NEWBORN SCREENING

The Newborn Screening Coalition urges Congress to provide $10 million to fund the Newborn Screening Saves Lives Act (P.L. 110-204) to enhance and assist states in improving state newborn screening programs, including providing education and training in newborn screening technologies, as well as coordinate follow-up care. The Coalition also encourages Congress to provide $7.5 million to fund the Centers for Disease Control and Prevention Newborn Screening Quality Assurance Program (NSQAP) to strengthen laboratory quality assurance programs.

The Reauthorization of the Newborn Screening Saves Lives Act (P.L. 110-204) is critical to ensure that the work of the Secretary’s Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC) continues its activities in support of newborn screening. In January 2014, the Senate passed The Newborn Screening Saves Lives Reauthorization Act (S. 1417). The companion bill in the House (H.R. 1281), sponsored by Representative Lucy Roybal-Allard (D-CA) and Representative Mike Simpson (R-ID) has bipartisan support and will hopefully pass later this year.

BASIC FACTS

- Newborn screening is used for the early identification of infants affected by certain genetic, metabolic, hormonal, and/or functional conditions.
- If diagnosed early, many heritable conditions can be cured or successfully treated.
- Newborn screening detects disorders that, if untreated, can cause death, or physical and intellectual disabilities.
- 98% of all infants born in the United States undergo newborn screening; however, the number and types of disorders for which newborns are tested varies from state to state. The American College of Medical Genetics, the American Academy of Pediatrics, the March of Dimes and the Secretary’s Advisory Committee on Heritable Disorders recommend screening all newborns for 31 treatable disorders and reporting on an additional 26 disorders.

NEWBORN SCREENING SAVES LIVES ACT (P.L. 110-204)

In 2008, Congress and the Administration recognized the need for federal guidance and resources to assist states in improving their newborn screening programs by enacting the Newborn Screening Saves Lives Act (P.L. 110-204). The Newborn Screening Coalition recommends Congress provide $10 million towards the Health Resources Services Administration (HRSA) newborn screening activities to:

- Enhance state programs to provide screening, counseling and health care services to newborns and children
- Assist in providing health care professionals with education about screening and training in relevant new technologies
- Develop and deliver educational programs about newborn screening counseling, testing, follow-up, treatment and specialty services to parents, families and patient advocacy and support groups
- Establish, maintain and operate a system to assess and coordinate treatment for disorders
CENTERS FOR DISEASE CONTROL AND PREVENTION

The CDC’s Newborn Screening Quality Assurance Program (NSQAP) is the only comprehensive program in the world devoted to ensuring the accuracy of newborn tests. The Newborn Screening Coalition recommends Congress fund the NSQAP program at $7.5 million in FY 2013 to:

- Strengthen and enhance laboratory quality assurance programs
- Enable public health laboratories to develop and refine screening tests, conduct pilot studies, and implement new methods to improve detection of treatable disorders
- Enhance newborn disorder detection through the Innovative Molecular Quality Program

NEWBORN SCREENING QUALITY ASSURANCE PROGRAM: SUCCESS STORIES

- Ensured accurate newborn testing in more than 500 laboratories nationwide, and assured correct identification of 5,000 to 6,000 infants with treatable diseases that may have otherwise died or been disabled.
- Conducted laboratory studies and testing improvements that substantially supported the addition of Severe Combined Immunodeficiency (SCID) to the DHHS Secretary’s Recommended Uniform Screening Panel (RUSP), including sponsoring pilot studies in Wisconsin and Massachusetts and ensuring testing quality. SCID is the first condition added to the original panel of 29 conditions, and states will use this recommendation as they consider adding SCID to their NBS test panels. Critical Congenital Heart Disease (CCHD) has been the latest recommendation to the RUSP.
- Provided critical technical support and quality assurance materials to assist state labs in Connecticut, Delaware, Wisconsin and Massachusetts in implementation of SCID newborn screening and provided funding for implementation in Michigan and Minnesota. The Connecticut NBS lab successfully identified a SCID baby within one week of beginning SCID screening.
- Established the innovative Molecular Assessment Program to provide guidance and technical expertise to NBS laboratories as they implemented molecular testing techniques to improve disease detection. This program assessed existing molecular NBS programs during on-site assessment visits to four state NBS laboratories.
- Initiated a program to improve testing for Sickle Cell Disease and Cystic Fibrosis in the US by expanding the diversity of available quality assurance materials in partnership with California and Ghana.
- Provided national leadership to develop guidance documents for NBS for Cystic Fibrosis, SCID and CCHD.

RECOMMENDED REPORT LANGUAGE

Health Resources Services Administration
Heritable Disorders, Newborn Screening

The Committee provides $10,000,000 to continue the heritable disorders newborn screening program as authorized by section 1109 of the Newborn Screening Saves Lives Act (P.L. 110-204). The Heritable Disorders program and work of the Advisory Committee on Heritable Disorders in Newborns and Children have been integral to assisting states in the adoption of additional screening for disorders, enhancing provider and consumer education and ensuring coordinated follow-up care.

Centers for Disease Control and Prevention
Environmental Health Laboratory
Newborn Screening Quality Assurance Program (NSQAP)

The Committee provides $11,000,000 to CDC’s Environmental Health Laboratory which houses the NSQAP. The program provides training, consultation, guidelines, proficiency testing and reference materials to nearly 500 laboratories responsible for newborn screening and conducts research on new newborn screening tests.

CONTACT

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CDC FUNDING
Newborn Screening
(Dollars in millions)

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