

110TH CONGRESS
1ST SESSION

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.

7 (2) However, there is a lack of uniformity in
8 the number of conditions for which newborns are
9 screened throughout the United States. While a new-
10 born may be screened and treated for a debilitating
11 condition in one State, in another State, the condi-
12 tion may go undetected and result in permanent dis-
13 ability or even death.

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

19 (4) In 2004, the American College of Medical
20 Genetics (ACMG) completed a report commissioned
21 by the Department of Health and Human Services
22 which recommended that every baby born in the
23 United States be screened for 29 specific disorders,
24 including certain metabolic conditions and hearing
25 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, especially during a public health
5 emergency, plays a critical role in the screening, di-
6 agnosis, referral, and treatment of these disorders.
7 Currently there is no national contingency plan for
8 maintaining continuity of newborn screening systems
9 following a public health emergency.

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

12 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
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-

1 viders aware of the availability of the edu-
2 cational programs supported pursuant to sub-
3 paragraph (A).

4 “(3) GRANTS FOR QUALITY NEWBORN SCREEN-
5 ING FOLLOWUP.—From funds appropriated under
6 subsection (h), the Secretary, acting through the As-
7 sociate Administrator and in consultation with the
8 Advisory Committee, shall award grants to eligible
9 entities to enable such entities to establish, main-
10 tain, and operate a system to assess and coordinate
11 treatment relating to congenital, genetic, and meta-
12 bolic disorders.

13 “(b) APPLICATION.—An eligible entity that desires to
14 receive a grant under this section shall submit an applica-
15 tion to the Secretary at such time, in such manner, and
16 accompanied by such information as the Secretary may
17 require.

18 “(c) SELECTION OF GRANT RECIPIENTS.—

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

24 “(2) APPROVAL FACTORS.—

1 “(A) REQUIREMENTS FOR APPROVAL.—An
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
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
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
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
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 risk of a disorder on a screening test;

1 “(C) ensure the seamless integration of
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
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
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
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
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 (A) by redesignating paragraph (3) as
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”;

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-
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:

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
12 in screening newborns and children for heritable dis-
13 orders, including quality assurance for newborn-
14 screening tests, performance evaluation services, and
15 technical assistance and technology transfer to new-
16 born screening laboratories to ensure analytic valid-
17 ity and utility of screening tests; and

18 “(2) population-based pilot testing for new
19 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**
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.

3 “(2) SUPPLIES AND SERVICES IN LIEU OF
4 AWARD FUNDS.—

5 “(A) IN GENERAL.—Upon the request of a
6 recipient of an award of a grant or contract
7 under paragraph (1), the Secretary may, sub-
8 ject to subparagraph (B), provide supplies,
9 equipment, and services for the purpose of aid-
10 ing the recipient in carrying out the purposes
11 for which the award is made and, for such pur-
12 poses, may detail to the recipient any officer or
13 employee of the Department of Health and
14 Human Services.

15 “(B) REDUCTION.—With respect to a re-
16 quest described in subparagraph (A), the Sec-
17 retary shall reduce the amount of payments
18 under the award involved by an amount equal
19 to the costs of detailing personnel and the fair
20 market value of any supplies, equipment, or
21 services provided by the Secretary. The Sec-
22 retary shall, for the payment of expenses in-
23 curred in complying with such request, expend
24 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 there-
11 after, the Secretary shall submit to the Committee on En-
12 ergy and Commerce of the House of Representatives, and
13 the Committee on Health, Education, Labor, and Pen-
14 sions of the Senate, a report that, with respect to the pre-
15 ceding 2 fiscal years—

16 “(1) contains information regarding the inci-
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
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.

20 “(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.

1 “(e) COORDINATION.—

2 “(1) IN GENERAL.—In carrying out this sec-
3 tion, the Secretary shall coordinate, to the extent
4 practicable, programs under this section with pro-
5 grams on birth defects and developmental disabilities
6 authorized under section 317C.

7 “(2) PRIORITY IN GRANTS AND CONTRACTS.—
8 In making grants and contracts under this section,
9 the Secretary shall give priority to entities that dem-
10 onstrate the ability to coordinate activities under a
11 grant or contract made under this section with exist-
12 ing birth defects surveillance activities.

13 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
14 purpose of carrying out this section, there are authorized
15 to be appropriated \$15,000,000 for fiscal year 2008 and
16 such sums as may be necessary for each of the fiscal years
17 2009 through 2012.”.

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