NEWBORN SCREENING

Policy Background

Newborn screening (NBS) is a critical public health program that facilitates the screening of babies for serious conditions for which early interventions or treatments are available.

Newborn screening programs consist of educational materials for parents, training for healthcare professionals, sample collection, testing, follow-up services, and quality assurance testing. Newborn screening reaches each of the four million babies born in the U.S. every year, with approximately 1 in 300 newborns diagnosed with a condition through screening. Early detection and treatment can help prevent intellectual and physical disabilities and life-threatening diseases. This fact sheet will provide some background on federal NBS policy over the last 20 years.

2000

The first federal newborn screening legislation is passed: The Children's Health Act (CHA). The newborn screening section of the CHA created the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) as well as established Department of Health and Human Services (HHS) grants for state and local public health agencies to improve and evaluate newborn screening. While the ACHDNC capacities were limited to mainly providing advice on the issuing of grants, its creation was an important step forward.

Advisory Committee on Heritable Disorders in Newborns and Children

The objective of the ACHDNC is to advise the HHS Secretary on policies and priorities that will help to reduce morbidity and mortality in newborns who have, or at risk for, heritable disorders. Specifically, the ACHDNC is empowered to make "...systematic evidence-based and peer-reviewed recommendations that...have the potential to significantly impact public health for which all newborns are screened." They make recommendation for the federal RUSP (see RUSP box), consider ways to aid states in their capacity to screen for conditions, and support the HRSA grant decision-making process.

2003

Health Resources and Services Administration (HRSA) commissions the American College of Medical Genetics (ACMG) to standardize newborn screening procedures.

2005

The ACHDNC endorsed the ACMG recommendations on standardization, which includes 29 conditions they recommended for inclusion on state newborn screening panels. By 2007, only ten states required infant screening for all the ACMG recommended conditions.

2008

In 2008, Congress passed the original Newborn Screening Saves Lives Act, which established national newborn screening guidelines and helped facilitate comprehensive newborn screening in every state. Key Provisions:

- Authorized HRSA to issue grants to enhance, improve, or expand screening services through training and education.
- Expanded definition of responsibilities of the ACHDNC (see ACHDNC Box).
- Established a clearinghouse for newborn screening information about current educational, support, and services intended for both families and healthcare professionals.

(over)

- Established a program at the Centers for Disease Control and Prevention (CDC) to help maintain laboratory quality and surveillance.
- Established the Hunter Kelly Research Program the National Institutes of Health's Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) to coordinate and expand research in newborn screening.

2014

The NBSSLA was first reauthorized in 2014, focusing on improving follow-up services and timeliness of the screening process.

- Follow-up services are the process of notifying the parents and physicians of a positive test to ensure the baby can receive the proper attention.
- Newborns are typically screened within 24–48 hours after birth, with a second round of screening occurring 10–14 days after birth. However, at the time of the 2014 reauthorization, screenings were often not occurring within the specified timeframe and the ACHDNC was working on recommendations to solve that issue.

Recommended Uniform Screening Panel (RUSP)

The Recommended Uniform Screening Panel or RUSP is a list of disorders that the Secretary of the HHS recommends for states to screen as part of their state universal NBS programs. Disorders on the RUSP are chosen based on evidence that supports the potential net benefit of screening, the ability of states to screen for the disorder, and the availability of effective treatments. It is recommended that every newborn be screened for all disorders on the RUSP. Today, there are 35 core conditions on the RUSP. Currently, all 50 states and the District of Columbia require screening for at least 31 RUSP conditions, with nine currently screening for all 35 conditions.

2019–2020

The current Reauthorization remains stagnated in the Senate. Following passage in the House in July 2019, the Senate HELP committee has yet to hold a markup on the bill. Below are key provisions found in the House bill:

- Reauthorizes the Health Resources and Services Administration (HRSA) grants to states to expand and improve their screening programs, educate parents and health care providers, and improve follow-up care for infants with a detected condition.
- Provides HRSA new ability to award grants to address pilot studies and to help re-engage patient who did not receive recommended follow-up appointments.
- Reauthorizes the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC).
- Directs ACHDNC to make the RUSP nomination process more transparent.
- Directs the National Academy of Medicine to conduct a study on how to modernize the newborn screening program.

EVERYLIFE FOUNDATION FOR RARE DISEASES

EveryLife Foundation for Rare Diseases
1012 14th Street, NW, Suite 500 • Washington, DC 20005 • 202-697-RARE (7273)
501(c)(3) nonprofit organization (Tax ID 26-4614274)

EveryLifeFoundation.org • @EveryLifeOrg