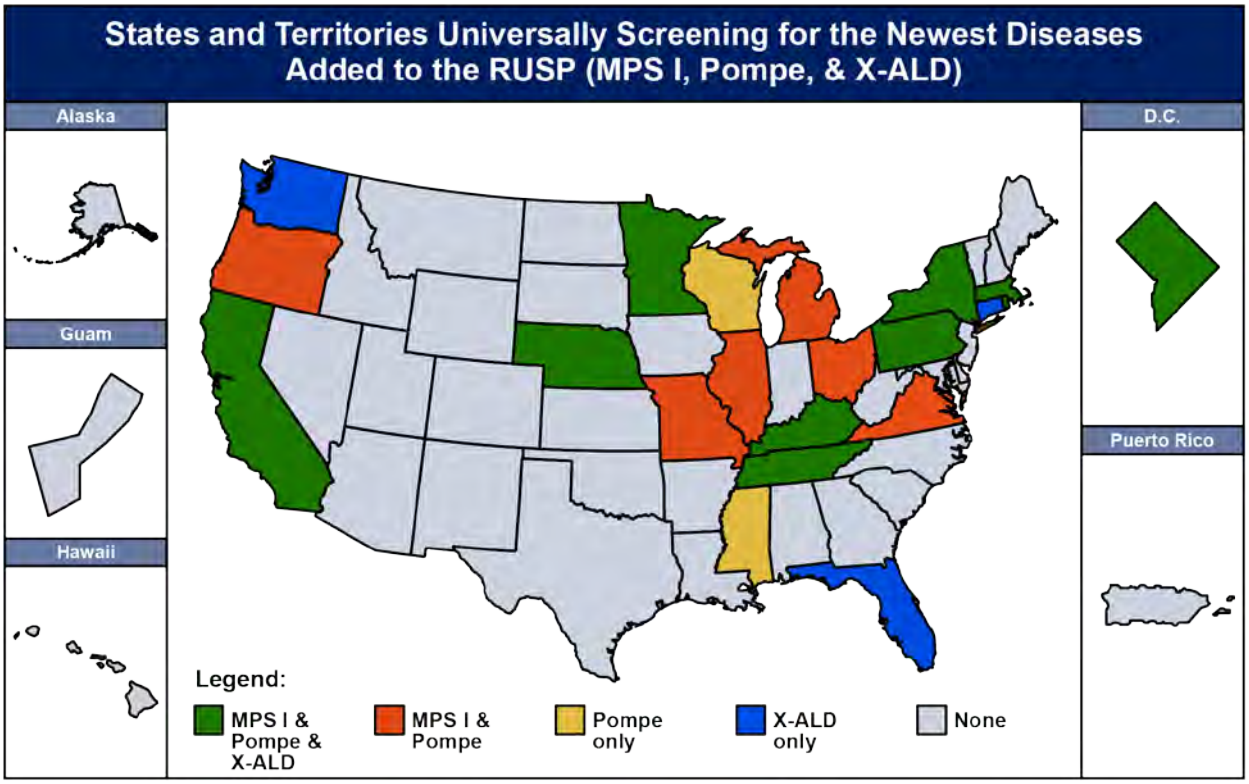
Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Newborn Screening Programs Universally Screening for X-ALD

California
Connecticut
District of Columbia
Florida
Kentucky
Massachusetts
Minnesota
Nebraska
New York
Pennsylvania
Rhode Island
Tennessee
Washington
Total: 13 programs

Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.

States and Territories Universally Screening for the Newest Diseases Added to the RUSP (MPS I, Pompe, & X-ALD)



Source: The Newborn Screening Technical Assistance and Evaluation Program (NewSTEPs), https://www.newsteps.org.