S. 1858

One Hundred Tenth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and eight

An Act

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Newborn Screening Saves Lives Act of 2007".

SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDER.

Section 1109 of the Public Health Service Act (42 U.S.C. 300b–8) is amended—

(1) by striking subsections (a), (b), and (c) and inserting the following:

"(a) AUTHORIZATION OF GRANT PROGRAM.—From amounts appropriated under subsection (j), the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the 'Administrator') and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children (referred to in this section as the 'Advisory Committee'), shall award grants to eligible entities to enable such entities—

"(1) 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 having or at risk for heritable disorders;

"(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening and training in relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

"(3) to develop and deliver educational programs (at appropriate literacy levels) about newborn screening counseling, testing, follow-up, treatment, and specialty services to parents, families, and patient advocacy and support groups; and

"(4) to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.

"(b) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means—

"(1) a State or a political subdivision of a State;

"(2) a consortium of 2 or more States or political subdivisions of States;

"(3) a territory;

"(4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

"(5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.

"(c) APPROVAL FACTORS.—An application submitted for a grant under subsection (a)(1) shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use amounts received under such grant to adopt and implement the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.";

(2) by redesignating subsections (d) through (i) as subsections (e) through (j), respectively;

(3) by inserting after subsection (c), the following:

"(d) COORDINATION.—The Secretary shall take all necessary steps to coordinate programs funded with grants received under this section and to coordinate with existing newborn screening activities."; and

(4) by striking subsection (j) (as so redesignated) and inserting the following:

"(j) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated—

"(1) to provide grants for the purpose of carrying activities under section (a)(1), $15,000,000 for fiscal year 2008; $15,187,500 for fiscal year 2009, $15,375,000 for fiscal year 2010, $15,562,500 for fiscal year 2011, and $15,750,000 for fiscal year 2012; and

"(2) to provide grant for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,000,000 for fiscal year 2008, $15,187,500 for fiscal year 2009, $15,375,000 for fiscal year 2010, $15,562,500 for fiscal year 2011, and $15,750,000 for fiscal year 2012.".

SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING PROGRAMS.

Section 1110 of the Public Health Service Act (42 U.S.C. 300b–9) is amended by adding at the end the following:

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2008, $5,062,500 for fiscal year 2009, $5,125,000 for fiscal year 2010, $5,187,500 for fiscal year 2011, and $5,250,000 for fiscal year 2012.".

SEC. 4. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

Section 1111 of the Public Health Service Act (42 U.S.C. 300b–10) is amended—

(1) in subsection (b)—

(A) by redesignating paragraph (3) as paragraph (6);

(B) in paragraph (2), by striking "and" after the semicolon;

(C) by inserting after paragraph (2) the following:

"(3) make systematic evidence-based and peer-reviewed recommendations that include the heritable disorders that have the potential to significantly impact public health for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening;

"(4) develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact of such expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

"(5) consider ways to ensure that all States attain the capacity to screen for the conditions described in paragraph (3), and include in such consideration the results of grant funding under section 1109; and";

(D) in paragraph (6) (as so redesignated by subparagraph (A)), by striking the period at the end and inserting ", which may include recommendations, advice, or information dealing with—

"(A) follow-up activities, including those necessary to achieve rapid diagnosis in the short-term, and those that ascertain long-term case management outcomes and appropriate access to related services;

"(B) implementation, monitoring, and evaluation of newborn screening activities, including diagnosis, screening, follow-up, and treatment activities;

"(C) diagnostic and other technology used in screening;

"(D) the availability and reporting of testing for conditions for which there is no existing treatment;

"(E) conditions not included in the recommended uniform screening panel that are treatable with Food and Drug Administration-approved products or other safe and effective treatments, as determined by scientific evidence and peer review;

"(F) minimum standards and related policies and procedures used by State newborn screening programs, such as language and terminology used by State newborn screening programs to include standardization of case definitions and names of disorders for which newborn screening tests are performed;

"(G) quality assurance, oversight, and evaluation of State newborn screening programs, including ensuring that tests and technologies used by each State meet established standards for detecting and reporting positive screening results;

"(H) public and provider awareness and education;

"(I) the cost and effectiveness of newborn screening and medical evaluation systems and intervention programs conducted by State-based programs;

"(J) identification of the causes of, public health impacts of, and risk factors for heritable disorders; and

"(K) coordination of surveillance activities, including standardized data collection and reporting, harmonization of laboratory definitions for heritable disorders and testing