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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

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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 2007''.

SEC. 2. FINDINGS.

Congress finds the following:

(1) Each year more than 4,000,000 babies born in the United States are screened by State and private laboratories to detect some conditions that may threaten their long-term health.

(2) However, there is a lack of uniformity in the number of conditions for which newborns are screened throughout the United States. While a newborn may be screened and treated for a debilitating condition in one State, in another State, the condition may go undetected and result in permanent disability or even death.

(3) Approximately 4,000 infants born each year are diagnosed with these detectable and treatable disorders. If diagnosed early, these conditions can be successfully managed or treated to prevent severe and often lifelong health consequences.

(4) In 2004, the American College of Medical Genetics (ACMG) completed a report commissioned by the Department of Health and Human Services which recommended that every baby born in the United States be screened for 29 specific disorders, including certain metabolic conditions and hearing deficiencies.

(5) Currently only 11 States and the District of Columbia require infants to be screened for all 29 of these recommended disorders.

(6) Continuity, especially during a public health emergency, plays a critical role in the screening, diagnosis, referral, and treatment of these disorders. Currently there is no national contingency plan for maintaining continuity of newborn screening systems following a public health emergency.

SEC. 3. AMENDMENT TO TITLE III OF THE PUBLIC HEALTH SERVICE ACT.

Part Q of title III of the Public Health Service Act (42 U.S.C. 280h et seq.) is amended by adding at the end the following:

"SEC. 399Z–1. NEWBORN SCREENING.

''(a) AUTHORIZATION OF GRANT PROGRAMS.—From funds appropriated under subsection (h), 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 to assist in providing health care profes-

sionals and newborn screening laboratory personnel with—

''(1) education in newborn screening; and

''(2) training in—

''(A) relevant and new technologies in newborn screening; and

''(B) congenital, genetic, and metabolic disorders.

''(b) APPLICATION.—An eligible entity that desires to receive a grant under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.

''(c) SELECTION OF GRANT RECIPIENTS.—

''(1) IN GENERAL.—Not later than 120 days after receiving an application under subsection (b), the Secretary, after considering the approval factors under paragraph (2), shall determine whether to award the eligible entity a grant under this section.

''(2) APPROVAL FACTORS.—

''(A) REQUIREMENTS FOR APPROVAL.—An application submitted under subsection (b) may not be approved by the Secretary unless the application contains assurances that the eligible entity—

"(i) will use grant funds only for the purposes specified in the approved application and in accordance with the requirements of this section; and

"(ii) will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the eligible entity under the grant.

"(B) EXISTING PROGRAMS.—Prior to awarding a grant under this section, the Secretary shall—

"(i) conduct an assessment of existing educational resources and training programs with respect to newborn screening; and

"(ii) take all necessary steps to minimize the duplication of the resources and programs described in clause (i) and ensure that funding under this section will supplement, not supplant, existing funding for such activities.

"(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.

''(e) USE OF GRANT FUNDS.—An eligible entity that receives a grant under subsection (a)(1) may use the grant funds to work with appropriate medical schools, nursing schools, schools of public health, schools of genetic counseling, internal education programs in State agencies, nongovernmental organizations, and professional organizations and societies to develop and deliver education and training programs that include—

''(1) continuing medical education programs for health care professionals and newborn screening laboratory personnel in newborn screening;

''(2) education, technical assistance, and training on new discoveries in newborn screening and the use of any related technology;

''(3) models to evaluate the prevalence of, and assess and communicate the risks of, congenital conditions, including the prevalence and risk of some of these conditions based on family history;

''(4) models to communicate effectively with parents and families about—

''(A) the process and benefits of newborn screening and the meaning of screening results,

including the possibility of false positive findings;

"(B) how to use information gathered from newborn screening;

"(C) the right of refusal of newborn screening, if applicable; and

"(D) the potential need for followup care after newborns are screened;

"(5) information and resources on coordinated systems of followup care after newborns are screened;

"(6) information on the disorders for which States require and offer newborn screening and options for newborn screening relating to conditions in addition to such disorders;

"(7) information on additional newborn screening that may not be required by the State, but that may be available from other sources; and

"(8) other items to carry out the purpose described in subsection (a)(1) as determined appropriate by the Secretary.

"(f) REPORTS TO CONGRESS.—

"(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall submit to the relevant committees of Congress reports—

''(A) evaluating the effectiveness and the impact of the grants awarded under this section—

''(i) in promoting newborn screening education, resources, and training for health care professionals;

''(ii) on the successful diagnosis and treatment of congenital, genetic, and metabolic disorders; and

''(iii) on the continued development of coordinated systems of followup care after newborns are screened;

''(B) describing and evaluating the effectiveness of the activities carried out with grant funds received under this section; and

''(C) that include recommendations for Federal, State, and local actions to support—

''(i) education and training in newborn screening; and

''(ii) followup care after newborns are screened.

''(2) TIMING OF REPORTS.—The Secretary shall submit—

''(A) an interim report that includes the information described in paragraph (1), not

later than 30 months after the date on which the first grant funds are awarded under this section; and

''(B) a subsequent report that includes the information described in paragraph (1), not later than 60 months after the date on which the first grant funds are awarded under this section.

''(g) DEFINITION OF 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) an Indian tribe or a hospital or outpatient health care facility of the Indian Health Service; or

''(5) other entities with appropriate expertise in newborn screening, as determined by the Secretary.

''(h) 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 may be necessary for each of fiscal years 2009 through 2012.''.

SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

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

(1) in subsection (c)(2)—

(A) in subparagraph (E), by striking ''and'' after the semicolon;

(B) by redesignating subparagraph (F) as subparagraph (G); and

(C) by inserting after subparagraph (E) the following:

''(F) an assurance that the entity has adopted and implemented, is in the process of adopting and implementing, or will use grant amounts received under this section to adopt and implement the guidelines and recommendations of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111 (referred to in this section as 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 and the reporting of results; and''; and

(2) in subsection (i), by striking ''such sums'' and all that follows through the period at the end and inserting ''$15,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012.''.

SEC. 5. 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 and such sums as may be necessary for each of the fiscal years 2009 through 2012.''.

SEC. 6. 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) in paragraph (1), by inserting ''and grants awarded under section 399Z–1'' before the semicolon;

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

(C) in paragraph (2), by striking ''and'' after the semicolon;

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

''(3) make systematic evidence-based and peer-reviewed recommendations that include the heritable disorders 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 program expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

''(5) consider ways to ensure that 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'';

(E) 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) followup 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;

"(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, 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);

(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 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 2007 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 Advi-

sory Committee pursuant to this subsection, including the justification for the determination.

''(e) ANNUAL REPORT.—Not later than 2 years after the date of enactment of the Newborn Screening Saves Lives Act of 2007, and each fiscal year thereafter, the Advisory Committee shall—

''(1) publish a report on peer-reviewed newborn screening guidelines in the United States;

''(2) submit such report to the appropriate committees of Congress, the Secretary, 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 2007.

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

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

''(2) such sums as may be necessary for each of the fiscal years 2009 through 2012.''.

SEC. 7. 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 individuals wanting to have children and expectant families; and

''(3) develop and 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, nonprofit, and other Internet websites of laboratories as determined appropriate by the Secretary 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 2007; 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—

"(1) $2,500,000 for fiscal year 2008; and

"(2) such sums as may be necessary for each of the fiscal years 2009 through 2012.".

SEC. 8. 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 7, 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) population-based pilot testing for new screening tools for evaluating use on a mass scale.

"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012.

"SEC. 1114. SURVEILLANCE PROGRAMS FOR HERITABLE DISORDERS SCREENING.

''(a) IN GENERAL.—The Secretary, acting through an Interagency Group consisting of the Director of the Agency for Healthcare Research and Quality, the Director of the Centers for Disease Control and Prevention, the Administrator, and the Director of the National Institutes of Health, shall build upon existing activities and infrastructure to carry out programs—

''(1) to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders;

''(2) to operate regional centers for the conduct of applied epidemiological research on effective interventions for such disorders for the prevention of poor health outcomes;

''(3) to provide information and education to the public on effective interventions for the prevention of poor health outcomes resulting from such disorders; and

''(4) to conduct research on and to promote the prevention of poor health outcomes resulting from

such disorders, and secondary health conditions among individuals with such disorders.

''(b) GRANTS AND CONTRACTS.—

''(1) IN GENERAL.—In carrying out subsection (a), the Secretary may make grants to and enter into contracts with public and nonprofit private entities.

''(2) SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS.—

''(A) IN GENERAL.—Upon the request of a recipient of an award of a grant or contract under paragraph (1), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the recipient in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

''(B) REDUCTION.—With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or

services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

''(3) APPLICATION FOR AWARD.—The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.

''(c) REPORTS TO CONGRESS.—

''(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall submit to the relevant committees of Congress reports—

''(A) containing information under paragraph (1) that is specific to various racial, ethnic, and socioeconomic groups;

''(B) containing an assessment of the extent to which various approaches of preventing heritable disorders and secondary health conditions among individuals with such disorders have been effective;

"(C) describing the activities carried out under this section;

"(D) containing information on the incidence and prevalence of individuals living with heritable disorders, information on the health status of individuals with such disorders including the extent to which such disorders have contributed to the incidence and prevalence of infant mortality, information on any health disparities experienced by such individuals, and recommendations for improving the health and wellness and quality of life of such individuals;

"(E) containing a summary of recommendations from all heritable disorders research conferences sponsored by the Centers for Disease Control and Prevention; and

"(F) containing any recommendations of the Secretary regarding this section.

"(2) TIMING OF REPORTS.—The Secretary shall submit—

"(A) an interim report that includes the information described in paragraph (1), not later than 30 months after the date on which the first grant funds are awarded under this section; and

''(B) a subsequent report that includes the information described in paragraph 1, not later than 60 months after the date on which the first grant funds are awarded under this section.

''(d) APPLICABILITY OF PRIVACY LAWS.—The provisions of this section shall be subject to the requirements of section 552a of title 5, United States Code. All Federal laws relating to the privacy of information shall apply to the data and information that is collected under this section.

''(e) COORDINATION.—

''(1) IN GENERAL.—In carrying out this section, the Secretary shall coordinate, to the extent practicable, programs under this section with programs on birth defects and developmental disabilities authorized under section 317C.

''(2) PRIORITY IN GRANTS AND CONTRACTS.—In making grants and contracts under this section, the Secretary shall give priority to entities that demonstrate the ability to coordinate activities under a grant or contract made under this section with existing birth defects surveillance activities.

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

to be appropriated $15,000,000 for fiscal year 2008 and such sums as may be necessary for each of the fiscal years 2009 through 2012.''.

SEC. 9. GRANTS.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.), as amended by section 8, is further amended by adding at the end the following:

''SEC. 1115. GRANTS.

''(a) AUTHORIZATION OF GRANT PROGRAM.—

''(1) IN GENERAL.—From funds appropriated under subsection (h), the Secretary, acting through the Administrator and in consultation with the Advisory Committee, shall award grants to eligible entities to—

''(A) enable such entities to develop and deliver educational programs about newborn screening to parents, families, and patient advocacy and support groups, such educational materials accompanying such educational programs to be provided at appropriate literacy levels; and

''(B) enable such entities to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.

''(2) AWARENESS OF THE AVAILABILITY OF PROGRAMS.—To the extent practicable, the Secretary shall make relevant health care providers aware of the availability of the educational programs supported pursuant to paragraph (1).

''(b) APPLICATION.—An eligible entity that desires to receive a grant under this section shall submit an application to the Secretary at such time, in such manner, and accompanied by such information as the Secretary may require.

''(c) SELECTION OF GRANT RECIPIENTS.—

''(1) IN GENERAL.—Not later than 120 days after receiving an application under subsection (b), the Secretary, after considering the approval factors under paragraph (2), shall determine whether to award the eligible entity a grant under this section.

''(2) APPROVAL FACTORS.—

''(A) REQUIREMENTS.—An application submitted under subsection (b) may not be approved by the Secretary unless the application contains assurances that the eligible entity—

''(i) will use grant funds only for the purposes specified in the approved application and in accordance with the requirements of this section; and

''(ii) will establish such fiscal control and fund accounting procedures as may be necessary to assure proper disbursement and accounting of Federal funds paid to the eligible entity under the grant.

''(B) EXISTING PROGRAMS.—Prior to awarding a grant under this section, the Secretary shall—

''(i) conduct an assessment of existing educational resources and training programs and coordinated systems of followup care with respect to newborn screening; and

''(ii) take all necessary steps to minimize the duplication of the resources and programs described in clause (i) and ensure that funding under this section will supplement, not supplant, existing funding for such activities.

''(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.

''(e) USE OF GRANT FUNDS.—

''(1) IN GENERAL.—An eligible entity that receives a grant under this section may use the grant funds—

''(A) for purposes of grants under subsection (a)(1)(A), to develop and deliver to parents, families, and patient advocacy and support groups, educational programs about newborn screening that include information on—

''(i) what newborn screening is and how it is performed;

''(ii) who performs newborn screening;

''(iii) where newborn screening is performed;

''(iv) the disorders for which the State requires newborns to be screened;

''(v) different options for newborn screening for disorders other than those included by the State in the mandated newborn screening program;

''(vi) the meaning of various screening results, including the possibility of false positive and false negative findings;

''(vii) the prevalence and risk of newborn disorders, including the increased risk

of disorders that may stem from family history;

''(viii) coordinated systems of followup care after newborns are screened; and

''(ix) other items to carry out the purpose described in subsection (a)(1) as determined appropriate by the Secretary; and

''(B) for purposes of grants under subsection (a)(1)(B), to—

''(i) expand on existing procedures and systems, where appropriate and available, for the timely reporting of newborn screening results to individuals, families, primary care physicians, and appropriate subspecialists such as in congenital, genetic, and metabolic disorders;

''(ii) coordinate ongoing followup treatment with individuals, families, primary care physicians, and appropriate subspecialists such as in congenital, genetic, and metabolic disorders after a newborn receives an indication of the presence or increased risk of a disorder on a screening test;

"(iii) ensure the seamless integration of confirmatory testing, tertiary care medical services, comprehensive genetic services including genetic counseling, and information about Food and Drug Administration-approved treatments as well as access to developing therapies by participation in approved clinical trials involving the primary health care of the infant;

"(iv) analyze data, if appropriate and available, collected from newborn screenings to identify populations at risk for disorders affecting newborns, examine and respond to health concerns, recognize and address relevant environmental, behavioral, socioeconomic, demographic, and other relevant risk factors;

"(v) collect, analyze and report data on the costs, benefits and effectiveness of such tests; and

"(vi) carry out such other activities as the Secretary may determine necessary.

"(f) REPORTS TO CONGRESS.—

"(1) IN GENERAL.—Subject to paragraph (2), the Secretary shall submit to the relevant committees of Congress reports—

"(A) evaluating the effectiveness and the impact of the grants awarded under this section—

"(i) in promoting newborn screening—

"(I) education and resources for families; and

"(II) education, resources, and training for health care professionals;

"(ii) on the successful diagnosis and treatment of congenital, genetic, and metabolic disorders; and

"(iii) on the continued development of coordinated systems of followup care after newborns are screened;

"(B) describing and evaluating the effectiveness of the activities carried out with grant funds received under this section; and

"(C) that include recommendations for Federal, State, and local actions to support—

"(i) education and training in newborn screening; and

''(ii) followup care after newborns are screened.

''(2) TIMING OF REPORTS.—The Secretary shall submit—

''(A) an interim report that includes the information described in paragraph (1), not later than 30 months after the date on which the first grant funds are awarded under this section; and

''(i) a subsequent report that includes the information described in paragraph (1), not later than 60 months after the date on which the first grant funds are awarded under this section.

''(g) 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) an Indian tribe or a hospital or outpatient health care facility of the Indian Health Service; or

''(5) other entities with appropriate expertise in newborn screening, as determined by the Secretary.

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

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

''(2) such sums as may be necessary for each of fiscal years 2009 through 2012.''.

SEC. 10. 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 9, is further amended by adding at the end the following:

''SEC. 1116. 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. 1117. HUNTER KELLY RESEARCH PROGRAM.

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

''(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, shall establish a research program (to be known as 'Hunter Kelly Newborn Screening Research Program') by expanding, carrying out, and coordinating research in—

''(A) identifying, developing, and testing the most promising new screening technologies, in order to improve already existing screening tests, which may include tests for Krabbe Dis-

ease and Insulin Dependent Diabetes Mellitus, and Turner Syndrome, increase the specificity of newborn screening, 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 and/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 designated by the Advisory Committee.

"(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) MONITORING AND RESULTS.—The Director shall—

''(1) monitor and report on the activities resulting from any funding distributed under this section; and

''(2) on an annual basis—

''(A) publish and disseminate the results of such monitoring on as wide a basis as is practicable, which may include incorporation of these results in other newborn screening reports and posting on the Internet Clearinghouse established under section 1112;

''(B) submit to the relevant committees of Congress the results of such evaluation, which may include incorporation of such results in other newborn screening reports being submitted to Congress.

''(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.

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

''(1) $7,000,000 for fiscal year 2008; and

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

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