I

[Committee Print]

[SHOWING THE TEXT OF THE BILL AS FORWARDED BY THE SUBCOMMITTEE ON HEALTH ON MARCH 11, 2008]

110TH CONGRESS
1ST SESSION

H. R. 3825

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.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 15, 2007

Ms. ROYBAL-ALLARD (for herself, Mr. SIMPSON, Mr. REYNOLDS, and Mr. WAXMAN) introduced the following bill; which was referred to the Committee on Energy and Commerce

---

A BILL

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 2008''.

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 are authorized to be appropriated—

''(1) to provide grants for the purpose of carrying out activities under subsection (a)(1), $15,000,000 for fiscal year 2009, $15,187,500 for

fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013; and

''(2) to provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013.''.

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 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.''.

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 results, and confirmatory testing and verification of positive results, in order to assess and enhance monitoring of newborn diseases.''; and

(2) in subsection (c)(2)—

(A) by redesignating subparagraphs (E), (F), and (G) as subparagraphs (F), (H), and (I), respectively;

(B) by inserting after subparagraph (D) the following:

''(E) the Commissioner of the Food and Drug Administration;''; and

(C) by inserting after subparagraph (F), as so redesignated, the following:

''(G) individuals with expertise in ethics and infectious diseases who have worked and published material in the area of newborn screening;''; and

(3) by adding at the end the following:

''(d) DECISION ON RECOMMENDATIONS.—

''(1) IN GENERAL.—Not later than 180 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation.

''(2) PENDING RECOMMENDATIONS.—The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment of the Newborn Screening Saves Lives Act of 2008 by not later than 180 days after the date of enactment of such Act.

''(3) DETERMINATIONS TO BE MADE PUBLIC.—The Secretary shall publicize any determination on adopting or rejecting a recommendation of the Advisory Committee pursuant to this subsection, including the justification for the determination.

''(e) ANNUAL REPORT.—Not later than 3 years after the date of enactment of the Newborn Screening Saves Lives Act of 2008, and each fiscal year thereafter, the Advisory Committee shall—

''(1) publish a report on peer-reviewed newborn screening guidelines, including follow-up and treatment, in the United States;

''(2) submit such report to the appropriate committees of Congress, the Secretary, the Interagency Coordinating Committee established under Section 1114, and the State departments of health; and

''(3) disseminate such report on as wide a basis as practicable, including through posting on the

internet clearinghouse established under section 1112.

''(f) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on the date of enactment of the Newborn Screening Saves Lives Act of 2008.

''(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.''.

SEC. 5. INFORMATION CLEARINGHOUSE.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.) is amended by adding at the end the following:

''SEC. 1112. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

''(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this part as the 'Administrator'), in consultation with the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish and

maintain a central clearinghouse of current educational and family support and services information, materials, resources, research, and data on newborn screening to—

''(1) enable parents and family members of newborns, health professionals, industry representatives, and other members of the public to increase their awareness, knowledge, and understanding of newborn screening;

''(2) increase awareness, knowledge, and understanding of newborn diseases and screening services for expectant individuals and families; and

''(3) maintain current data on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as determined by the Advisory Committee under section 1111.

''(b) INTERNET AVAILABILITY.—The Secretary, acting through the Administrator, shall ensure that the clearinghouse described under subsection (a)—

''(1) is available on the Internet;

''(2) includes an interactive forum;

''(3) is updated on a regular basis, but not less than quarterly; and

''(4) provides—

"(A) links to Government-sponsored, non-profit, and other Internet websites of laboratories that have demonstrated expertise in newborn screening that supply research-based information on newborn screening tests currently available throughout the United States;

"(B) information about newborn conditions and screening services available in each State from laboratories certified under subpart 2 of part F of title III, including information about supplemental screening that is available but not required, in the State where the infant is born;

"(C) current research on both treatable and not-yet treatable conditions for which newborn screening tests are available;

"(D) the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized under the Newborn Screening Saves Lives Act of 2008; and

"(E) other relevant information as determined appropriate by the Secretary.

"(c) NONDUPLICATION.—In developing the clearinghouse under this section, the Secretary shall ensure that

such clearinghouse minimizes duplication and supplements, not supplants, existing information sharing efforts.

''(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.''.

SEC. 6. LABORATORY QUALITY AND SURVEILLANCE.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.), as amended by section 5, is further amended by adding at the end the following:

''SEC. 1113. LABORATORY QUALITY.

''(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, shall provide for—

''(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and

''(2) appropriate quality control and other performance test materials to evaluate the performance of new screening tools.

''(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.

''SEC. 1114. INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

''(a) PURPOSE.—It is the purpose of this section to—

''(1) assess existing activities and infrastructure, including activities on birth defects and developmental disabilities authorized under section 317C, in order 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 under section 1111, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders; and

''(2) make recommendations for the establishment of regional centers for the conduct of applied epidemiological research on effective interventions to

promote the prevention of poor health outcomes resulting from such disorders as well as providing information and education to the public on such effective interventions.

''(b) ESTABLISHMENT.—The Secretary shall establish an Interagency Coordinating Committee on Newborn and Child Screening (referred to in this section as the 'Interagency Coordinating Committee') to carry out the purpose of this section.

''(c) COMPOSITION.—The Interagency Coordinating Committee shall be composed of the Director of the Centers for Disease Control and Prevention, the Administrator, the Director of the Agency for Healthcare Research and Quality, and the Director of the National Institutes of Health, or their designees.

''(d) ACTIVITIES.—The Interagency Coordinating Committee shall—

''(1) report to the Secretary and the appropriate committees of Congress on its recommendations related to the purpose described in subsection (a); and

''(2) carry out other activities determined appropriate by the Secretary.

''(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized

to be appropriated $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.''.

SEC. 7. CONTINGENCY PLANNING.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.), as amended by section 6, is further amended by adding at the end the following:

''SEC. 1115. NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.

''(a) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator and State departments of health (or related agencies), shall develop a national contingency plan for newborn screening for use by a State, region, or consortia of States in the event of a public health emergency.

''(b) CONTENTS.—The contingency plan developed under subsection (a) shall include a plan for—

''(1) the collection and transport of specimens;

''(2) the shipment of specimens to State newborn screening laboratories;

''(3) the processing of specimens;

''(4) the reporting of screening results to physicians and families;

''(5) the diagnostic confirmation of positive screening results;

''(6) ensuring the availability of treatment and management resources;

''(7) educating families about newborn screening; and

''(8) carrying out other activities determined appropriate by the Secretary.

''SEC. 1116. HUNTER KELLY RESEARCH PROGRAM.

''(a) NEWBORN SCREENING ACTIVITIES.—

''(1) IN GENERAL.—The Secretary, in conjunction with the Director of the National Institutes of Health and taking into consideration the recommendations of the Advisory Committee, may continue carrying out, coordinating, and expanding research in newborn screening (to be known as 'Hunter Kelly Newborn Screening Research Program') including—

''(A) identifying, developing, and testing the most promising new screening technologies, in order to improve already existing screening tests, increase the specificity of newborn screen-

ing, and expand the number of conditions for which screening tests are available;

"(B) experimental treatments and disease management strategies for additional newborn conditions, and other genetic, metabolic, hormonal, or functional conditions that can be detected through newborn screening for which treatment is not yet available; and

"(C) other activities that would improve newborn screening, as identified by the Director.

"(2) ADDITIONAL NEWBORN CONDITION.—For purposes of this subsection, the term 'additional newborn condition' means any condition that is not one of the core conditions recommended by the Advisory Committee and adopted by the Secretary.

"(b) FUNDING.—In carrying out the research program under this section, the Secretary and the Director shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such entities will work in consultation with the appropriate State departments of health, and, as practicable, focus their research on screening technology not currently performed in the States in which the entities are located, and

the conditions on the uniform screening panel (or the standard test existing on the uniform screening panel).

''(c) REPORTS.—The Director is encouraged to include information about the activities carried out under this section in the biennial report required under section 403 of the National Institutes of Health Reform Act of 2006. If such information is included, the Director shall make such information available to be included on the Internet Clearinghouse established under section 1112.

''(d) NONDUPLICATION.—In carrying out programs under this section, the Secretary shall minimize duplication and supplement, not supplant, existing efforts of the type carried out under this section.

''(e) PEER REVIEW.—Nothing in this section shall be construed to interfere with the scientific peer-review process at the National Institutes of Health.''.