110TH CONGRESS
1ST SESSION

S. 1712

To amend the Public Health Service Act to improve newborn screening activities, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JUNE 27, 2007

Mrs. CLINTON introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To amend the Public Health Service Act to improve newborn screening activities, 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.

(a) SHORT TITLE.—This Act may be cited as the ''Screening for Health of Infants and Newborns Act'' or the ''SHINE Act''.

SEC. 2. PURPOSES.

The purposes of this Act are the following:

(1) To ensure the health and quality of life of all newborns in the United States by enhancing the

capacity to screen for heritable diseases. This enhanced capacity will assist the States in making progress toward the following goals:

(A) All babies born in hospitals in the United States and the territories of the United States should have access to, and be screened for, certain core conditions.

(B) Appropriate newborn screening evaluations should be conducted for all newborns to allow appropriate referrals and provisions for early medical intervention.

(C) Newborn screening data collection should be standardized, and conditions detected by newborn screening should be tracked and monitored.

(D) Information on newborn screening and conditions for which a patient can be screened should be readily accessible, current, and understandable to both health care providers and parents. Information should include the following:

(i) A component for rehabilitation, medical, and early intervention options that ensure linkage to any new and existing national or State system of intervention.

(ii) Rehabilitative services for newborns with the conditions.

(E) Newborn screening should be expanded to include more conditions, and additional newborn screening tests should be developed to enhance the health of newborns.

(2) To expand newborn screening, and improve systems to make newborn screening more efficient and effective, by authorizing—

(A) statewide newborn screening and medical evaluation systems and intervention programs;

(B) technical assistance;

(C) national demonstration grant programs; and

(D) interagency collaborations between the appropriate Federal agencies, including the Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, and National Institutes of Health.

SEC. 3. NEWBORN SCREENING GUIDELINES AND GRANT PROGRAMS.

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. RECOMMENDED GUIDELINES FOR NEWBORN SCREENING AND DATA COLLECTION; MONITORING AND EVALUATION.

''(a) RECOMMENDED GUIDELINES FOR NEWBORN SCREENING AND DATA COLLECTION.—

''(1) IN GENERAL.—The Director of the Centers for Disease Control and Prevention (referred to in this section as the 'Director'), in collaboration with the Associate Administrator of the Maternal and Child Health Bureau of the Health Resources and Services Administration and the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children (referred to in this section as the 'Advisory Committee'), shall develop specific guidelines that the States may follow in reporting newborn screening data, as requested by the Advisory Committee, from newborn screening tests, including the screening tests for the core conditions designated by the Newborn Screening Expert Group convened by the American College of Medical Genet-

ics, as commissioned by the Health Resources and Services Administration.

''(2) GUIDELINES.—The guidelines developed under paragraph (1) shall include—

''(A) standardizing the case definitions and names of the disorders for which newborn screening tests are performed and the definitions of performance measures used to evaluate such tests so that performance criteria and outcomes among all States may be evaluated;

''(B) establishing procedures for standardized newborn screening data collection and reporting; and

''(C) ensuring that tests and technologies used by each State meet established standards for detecting and reporting positive screening results.

''(3) IMPLEMENTATION.—The Director shall submit the guidelines described in this subsection to the Secretary. Not later than 90 days after receiving the guidelines, the Secretary, in consultation with the Director, the Administrator of the Health Resources and Services Administration (referred to in this section as the 'Administrator'), and the Assist-

ant Administrator of the Maternal and Child Health Bureau, shall implement such guidelines.

''(4) ANNUAL REPORT.—Not later than 2 years after the date of enactment of the Screening for Health of Infants and Newborns Act, and each year thereafter, the Advisory Committee shall—

''(A) publish an annual report on newborn screening guidelines in the United States;

''(B) submit such report to the appropriate committees of Congress, the Secretary, and the State departments of health; and

''(C) disseminate such report on as wide a basis as practicable.

''(b) RECOMMENDED GUIDELINES FOR MONITORING, EVALUATION, AND SURVEILLANCE OF NEWBORN SCREENING.—

''(1) IN GENERAL.—

''(A) DEVELOPMENT.—The Secretary, acting through the Administrator and in consultation with the Director and the Advisory Committee, shall develop guidelines to—

''(i) monitor and evaluate newborn screening activities, including diagnosis, screening, follow-up, and treatment activities, in the United States; and

"(ii) coordinate the results of surveillance activities in order to enhance monitoring of newborn diseases.

"(B) DUTIES.—In carrying out this paragraph, the Administrator, in consultation with the Advisory Committee and the Director, shall collaborate with non-Governmental organizations, such as the Joint Commission on Accreditation of Hospital Organizations, laboratories certified by the Clinical Laboratory Improvement Amendment (referred to in the part as 'CLIA'), and the Association of Public Health Laboratories to ensure effective monitoring and evaluation of newborn screening activities.

"(2) IMPLEMENTATION.—Not later than 90 days after the development of the guidelines under paragraph (1), the Secretary, in consultation with the Director, the Administrator, and the Assistant Administrator of the Maternal and Child Health Bureau, shall implement such guidelines.

"(c) SURVEILLANCE AND IDENTIFICATION RESEARCH.—The Secretary, acting through the Director and the National Center on Birth Defects and Developmental Disabilities, and in consultation with the Administrator and Advisory Committee, shall develop a surveillance sys-

tem for newborn screening. The system shall use the standardized procedures and guidelines developed under subsection (b) for data management and tracking program effectiveness and costs, in order to—

''(1) ensure quality monitoring of newborn screening and medical evaluation systems and intervention programs;

''(2) provide technical assistance on data collection and management;

''(3) study the cost and effectiveness of newborn screening and medical evaluation systems and intervention programs conducted by State-based programs in order to answer issues of importance to national and State policymakers; and

''(4) identify the causes of, and risk factors for, heritable disorders.

''(d) ADVISORY COMMITTEE MEETINGS.—The Advisory Committee shall meet not less than annually to—

''(1) assess the implementation of the guidelines and surveillance activities developed under this section;

''(2) advise the Secretary with respect to—

''(A) such guidelines; and

''(B) monitoring and evaluating newborn screening and surveillance activities;

''(3) consider ways to ensure that States attain the capacity to screen for the core conditions described in subsection (a)(1), and include in such consideration the results of the demonstration projects funded under section 1115; and

''(4) consider any addition to the list of the core conditions described in subsection (a)(1), and include in such consideration the results of the demonstration projects funded under section 1116.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

''(1) $10,000,000 for fiscal year 2008; and

''(2) such sums as necessary for fiscal year 2009 through 2012.

''SEC. 1113. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

''(a) CLEARINGHOUSE.—The Secretary shall direct the Maternal and Child Health Bureau of the Health Resources and Services Administration, working through the Regional Genetic and Newborn Screening Collaborative Groups of such Bureau, the National Coordinating Center, and the National Newborn Screening and Genetic Resource Center, to collaborate with the Director of the Centers for Disease Control and Prevention and the National

Library of Medicine of the National Institutes of Health to 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 individuals wishing to have children and expectant families; and

''(3) develop and maintain current data on quality indicators to measure performance of newborn screening entities, such as false-positive rates and other quality indicators as determined by the Advisory Committee described under section 1112.

''(b) INTERNET AVAILABILITY.—The Health Resources and Services Administration 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 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, including the ability of infants to obtain additional comprehensive screening services that may not be required in the State where the infant is born, from CLIA-certified laboratories for disorders;

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

''(D) information about newborn diseases and screening services available in each State; and

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

''(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

''(1) $5,000,000 for fiscal year 2008; and

''(2) such sums as necessary for fiscal years 2009 through 2012.

"SEC. 1114. INTERAGENCY GRANT REVIEW PANEL.

''(a) DEFINITION OF SHINE GRANT PROGRAM.—In this section, the term 'Screening for Health of Infants and Newborns grant program' or 'SHINE grant program' means any grant program under section 1115 or 1116.

''(b) REVIEW PANEL.—The Secretary shall appoint an Interagency Grant Review Panel to review grant applications and provide oversight of the SHINE grant program.

''(c) MEMBERSHIP.—The Secretary shall ensure that the Interagency Grant Review Panel includes representation from all appropriate Federal agencies, including the Agency for Healthcare Research and Quality, the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, and the National Institutes of Health.

''(d) DUTIES.—

''(1) DUTIES OF THE SECRETARY.—After the last day of the application period for a SHINE

grant program, the Secretary shall forward the grant applications received for the program to the Interagency Grant Review Panel.

''(2) DUTIES OF THE INTERAGENCY GRANT REVIEW PANEL.—

''(A) SELECTION OF GRANT RECIPIENTS.—Upon receipt of the grant applications for a SHINE grant program from the Secretary, the Interagency Grant Review Panel shall review the applications for grants under the program and shall select, on a competitive basis, all of the grant recipients for the program and the amount of each grant award.

''(B) SUBMISSION OF GRANT RECIPIENTS.—The Interagency Grant Review Panel shall submit the list of award recipients for grants under a SHINE grant program to the Secretary at a time determined by the Secretary, but not later than 90 days after the last day of the application period for a grant under such program.

''(C) OVERSIGHT OF GRANTS.—The Interagency Grant Review Panel shall provide oversight of the programs and activities funded by grants under a SHINE grant program, and

shall report to the Secretary on the program and activities as the Secretary or the Panel determines necessary.

"SEC. 1115. CAPACITY GRANT PROGRAM.

"(a) IN GENERAL.—The Secretary shall award grants, in conjunction with the Interagency Grant Review Panel established under section 1114, to eligible entities for demonstration projects that increase the capacity of a State to screen for all of the core conditions designated by the Advisory Committee described under section 1112. Such grants shall be made on a competitive basis.

"(b) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

"(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

"(2) be a public or private organization, including an academic research center, medical center, physician group, newborn screening program, or CLIA-certified laboratory with expertise in newborn metabolic screening;

"(3) provide assurance that such organization will work in consultation with the appropriate State department of health;

''(4) have the capacity to perform the core newborn screening tests described in subsection (a) and to collect and report data on the costs, benefits, and effectiveness of such tests, in consultation with the appropriate State department of health and in accordance with the guidelines implemented under section 1112;

''(5) demonstrate sustainability of such activities based on the outcomes of the demonstration project; and

''(6) if applicable, submit to the Secretary a plan for follow-up, diagnosis, and treatment of those infants who test positive on newborn screening tests developed under this section.

''(c) REPORT TO SECRETARY AND INTERAGENCY PANEL.—An organization that receives a grant under this section shall, on an annual basis, submit to the Secretary and the Interagency Grant Review Panel established under section 1114 a report that describes the activities conducted pursuant to such grant and the outcomes of such activities.

''(d) EVALUATION AND RESULTS.—The Secretary shall—

''(1) evaluate the demonstration projects funded under this section; and

''(2) on an annual basis—

''(A) publish and disseminate the results of such evaluation on as wide a basis as is practicable; and

''(B) submit to the appropriate committees of Congress the results of such evaluation.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

''(1) $10,000,000 for fiscal year 2008; and

''(2) such sums as necessary for fiscal years 2009 through 2012.

''SEC. 1116. HUNTER KELLY GRANT PROGRAM.

''(a) ADDITIONAL NEWBORN SCREENING TESTS GRANTS.—

''(1) IN GENERAL.—The Secretary shall award grants (to be known as Hunter Kelly Newborn Screening grants), in conjunction with the Interagency Grant Review Panel established under section 1114, to eligible entities to carry out demonstration projects that develop screening tests for additional newborn conditions, such as tests for Krabbe disease and Insulin Dependent Diabetes Mellitus, or develop multiple markers to increase the

specificity of newborn screening tests. Such grants shall be made on a competitive basis.

''(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 designated by the Advisory Committee described under section 1112.

''(b) ELIGIBILITY.—To be eligible to receive a grant under this section, an entity shall—

''(1) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require;

''(2) be a public or private organization including, an academic research center, medical center, physician group, newborn screening program, or CLIA-certified laboratory with expertise in newborn metabolic screening;

''(3) provide assurance that such entity will work in consultation with the appropriate State department of health;

''(4) submit to the Secretary a strategic plan for performing additional newborn screening tests and for collecting and reporting data on the costs, benefits, and effectiveness of such tests, in consulta-

tion with the appropriate State department of health;

''(5) demonstrate sustainability of such activities based on the outcomes of the demonstration project;

''(6) provide assurance that the entity will develop newborn screening tests that are not currently performed in the State in which the entity is located; and

''(7) if applicable, submit to the Secretary a plan for short- and long-term follow-up, diagnosis, and treatment of those infants who test positive on newborn screening tests developed under this section.

''(c) REPORT TO SECRETARY AND INTERAGENCY PANEL.—An organization that receives a grant under this section shall, on an annual basis, submit to the Secretary and the Interagency Grant Review Panel established under section 1114 a report that describes the activities conducted pursuant to such grant and the outcomes of such activities.

''(d) EVALUATION AND RESULTS.—The Secretary shall—

''(1) evaluate the demonstration projects funded under this section; and

''(2) on an annual basis—

''(A) publish and disseminate the results of such evaluation on as wide a basis as is practicable; and

''(B) submit to the appropriate committees of Congress the results of such evaluation.

''(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

''(1) $30,000,000 for fiscal year 2008; and

''(2) such sums as necessary for fiscal years 2009 through 2012.

''SEC. 1117. PRIVACY PROTECTIONS.

''Except to the extent inconsistent with this part, the provision of information pursuant to sections 1112 through 1116, and any subsequent transfer of such information in accordance with those sections, are subject to any requirement that would otherwise apply under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996.''.

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