S. 634

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 SENATE OF THE UNITED STATES

February 15, 2007

Mr. Dodd (for himself and Mr. Hatch) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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.

- 1 Be it enacted by the Senate and House of Representa-
- 2 tives of the United States of America in Congress assembled,
- 3 SECTION 1. SHORT TITLE.
- 4 This Act may be cited as the "Newborn Screening
- 5 Saves Lives Act of 2007".

1 SEC. 2. FINDINGS.

- 2 Congress finds the following:
- 3 (1) Each year more than 4,000,000 babies born 4 in the United States are screened by State and pri-5 vate laboratories to detect some conditions that may 6 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.

- 1 (5) Currently only 11 States and the District of
 2 Columbia require infants to be screened for all 29 of
 3 these recommended disorders.
 4 (6) Continuity aspecially during a public health
- (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.

10 SEC. 3. AMENDMENT TO TITLE III OF THE PUBLIC HEALTH

- 11 SERVICE ACT.
- Part Q of title III of the Public Health Service Act 13 (42 U.S.C. 280h et seq.) is amended by adding at the end 14 the following:
- 15 "SEC. 399AA. NEWBORN SCREENING.
- 16 "(a) Authorization of Grant Programs.—
- 17 "(1) Grants to assist health care profes-18 SIONALS.—From funds appropriated under sub-19 section (h), the Secretary, acting through the Asso-20 ciate Administrator of the Maternal and Child 21 Health Bureau of the Health Resources and Services 22 Administration (referred to in this section as the 23 'Associate Administrator') and in consultation with 24 the Advisory Committee on Heritable Disorders in 25 Newborns and Children (referred to in this section

| 1 | as the 'Advisory Committee'), shall award grants to |
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| 2 | eligible entities to enable such entities to assist in |
| 3 | providing health care professionals and newborn |
| 4 | screening laboratory personnel with— |
| 5 | "(A) education in newborn screening; and |
| 6 | "(B) training in— |
| 7 | "(i) relevant and new technologies in |
| 8 | newborn screening; and |
| 9 | "(ii) congenital, genetic, and meta- |
| 10 | bolic disorders. |
| 11 | "(2) Grants to assist families.— |
| 12 | "(A) In general.—From funds appro- |
| 13 | priated under subsection (h), the Secretary, act- |
| 14 | ing through the Associate Administrator and in |
| 15 | consultation with the Advisory Committee, shall |
| 16 | award grants to eligible entities to enable such |
| 17 | entities to develop and deliver educational pro- |
| 18 | grams about newborn screening to parents, |
| 19 | families, and patient advocacy and support |
| 20 | groups. The educational materials accom- |
| 21 | panying such educational programs shall be |
| 22 | provided at appropriate literacy levels. |
| 23 | "(B) Awareness of the availability |
| 24 | OF PROGRAMS.—To the extent practicable, the |
| 25 | Secretary shall make relevant health care pro- |

viders aware of the availability of the educational programs supported pursuant to subparagraph (A).

"(3) Grants for quality newborn screenIng followup.—From funds appropriated under
subsection (h), the Secretary, acting through the Associate Administrator and in consultation with the
Advisory Committee, shall award grants to eligible
entities to enable such entities to establish, maintain, and operate a system to assess and coordinate
treatment relating to 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.

18 "(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.

24 "(2) APPROVAL FACTORS.—

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| 1 | "(A) Requirements for approval.—An |
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| 2 | application submitted under subsection (b) may |
| 3 | not be approved by the Secretary unless the ap- |
| 4 | plication contains assurances that the eligible |
| 5 | entity— |
| 6 | "(i) will use grant funds only for the |
| 7 | purposes specified in the approved applica- |
| 8 | tion and in accordance with the require- |
| 9 | ments of this section; and |
| 10 | "(ii) will establish such fiscal control |
| 11 | and fund accounting procedures as may be |
| 12 | necessary to assure proper disbursement |
| 13 | and accounting of Federal funds paid to |
| 14 | the eligible entity under the grant. |
| 15 | "(B) Existing programs.—Prior to |
| 16 | awarding a grant under this section, the Sec- |
| 17 | retary shall— |
| 18 | "(i) conduct an assessment of existing |
| 19 | educational resources and training pro- |
| 20 | grams and coordinated systems of followup |
| 21 | care with respect to newborn screening; |
| 22 | and |
| 23 | "(ii) take all necessary steps to mini- |
| 24 | mize the duplication of the resources and |
| 25 | programs described in clause (i). |

| 1 | "(d) COORDINATION.—The Secretary shall take all |
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| 2 | necessary steps to coordinate programs funded with |
| 3 | grants received under this section. |
| 4 | "(e) USE OF GRANT FUNDS.— |
| 5 | "(1) Grants to assist health care profes- |
| 6 | SIONALS.—An eligible entity that receives a grant |
| 7 | under subsection (a)(1) may use the grant funds to |
| 8 | work with appropriate medical schools, nursing |
| 9 | schools, schools of public health, schools of genetic |
| 10 | counseling, internal education programs in State |
| 11 | agencies, nongovernmental organizations, and pro- |
| 12 | fessional organizations and societies to develop and |
| 13 | deliver education and training programs that in- |
| 14 | clude— |
| 15 | "(A) continuing medical education pro- |
| 16 | grams for health care professionals and new- |
| 17 | born screening laboratory personnel in newborn |
| 18 | screening; |
| 19 | "(B) education, technical assistance, and |
| 20 | training on new discoveries in newborn screen- |
| 21 | ing and the use of any related technology; |
| 22 | "(C) models to evaluate the prevalence of, |
| 23 | and assess and communicate the risks of, con- |
| 24 | genital conditions, including the prevalence and |

| 1 | risk of some of these conditions based on family |
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| 2 | history; |
| 3 | "(D) models to communicate effectively |
| 4 | with parents and families about— |
| 5 | "(i) the process and benefits of new- |
| 6 | born screening; |
| 7 | "(ii) how to use information gathered |
| 8 | from newborn screening; |
| 9 | "(iii) the meaning of screening re- |
| 10 | sults, including the possibility of false posi- |
| 11 | tive findings; |
| 12 | "(iv) the right of refusal of newborn |
| 13 | screening, if applicable; and |
| 14 | "(v) the potential need for followup |
| 15 | care after newborns are screened; |
| 16 | "(E) information and resources on coordi- |
| 17 | nated systems of followup care after newborns |
| 18 | are screened; |
| 19 | "(F) information on the disorders for |
| 20 | which States require and offer newborn screen- |
| 21 | ing and options for newborn screening relating |
| 22 | to conditions in addition to such disorders; |
| 23 | "(G) information on additional newborn |
| 24 | screening that may not be required by the |

| 1 | State, but that may be available from other |
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| 2 | sources; and |
| 3 | "(H) other items to carry out the purpose |
| 4 | described in subsection (a)(1) as determined ap- |
| 5 | propriate by the Secretary. |
| 6 | "(2) Grants to assist families.—An eligible |
| 7 | entity that receives a grant under subsection (a)(2) |
| 8 | may use the grant funds to develop and deliver to |
| 9 | parents, families, and patient advocacy and support |
| 10 | groups, educational programs about newborn screen- |
| 11 | ing that include information on— |
| 12 | "(A) what newborn screening is; |
| 13 | "(B) how newborn screening is performed; |
| 14 | "(C) who performs newborn screening; |
| 15 | "(D) where newborn screening is per- |
| 16 | formed; |
| 17 | "(E) the disorders for which the State re- |
| 18 | quires newborns to be screened; |
| 19 | "(F) different options for newborn screen- |
| 20 | ing for disorders other than those included by |
| 21 | the State in the mandated newborn screening |
| 22 | program; |
| 23 | "(G) the meaning of various screening re- |
| 24 | sults, including the possibility of false positive |
| 25 | and false negative findings; |

| 1 | "(H) the prevalence and risk of newborn |
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| 2 | disorders, including the increased risk of dis- |
| 3 | orders that may stem from family history; |
| 4 | "(I) coordinated systems of followup care |
| 5 | after newborns are screened; and |
| 6 | "(J) other items to carry out the purpose |
| 7 | described in subsection (a)(2) as determined ap- |
| 8 | propriate by the Secretary. |
| 9 | "(3) Grants for quality newborn screen- |
| 10 | ING FOLLOWUP.—An eligible entity that receives a |
| 11 | grant under subsection (a)(3) shall use the grant |
| 12 | funds to— |
| 13 | "(A) expand on existing procedures and |
| 14 | systems, where appropriate and available, for |
| 15 | the timely reporting of newborn screening re- |
| 16 | sults to individuals, families, primary care phy- |
| 17 | sicians, and subspecialists in congenital, ge- |
| 18 | netic, and metabolic disorders; |
| 19 | "(B) coordinate ongoing followup treat- |
| 20 | ment with individuals, families, primary care |
| 21 | physicians, and subspecialists in congenital, ge- |
| 22 | netic, and metabolic disorders after a newborn |
| 23 | receives an indication of the presence or in- |
| 24 | creased rick of a disorder on a screening test. |

| 1 | "(C) ensure the seamless integration of |
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| 2 | confirmatory testing, tertiary care medical serv- |
| 3 | ices, comprehensive genetic services including |
| 4 | genetic counseling, and information about ac- |
| 5 | cess to developing therapies by participation in |
| 6 | approved clinical trials involving the primary |
| 7 | health care of the infant; |
| 8 | "(D) analyze data, if appropriate and |
| 9 | available, collected from newborn screenings to |
| 10 | identify populations at risk for disorders affect- |
| 11 | ing newborns, examine and respond to health |
| 12 | concerns, recognize and address relevant envi- |
| 13 | ronmental, behavioral, socioeconomic, demo- |
| 14 | graphic, and other relevant risk factors; and |
| 15 | "(E) carry out such other activities as the |
| 16 | Secretary may determine necessary. |
| 17 | "(f) Reports to Congress.— |
| 18 | "(1) In general.—Subject to paragraph (2), |
| 19 | the Secretary shall submit to the appropriate com- |
| 20 | mittees of Congress reports— |
| 21 | "(A) evaluating the effectiveness and the |
| 22 | impact of the grants awarded under this sec- |
| 23 | tion— |
| 24 | "(i) in promoting newborn screen- |
| 25 | ing— |

| 1 | "(I) education and resources for |
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| 2 | families; and |
| 3 | "(II) education, resources, and |
| 4 | training for health care professionals; |
| 5 | "(ii) on the successful diagnosis and |
| 6 | treatment of congenital, genetic, and meta- |
| 7 | bolic disorders; and |
| 8 | "(iii) on the continued development of |
| 9 | coordinated systems of followup care after |
| 10 | newborns are screened; |
| 11 | "(B) describing and evaluating the effec- |
| 12 | tiveness of the activities carried out with grant |
| 13 | funds received under this section; and |
| 14 | "(C) that include recommendations for |
| 15 | Federal actions to support— |
| 16 | "(i) education and training in new- |
| 17 | born screening; and |
| 18 | "(ii) followup care after newborns are |
| 19 | screened. |
| 20 | "(2) Timing of Reports.—The Secretary shall |
| 21 | submit— |
| 22 | "(A) an interim report that includes the |
| 23 | information described in paragraph (1), not |
| 24 | later than 30 months after the date on which |

| 1 | the first grant funds are awarded under this |
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| 2 | section; and |
| 3 | "(B) a subsequent report that includes the |
| 4 | information described in paragraph (1), not |
| 5 | later than 60 months after the date on which |
| 6 | the first grant funds are awarded under this |
| 7 | section. |
| 8 | "(g) Definition of Eligible Entity.—In this sec- |
| 9 | tion, the term 'eligible entity' means— |
| 10 | "(1) a State or a political subdivision of a |
| 11 | State; |
| 12 | "(2) a consortium of 2 or more States or polit- |
| 13 | ical subdivisions of States; |
| 14 | "(3) a territory; |
| 15 | "(4) an Indian tribe or a hospital or outpatient |
| 16 | health care facility of the Indian Health Service; or |
| 17 | "(5) a nongovernmental organization with ap- |
| 18 | propriate expertise in newborn screening, as deter- |
| 19 | mined by the Secretary. |
| 20 | "(h) National Contingency Plan for Newborn |
| 21 | Screening.— |
| 22 | "(1) In general.—Not later than 180 days |
| 23 | after the date of enactment of this section, the Sec- |
| 24 | retary, acting through the Director of the Centers |
| 25 | for Disease Control and Prevention and in consulta- |

| 1 | tion with the Associate Administrator, shall develop |
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| 2 | a national contingency plan for newborn screening |
| 3 | for use in the event of a public health emergency. |
| 4 | "(2) Requirements.—The contingency plan |
| 5 | developed under paragraph (1) shall include a plan |
| 6 | for— |
| 7 | "(A) the collection and transport of speci- |
| 8 | mens; |
| 9 | "(B) the shipment of specimens to State |
| 10 | newborn screening laboratories; |
| 11 | "(C) the processing of specimens; |
| 12 | "(D) the reporting of screening results to |
| 13 | physicians and families; |
| 14 | "(E) the diagnostic confirmation of posi- |
| 15 | tive screening results; |
| 16 | "(F) ensuring the availability of treatment |
| 17 | and management resources; |
| 18 | "(G) educating families about newborn |
| 19 | screening; and |
| 20 | "(H) carrying out other activities deter- |
| 21 | mined appropriate by the Secretary. |
| 22 | "(i) AUTHORIZATION OF APPROPRIATIONS.—There |
| 23 | are authorized to be appropriated to carry out this sec- |
| 24 | tion— |
| 25 | "(1) \$15,000,000 for fiscal year 2008; and |

| 1 | "(2) such sums as may be necessary for each |
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| 2 | of fiscal years 2009 through 2012.". |
| 3 | SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR |
| 4 | HERITABLE DISORDERS. |
| 5 | Section 1109 of the Public Health Service Act (42 |
| 6 | U.S.C. 300b–8) is amended— |
| 7 | (1) in subsection $(c)(2)$ — |
| 8 | (A) in subparagraph (E), by striking |
| 9 | "and" after the semicolon; |
| 10 | (B) by redesignating subparagraph (F) as |
| 11 | subparagraph (G); and |
| 12 | (C) by inserting after subparagraph (E) |
| 13 | the following: |
| 14 | "(F) an assurance that the entity has |
| 15 | adopted and implemented, is in the process of |
| 16 | adopting and implementing, or will use grant |
| 17 | amounts received under this section to adopt |
| 18 | and implement the guidelines and recommenda- |
| 19 | tions of the Advisory Committee on Heritable |
| 20 | Disorders in Newborns and Children established |
| 21 | under section 1111 (referred to in this section |
| 22 | as the 'Advisory Committee') that are adopted |
| 23 | by the Secretary and in effect at the time the |
| 24 | grant is awarded or renewed under this section, |
| 25 | which shall include the screening of each new- |

| 1 | born for the heritable disorders recommended |
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| 2 | by the Advisory Committee and adopted by the |
| 3 | Secretary and the reporting of results; and"; |
| 4 | and |
| 5 | (2) in subsection (i), by striking "such sums" |
| 6 | and all that follows through the period at the end |
| 7 | and inserting "\$25,000,000 for fiscal year 2008 and |
| 8 | such sums as may be necessary for each of the fiscal |
| 9 | years 2009 through 2012.". |
| 10 | SEC. 5. EVALUATING THE EFFECTIVENESS OF NEWBORN- |
| 11 | AND CHILD-SCREENING PROGRAMS. |
| 12 | Section 1110 of the Public Health Service Act (42 |
| 13 | U.S.C. 300b-9) is amended by adding at the end the fol- |
| 14 | lowing: |
| 15 | "(d) Authorization of Appropriations.—There |
| 16 | are authorized to be appropriated to carry out this section |
| 17 | \$5,000,000 for fiscal year 2008 and such sums as may |
| 18 | be necessary for each of the fiscal years 2009 through |
| 19 | 2012.". |
| 20 | SEC. 6. ADVISORY COMMITTEE ON HERITABLE DISORDERS |
| 21 | IN NEWBORNS AND CHILDREN. |
| 22 | Section 1111 of the Public Health Service Act (42 |
| 23 | U.S.C. 300b–10) is amended— |
| 24 | (1) in subsection (b)— |

| 1 | (A) by redesignating paragraph (3) as |
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| 2 | paragraph (5); |
| 3 | (B) in paragraph (2), by striking "and" |
| 4 | after the semicolon; |
| 5 | (C) by inserting after paragraph (2) the |
| 6 | following: |
| 7 | "(3) recommend a uniform screening panel for |
| 8 | newborn screening programs that includes the heri- |
| 9 | table disorders for which all newborns should be |
| 10 | screened, including secondary conditions that may be |
| 11 | identified as a result of the laboratory methods used |
| 12 | for screening; |
| 13 | "(4) develop a model decision-matrix for new- |
| 14 | born screening program expansion, and periodically |
| 15 | update the recommended uniform screening panel |
| 16 | described in paragraph (3) based on such decision- |
| 17 | matrix; and"; and |
| 18 | (D) in paragraph (5) (as redesignated by |
| 19 | subparagraph (A)), by striking the period at the |
| 20 | end and inserting ", including recommenda- |
| 21 | tions, advice, or information dealing with— |
| 22 | "(A) followup activities, including those |
| 23 | necessary to achieve rapid diagnosis in the |
| 24 | short term, and those that ascertain long-term |

| 1 | case management outcomes and appropriate ac- |
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| 2 | cess to related services; |
| 3 | "(B) diagnostic and other technology used |
| 4 | in screening; |
| 5 | "(C) the availability and reporting of test- |
| 6 | ing for conditions for which there is no existing |
| 7 | treatment; |
| 8 | "(D) minimum standards and related poli- |
| 9 | cies and procedures for State newborn screen- |
| 10 | ing programs; |
| 11 | "(E) quality assurance, oversight, and |
| 12 | evaluation of State newborn screening pro- |
| 13 | grams; |
| 14 | "(F) data collection for assessment of new- |
| 15 | born screening programs; |
| 16 | "(G) public and provider awareness and |
| 17 | education; |
| 18 | "(H) language and terminology used by |
| 19 | State newborn screening programs; |
| 20 | "(I) confirmatory testing and verification |
| 21 | of positive results; and |
| 22 | "(J) harmonization of laboratory defini- |
| 23 | tions for results that are within the expected |
| 24 | range and results that are outside of the ex- |
| 25 | pected range."; and |

| 1 | (2) by adding at the end the following: |
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| 2 | "(d) Decision on Recommendations.— |
| 3 | "(1) In general.—Not later than 180 days |
| 4 | after the Advisory Committee issues a recommenda- |
| 5 | tion pursuant to this section, the Secretary shall |
| 6 | adopt or reject such recommendation. |
| 7 | "(2) Pending recommendations.—The Sec- |
| 8 | retary shall adopt or reject any recommendation |
| 9 | issued by the Advisory Committee that is pending on |
| 10 | the date of enactment of the Newborn Screening |
| 11 | Saves Lives Act of 2007 by not later than 180 days |
| 12 | after the date of enactment of such Act. |
| 13 | "(3) Determinations to be made public.— |
| 14 | The Secretary shall publicize any determination on |
| 15 | adopting or rejecting a recommendation of the Advi- |
| 16 | sory Committee pursuant to this subsection, includ- |
| 17 | ing the justification for the determination. |
| 18 | "(e) Continuation of Operation of Com- |
| 19 | MITTEE.—Notwithstanding section 14 of the Federal Ad- |
| 20 | visory Committee Act (5 U.S.C. App.), the Advisory Com- |
| 21 | mittee shall continue to operate during the 5-year period |
| 22 | beginning on the date of enactment of the Newborn |
| 23 | Screening Saves Lives Act of 2007.". |

1 SEC. 7. LABORATORY QUALITY AND SURVEILLANCE.

- 2 Part A of title XI of the Public Health Service Act
- 3 (42 U.S.C. 300b-1 et seq.) is amended by adding at the
- 4 end the following:

5 "SEC. 1112. LABORATORY QUALITY.

- 6 "(a) IN GENERAL.—The Secretary, acting through
- 7 the Director of the Centers for Disease Control and Pre-
- 8 vention and in consultation with the Advisory Committee
- 9 on Heritable Disorders in Newborns and Children estab-
- 10 lished under section 1111, shall provide for—
- 11 "(1) quality assurance for laboratories involved
- in screening newborns and children for heritable dis-
- orders, including quality assurance for newborn-
- screening tests, performance evaluation services, and
- technical assistance and technology transfer to new-
- born screening laboratories to ensure analytic valid-
- ity and utility of screening tests; and
- 18 "(2) population-based pilot testing for new
- screening tools for evaluating use on a mass scale.
- 20 "(b) AUTHORIZATION OF APPROPRIATIONS.—For the
- 21 purpose of carrying out this section, there are authorized
- 22 to be appropriated \$5,000,000 for fiscal year 2008 and
- 23 such sums as may be necessary for each of the fiscal years
- 24 2009 through 2012.

| 1 | "SEC. 1113. SURVEILLANCE PROGRAMS FOR HERITABLE |
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| 2 | DISORDERS SCREENING. |
| 3 | "(a) In General.—The Secretary, acting through |
| 4 | the Director of the Centers for Disease Control and Pre- |
| 5 | vention, in consultation with the Associate Administrator |
| 6 | of the Maternal and Child Health Bureau of the Health |
| 7 | Resources and Services Administration, shall carry out |
| 8 | programs— |
| 9 | "(1) to collect, analyze, and make available data |
| 10 | on the heritable disorders recommended by the Advi- |
| 11 | sory Committee on Heritable Disorders in Newborns |
| 12 | and Children established under section 1111, includ- |
| 13 | ing data on the causes of such disorders and on the |
| 14 | incidence and prevalence of such disorders; |
| 15 | "(2) to operate regional centers for the conduct |
| 16 | of applied epidemiological research on the prevention |
| 17 | of such disorders; |
| 18 | "(3) to provide information and education to |
| 19 | the public on the prevention of such disorders; and |
| 20 | "(4) to conduct research on and to promote the |
| 21 | prevention of such disorders, and secondary health |
| 22 | conditions among individuals with such disorders. |
| 23 | "(b) Grants and Contracts.— |
| 24 | "(1) In general.—In carrying out subsection |
| 25 | (a), the Secretary may make grants to and enter |

1 into contracts with public and nonprofit private enti-2 ties.

"(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.

1 "(3) APPLICATION FOR AWARD.—The Secretary 2 may make an award of a grant or contract under 3 paragraph (1) only if an application for the award 4 is submitted to the Secretary and the application is 5 in such form, is made in such manner, and contains 6 such agreements, assurances, and information as the 7 Secretary determines to be necessary to carry out 8 the purposes for which the award is to be made. 9 "(c) BIENNIAL REPORT.—Not later than February 10 1 of fiscal year 2008 and of every second such year thereafter, the Secretary shall submit to the Committee on En-11 12 ergy and Commerce of the House of Representatives, and the Committee on Health, Education, Labor, and Pensions of the Senate, a report that, with respect to the pre-14 15 ceding 2 fiscal years— "(1) contains information regarding the inci-16 17 dence and prevalence of heritable disorders and the 18 health status of individuals with such disorders and 19 the extent to which such disorders have contributed 20 to the incidence and prevalence of infant mortality 21 and affected quality of life; 22 "(2) contains information under paragraph (1) 23 that is specific to various racial and ethnic groups 24 (including Hispanics, non-Hispanic whites, Blacks, 25 Native Americans, and Asian Americans);

| 1 | "(3) contains an assessment of the extent to |
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| 2 | which various approaches of preventing heritable dis- |
| 3 | orders and secondary health conditions among indi- |
| 4 | viduals with such disorders have been effective; |
| 5 | "(4) describes the activities carried out under |
| 6 | this section; |
| 7 | "(5) contains information on the incidence and |
| 8 | prevalence of individuals living with heritable dis- |
| 9 | orders, information on the health status of individ- |
| 10 | uals with such disorders, information on any health |
| 11 | disparities experienced by such individuals, and rec- |
| 12 | ommendations for improving the health and wellness |
| 13 | and quality of life of such individuals; |
| 14 | "(6) contains a summary of recommendations |
| 15 | from all heritable disorders research conferences |
| 16 | sponsored by the Centers for Disease Control and |
| 17 | Prevention; and |
| 18 | "(7) contains any recommendations of the Sec- |
| 19 | retary regarding this section. |
| | |

- "(d) APPLICABILITY OF PRIVACY LAWS.—The provi-21 sions of this section shall be subject to the requirements 22 of section 552a of title 5, United States Code. All Federal 23 laws relating to the privacy of information shall apply to 24 the data and information that is collected under this sec-
- 25 tion.

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"(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.".

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