

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1396) to authorize a major medical facility project to modernize inpatient wards at the Department of Veterans Affairs Medical Center in Atlanta, Georgia.

There being no objection, the Senate proceeded to consider the bill.

Mr. HARKIN. Mr. President, I ask unanimous consent that the bill be read a third time, passed, and the motion to reconsider be laid upon the table; that any statements be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 1396) was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 1396

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

**SECTION 1. AUTHORIZATION OF MAJOR MEDICAL FACILITY PROJECT, ATLANTA, GEORGIA.**

The Secretary of Veterans Affairs may carry out a major medical facility project for modernization of inpatient wards at the Department of Veterans Affairs Medical Center, Atlanta, Georgia, in an amount not to exceed \$20,534,000.

**ERNEST CHILDERS DEPARTMENT OF VETERANS AFFAIRS OUTPATIENT CLINIC**

Mr. HARKIN. Mr. President, I ask unanimous consent that the Committee on Veterans' Affairs be discharged from further consideration of S. 1585 and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1585) to designate the Department of Veterans Affairs Outpatient Clinic in Tulsa, Oklahoma, as the "Ernest Childers Department of Veterans Affairs Outpatient Clinic."

There being no objection, the Senate proceeded to consider the bill.

Mr. HARKIN. Mr. President, I ask unanimous consent that the bill be read a third time, passed, and the motion to reconsider be laid upon the table; that any statements relating to the bill be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 1585) was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 1585

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

**SECTION 1. DESIGNATION OF ERNEST CHILDERS DEPARTMENT OF VETERANS AFFAIRS OUTPATIENT CLINIC.**

(a) DESIGNATION.—The Department of Veterans Affairs Outpatient Clinic in Tulsa, Oklahoma, shall be known and designated as the "Ernest Childers Department of Veterans Affairs Outpatient Clinic".

(b) REFERENCES.—Any reference in any law, regulation, map, document, record, or

other paper of the United States to the outpatient clinic referred to in subsection (a) shall be considered to be a reference to the "Ernest Childers Department of Veterans Affairs Outpatient Clinic".

**LIEUTENANT COLONEL CLEMENT C. VAN WAGONER DEPARTMENT OF VETERANS AFFAIRS CLINIC**

Mr. HARKIN. Mr. President, I ask unanimous consent that the Veterans' Affairs Committee be discharged from further consideration of S. 2339, and that the Senate then proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 2339) to designate the Department of Veterans Affairs clinic in Alpena, Michigan, as the "Lieutenant Colonel Clement C. Van Wagoner Department of Veterans Affairs Clinic."

There being no objection, the Senate proceeded to consider the bill.

Mr. HARKIN. I ask unanimous consent that the bill be read a third time, passed, the motions to reconsider be laid upon the table, and any statements be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 2339) was ordered to be engrossed for a third reading, was read the third time and passed, as follows:

S. 2339

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

**SECTION 1. DESIGNATION OF LIEUTENANT COLONEL CLEMENT C. VAN WAGONER DEPARTMENT OF VETERANS AFFAIRS CLINIC.**

(a) DESIGNATION.—The Department of Veterans Affairs clinic located in Alpena, Michigan, shall after the date of the enactment of this Act be known and designated as the "Lieutenant Colonel Clement C. Van Wagoner Department of Veterans Affairs Clinic".

(b) REFERENCES.—Any reference in any law, regulation, map, document, record, or other paper of the United States to the clinic referred to in subsection (a) shall be considered to be a reference to the Lieutenant Colonel Clement C. Van Wagoner Department of Veterans Affairs Clinic.

**NEWBORN SCREENING SAVES LIVES ACT OF 2007**

Mr. HARKIN. Mr. President, I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 522, S. 1858.

The PRESIDING OFFICER. The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1858) 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.

There being no objection, the Senate proceeded to consider the bill, which had been reported from the Committee on Health, Education, Labor and Pensions, with an amendment to strike all

after the enacting clause and insert in lieu thereof the following:

**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”;

(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) 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);

(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 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 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 2007, 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, 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, \$1,000,000 for fiscal year 2008, \$1,012,500 for fiscal year 2009, \$1,025,000 for fiscal year 2010, \$1,037,500 for fiscal year 2011, and \$1,050,000 for fiscal year 2012.”.

**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 Re-

sources 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 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, \$2,500,000 for fiscal year 2008, \$2,531,250 for fiscal year 2009, \$2,562,500 for fiscal year 2010, \$2,593,750 for fiscal year 2011, and \$2,625,000 for fiscal year 2012.”.

**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 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. 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 identify 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 or the National Institutes of Health; 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) 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.

“(e) **AUTHORIZATION OF APPROPRIATIONS.**—For the purpose of carrying out this section, there are authorized to be appropriated \$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. 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 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 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.”

Mr. HARKIN. I ask unanimous consent that the amendment at the desk be considered and agreed to, the committee reported substitute, as amended, be agreed to, the bill as amended be read a third time, passed, the motion to reconsider be laid on the table, and any statements be printed in the RECORD.

The PRESIDING OFFICER. Without objection, it is so ordered.

The amendment (No. 3852) was agreed to.

(The amendment is printed in today’s RECORD under “Text of Amendments.”)

The committee amendment in the nature of a substitute, as amended, was agreed to.

The bill (S. 1858), as amended, was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 1858

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 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;”;

(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;”;

(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 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 2007, 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 2007.

“(g) **AUTHORIZATION OF APPROPRIATIONS.**—There are authorized to be appropriated to carry out this section, \$1,000,000 for fiscal year 2008, \$1,012,500 for fiscal year 2009, \$1,025,000 for fiscal year 2010, \$1,037,500 for fiscal year 2011, and \$1,050,000 for fiscal year 2012.”.

### **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 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, \$2,500,000 for fiscal year 2008, \$2,531,250 for fiscal year 2009, \$2,562,500 for fiscal year 2010, \$2,593,750 for fiscal year 2011, and \$2,625,000 for fiscal year 2012.”

**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 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. 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 2008, \$1,012,500 for fiscal year 2009, \$1,025,000 for fiscal year 2010, \$1,037,500 for fiscal year 2011, and \$1,050,000 for fiscal year 2012.”

**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 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 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.”