

109TH CONGRESS
2D SESSION

H. R. 5397

To amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 16, 2006

Ms. ROYBAL-ALLARD (for herself and Mr. SIMPSON) introduced the following bill; which was referred to the Committee on Energy and Commerce

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 2006”.

1 **SEC. 2. FINDINGS.**

2 Congress finds the following:

3 (1) Currently, it is possible to test for more
4 than 30 disorders through newborn screening.

5 (2) There is a lack of uniform newborn screen-
6 ing throughout the United States. While a newborn
7 with a debilitating condition may receive screening,
8 early detection, and treatment in 1 location, in an-
9 other location the condition may go undetected and
10 result in catastrophic consequences.

11 (3) Each year more than 4,000,000 babies are
12 screened by State and private laboratories to detect
13 conditions that may threaten their long-term health.

14 (4) There are more than 2,000 babies born
15 every year in the United States with detectable and
16 treatable disorders that go unscreened through new-
17 born screening.

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

20 Part Q of title III of the Public Health Service Act
21 (42 U.S.C. 280h et seq.) is amended by adding at the end
22 the following:

23 **“SEC. 399AA. NEWBORN SCREENING.**

24 **“(a) AUTHORIZATION OF GRANT PROGRAMS.—**

25 **“(1) GRANTS TO ASSIST HEALTH CARE PROFES-**
26 **SIONALS.—From funds appropriated under sub-**

1 section (h), the Secretary, acting through the Asso-
2 ciate Administrator of the Maternal and Child
3 Health Bureau of the Health Resources and Services
4 Administration (referred to in this section as the
5 ‘Associate Administrator’) and in consultation with
6 the Advisory Committee on Heritable Disorders in
7 Newborns and Children (referred to in this section
8 as the ‘Advisory Committee’), shall award grants to
9 eligible entities to enable such entities to assist in
10 providing health care professionals and newborn
11 screening laboratory personnel with—

12 “(A) education in newborn screening; and

13 “(B) training in—

14 “(i) relevant and new technologies in
15 newborn screening; and

16 “(ii) congenital, genetic, and meta-
17 bolic disorders.

18 “(2) GRANTS TO ASSIST FAMILIES.—

19 “(A) IN GENERAL.—From funds appro-
20 priated under subsection (h), the Secretary, act-
21 ing through the Associate Administrator and in
22 consultation with the Advisory Committee, shall
23 award grants to eligible entities to enable such
24 entities to develop and deliver educational pro-
25 grams about newborn screening to parents,

1 families, and patient advocacy and support
2 groups. The educational materials accom-
3 panying such educational programs shall be
4 provided at appropriate literacy levels.

5 “(B) AWARENESS OF THE AVAILABILITY
6 OF PROGRAMS.—To the extent practicable, the
7 Secretary shall make relevant health care pro-
8 viders aware of the availability of the edu-
9 cational programs supported pursuant to sub-
10 paragraph (A).

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

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

25 “(c) SELECTION OF GRANT RECIPIENTS.—

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

6 “(2) APPROVAL FACTORS.—

7 “(A) REQUIREMENTS FOR APPROVAL.—An
8 application submitted under subsection (b) may
9 not be approved by the Secretary unless the ap-
10 plication contains assurances that the eligible
11 entity—

12 “(i) will use grant funds only for the
13 purposes specified in the approved applica-
14 tion and in accordance with the require-
15 ments of this section; and

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

21 “(B) EXISTING PROGRAMS.—Prior to
22 awarding a grant under this section, the Sec-
23 retary shall—

24 “(i) conduct an assessment of existing
25 educational resources and training pro-

1 grams and coordinated systems of followup
2 care with respect to newborn screening;
3 and

4 “(ii) take all necessary steps to mini-
5 mize the duplication of the resources and
6 programs described in clause (i).

7 “(d) COORDINATION.—The Secretary shall take all
8 necessary steps to coordinate programs funded with
9 grants received under this section.

10 “(e) USE OF GRANT FUNDS.—

11 “(1) GRANTS TO ASSIST HEALTH CARE PROFES-
12 SIONALS.—An eligible entity that receives a grant
13 under subsection (a)(1) may use the grant funds to
14 work with appropriate medical schools, nursing
15 schools, schools of public health, schools of genetic
16 counseling, internal education programs in State
17 agencies, nongovernmental organizations, and pro-
18 fessional organizations and societies to develop and
19 deliver education and training programs that in-
20 clude—

21 “(A) continuing medical education pro-
22 grams for health care professionals and new-
23 born screening laboratory personnel in newborn
24 screening;

1 “(B) education, technical assistance, and
2 training on new discoveries in newborn screen-
3 ing and the use of any related technology;

4 “(C) models to evaluate the prevalence of,
5 and assess and communicate the risks of, con-
6 genital conditions, including the prevalence and
7 risk of some of these conditions based on family
8 history;

9 “(D) models to communicate effectively
10 with parents and families about—

11 “(i) the process and benefits of new-
12 born screening;

13 “(ii) how to use information gathered
14 from newborn screening;

15 “(iii) the meaning of screening re-
16 sults, including the possibility of false posi-
17 tive findings;

18 “(iv) the right of refusal of newborn
19 screening, if applicable; and

20 “(v) the potential need for followup
21 care after newborns are screened;

22 “(E) information and resources on coordi-
23 nated systems of followup care after newborns
24 are screened;

1 “(F) information on the disorders for
2 which States require and offer newborn screen-
3 ing and options for newborn screening relating
4 to conditions in addition to such disorders;

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

9 “(H) other items to carry out the purpose
10 described in subsection (a)(1) as determined ap-
11 propriate by the Secretary.

12 “(2) GRANTS TO ASSIST FAMILIES.—An eligible
13 entity that receives a grant under subsection (a)(2)
14 may use the grant funds to develop and deliver to
15 parents, families, and patient advocacy and support
16 groups, educational programs about newborn screen-
17 ing that include information on—

18 “(A) what newborn screening is;

19 “(B) how newborn screening is performed;

20 “(C) who performs newborn screening;

21 “(D) where newborn screening is per-
22 formed;

23 “(E) the disorders for which the State re-
24 quires newborns to be screened;

1 “(F) different options for newborn screen-
2 ing for disorders other than those included by
3 the State in the mandated newborn screening
4 program;

5 “(G) the meaning of various screening re-
6 sults, including the possibility of false positive
7 and false negative findings;

8 “(H) the prevalence and risk of newborn
9 disorders, including the increased risk of dis-
10 orders that may stem from family history;

11 “(I) coordinated systems of followup care
12 after newborns are screened; and

13 “(J) other items to carry out the purpose
14 described in subsection (a)(2) as determined ap-
15 propriate by the Secretary.

16 “(3) GRANTS FOR QUALITY NEWBORN SCREEN-
17 ING FOLLOWUP.—An eligible entity that receives a
18 grant under subsection (a)(3) shall use the grant
19 funds to—

20 “(A) expand on existing procedures and
21 systems, where appropriate and available, for
22 the timely reporting of newborn screening re-
23 sults to individuals, families, primary care phy-
24 sicians, and subspecialists in congenital, ge-
25 netic, and metabolic disorders;

1 “(B) coordinate ongoing followup treat-
2 ment with individuals, families, primary care
3 physicians, and subspecialists in congenital, ge-
4 netic, and metabolic disorders after a newborn
5 receives an indication of the presence or in-
6 creased risk of a disorder on a screening test;

7 “(C) ensure the seamless integration of
8 confirmatory testing, tertiary care medical serv-
9 ices, comprehensive genetic services including
10 genetic counseling, and information about ac-
11 cess to developing therapies by participation in
12 approved clinical trials involving the primary
13 health care of the infant;

14 “(D) analyze data, if appropriate and
15 available, collected from newborn screenings to
16 identify populations at risk for disorders affect-
17 ing newborns, examine and respond to health
18 concerns, recognize and address relevant envi-
19 ronmental, behavioral, socioeconomic, demo-
20 graphic, and other relevant risk factors; and

21 “(E) carry out such other activities as the
22 Secretary may determine necessary.

23 “(f) REPORTS TO CONGRESS.—

1 “(1) IN GENERAL.—Subject to paragraph (2),
2 the Secretary shall submit to the appropriate com-
3 mittees of Congress reports—

4 “(A) evaluating the effectiveness and the
5 impact of the grants awarded under this sec-
6 tion—

7 “(i) in promoting newborn screen-
8 ing—

9 “(I) education and resources for
10 families; and

11 “(II) education, resources, and
12 training for health care professionals;

13 “(ii) on the successful diagnosis and
14 treatment of congenital, genetic, and meta-
15 bolic disorders; and

16 “(iii) on the continued development of
17 coordinated systems of followup care after
18 newborns are screened;

19 “(B) describing and evaluating the effec-
20 tiveness of the activities carried out with grant
21 funds received under this section; and

22 “(C) that include recommendations for
23 Federal actions to support—

24 “(i) education and training in new-
25 born screening; and

1 “(ii) followup care after newborns are
2 screened.

3 “(2) TIMING OF REPORTS.—The Secretary shall
4 submit—

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

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

15 “(g) DEFINITION OF ELIGIBLE ENTITY.—In this sec-
16 tion, the term ‘eligible entity’ means—

17 “(1) a State or a political subdivision of a
18 State;

19 “(2) a consortium of 2 or more States or polit-
20 ical subdivisions of States;

21 “(3) a territory;

22 “(4) an Indian tribe or a hospital or outpatient
23 health care facility of the Indian Health Service; or

1 “(5) a nongovernmental organization with ap-
 2 propriate expertise in newborn screening, as deter-
 3 mined by the Secretary.

4 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
 5 are authorized to be appropriated to carry out this sec-
 6 tion—

7 “(1) \$15,000,000 for fiscal year 2007; and

8 “(2) such sums as may be necessary for each
 9 of fiscal years 2008 through 2011.”.

10 **SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR**
 11 **HERITABLE DISORDERS.**

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

14 (1) in subsection (c)(2)—

15 (A) in subparagraph (E), by striking
 16 “and” after the semicolon;

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

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

21 “(F) an assurance that the entity has
 22 adopted and implemented, is in the process of
 23 adopting and implementing, or will use grant
 24 amounts received under this section to adopt
 25 and implement the guidelines and recommenda-

1 tions of the Advisory Committee on Heritable
 2 Disorders in Newborns and Children established
 3 under section 1111 (referred to in this section
 4 as the ‘Advisory Committee’) that are adopted
 5 by the Secretary and in effect at the time the
 6 grant is awarded or renewed under this section,
 7 which shall include the screening of each new-
 8 born for the heritable disorders recommended
 9 by the Advisory Committee and adopted by the
 10 Secretary and the reporting of results; and”;
 11 and

12 (2) in subsection (i), by striking “such sums”
 13 and all that follows through the period at the end
 14 and inserting “\$25,000,000 for fiscal year 2007 and
 15 such sums as may be necessary for each of the fiscal
 16 years 2008 through 2011.”.

17 **SEC. 5. EVALUATING THE EFFECTIVENESS OF NEWBORN-**
 18 **AND CHILD-SCREENING PROGRAMS.**

19 Section 1110 of the Public Health Service Act (42
 20 U.S.C. 300b–9) is amended by adding at the end the fol-
 21 lowing:

22 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
 23 are authorized to be appropriated to carry out this section
 24 \$5,000,000 for fiscal year 2007 and such sums as may

1 be necessary for each of the fiscal years 2008 through
2 2011.”.

3 **SEC. 6. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
4 **IN NEWBORNS AND CHILDREN.**

5 Section 1111 of the Public Health Service Act (42
6 U.S.C. 300b–10) is amended—

7 (1) in subsection (b)—

8 (A) by redesignating paragraph (3) as
9 paragraph (5);

10 (B) in paragraph (2), by striking “and”
11 after the semicolon;

12 (C) by inserting after paragraph (2) the
13 following:

14 “(3) recommend a uniform screening panel for
15 newborn screening programs that includes the heri-
16 table disorders for which all newborns should be
17 screened, including secondary conditions that may be
18 identified as a result of the laboratory methods used
19 for screening;

20 “(4) develop a model decision-matrix for new-
21 born screening program expansion, and periodically
22 update the recommended uniform screening panel
23 described in paragraph (3) based on such decision-
24 matrix; and”; and

1 (D) in paragraph (5) (as redesignated by
2 subparagraph (A)), by striking the period at the
3 end and inserting “, including recommenda-
4 tions, advice, or information dealing with—

5 “(A) followup activities, including those
6 necessary to achieve rapid diagnosis in the
7 short term, and those that ascertain long-term
8 case management outcomes and appropriate ac-
9 cess to related services;

10 “(B) diagnostic and other technology used
11 in screening;

12 “(C) the availability and reporting of test-
13 ing for conditions for which there is no existing
14 treatment;

15 “(D) minimum standards and related poli-
16 cies and procedures for State newborn screen-
17 ing programs;

18 “(E) quality assurance, oversight, and
19 evaluation of State newborn screening pro-
20 grams;

21 “(F) data collection for assessment of new-
22 born screening programs;

23 “(G) public and provider awareness and
24 education;

1 “(H) language and terminology used by
2 State newborn screening programs;

3 “(I) confirmatory testing and verification
4 of positive results; and

5 “(J) harmonization of laboratory defini-
6 tions for results that are within the expected
7 range and results that are outside of the ex-
8 pected range.”; and

9 (2) by adding at the end the following:

10 “(d) DECISION ON RECOMMENDATIONS.—

11 “(1) IN GENERAL.—Not later than 180 days
12 after the Advisory Committee issues a recommenda-
13 tion pursuant to this section, the Secretary shall
14 adopt or reject such recommendation.

15 “(2) PENDING RECOMMENDATIONS.—The Sec-
16 retary shall adopt or reject any recommendation
17 issued by the Advisory Committee that is pending on
18 the date of enactment of the Newborn Screening
19 Saves Lives Act of 2006 by not later than 180 days
20 after the date of enactment of such Act.

21 “(3) DETERMINATIONS TO BE MADE PUBLIC.—

22 The Secretary shall publicize any determination on
23 adopting or rejecting a recommendation of the Advi-
24 sory Committee pursuant to this subsection, includ-
25 ing the justification for the determination.

1 “(e) CONTINUATION OF OPERATION OF COM-
 2 MITTEE.—Notwithstanding section 14 of the Federal Ad-
 3 visory Committee Act (5 U.S.C. App.), the Advisory Com-
 4 mittee shall continue to operate during the 5-year period
 5 beginning on the date of enactment of the Newborn
 6 Screening Saves Lives Act of 2006.”.

7 **SEC. 7. LABORATORY QUALITY AND SURVEILLANCE.**

8 Part A of title XI of the Public Health Service Act
 9 (42 U.S.C. 300b–1 et seq.) is amended by adding at the
 10 end the following:

11 **“SEC. 1112. LABORATORY QUALITY.**

12 “(a) IN GENERAL.—The Secretary, acting through
 13 the Director of the Centers for Disease Control and Pre-
 14 vention and in consultation with the Advisory Committee
 15 on Heritable Disorders in Newborns and Children estab-
 16 lished under section 1111, shall provide for—

17 “(1) quality assurance for laboratories involved
 18 in screening newborns and children for heritable dis-
 19 orders, including quality assurance for newborn-
 20 screening tests, performance evaluation services, and
 21 technical assistance and technology transfer to new-
 22 born screening laboratories to ensure analytic valid-
 23 ity and utility of screening tests; and

24 “(2) population-based pilot testing for new
 25 screening tools for evaluating use on a mass scale.

1 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated \$5,000,000 for fiscal year 2007 and
4 such sums as may be necessary for each of the fiscal years
5 2008 through 2011.

6 **“SEC. 1113. SURVEILLANCE PROGRAMS FOR HERITABLE**
7 **DISORDERS SCREENING.**

8 “(a) IN GENERAL.—The Secretary, acting through
9 the Director of the Centers for Disease Control and Pre-
10 vention, shall carry out programs—

11 “(1) to collect, analyze, and make available data
12 on the heritable disorders recommended by the Advi-
13 sory Committee on Heritable Disorders in Newborns
14 and Children established under section 1111, includ-
15 ing data on the causes of such disorders and on the
16 incidence and prevalence of such disorders;

17 “(2) to operate regional centers for the conduct
18 of applied epidemiological research on the prevention
19 of such disorders;

20 “(3) to provide information and education to
21 the public on the prevention of such disorders; and

22 “(4) to conduct research on and to promote the
23 prevention of such disorders, and secondary health
24 conditions among individuals with such disorders.

25 “(b) GRANTS AND CONTRACTS.—

1 “(1) IN GENERAL.—In carrying out subsection
2 (a), the Secretary may make grants to and enter
3 into contracts with public and nonprofit private enti-
4 ties.

5 “(2) SUPPLIES AND SERVICES IN LIEU OF
6 AWARD FUNDS.—

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

17 “(B) REDUCTION.—With respect to a re-
18 quest described in subparagraph (A), the Sec-
19 retary shall reduce the amount of payments
20 under the award involved by an amount equal
21 to the costs of detailing personnel and the fair
22 market value of any supplies, equipment, or
23 services provided by the Secretary. The Sec-
24 retary shall, for the payment of expenses in-

1 curred in complying with such request, expend
2 the amounts withheld.

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

11 “(c) BIENNIAL REPORT.—Not later than February
12 1 of fiscal year 2007 and of every second such year there-
13 after, the Secretary shall submit to the Committee on En-
14 ergy and Commerce of the House of Representatives, and
15 the Committee on Health, Education, Labor, and Pen-
16 sions of the Senate, a report that, with respect to the pre-
17 ceding 2 fiscal years—

18 “(1) contains information regarding the inci-
19 dence and prevalence of heritable disorders and the
20 health status of individuals with such disorders and
21 the extent to which such disorders have contributed
22 to the incidence and prevalence of infant mortality
23 and affected quality of life;

24 “(2) contains information under paragraph (1)
25 that is specific to various racial and ethnic groups

1 (including Hispanics, non-Hispanic whites, Blacks,
2 Native Americans, and Asian Americans);

3 “(3) contains an assessment of the extent to
4 which various approaches of preventing heritable dis-
5 orders and secondary health conditions among indi-
6 viduals with such disorders have been effective;

7 “(4) describes the activities carried out under
8 this section;

9 “(5) contains information on the incidence and
10 prevalence of individuals living with heritable dis-
11 orders, information on the health status of individ-
12 uals with such disorders, information on any health
13 disparities experienced by such individuals, and rec-
14 ommendations for improving the health and wellness
15 and quality of life of such individuals;

16 “(6) contains a summary of recommendations
17 from all heritable disorders research conferences
18 sponsored by the Centers for Disease Control and
19 Prevention; and

20 “(7) contains any recommendations of the Sec-
21 retary regarding this section.

22 “(d) APPLICABILITY OF PRIVACY LAWS.—The provi-
23 sions of this section shall be subject to the requirements
24 of section 552a of title 5, United States Code. All Federal
25 laws relating to the privacy of information shall apply to

1 the data and information that is collected under this sec-
2 tion.

3 “(e) COORDINATION.—

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

9 “(2) PRIORITY IN GRANTS AND CONTRACTS.—

10 In making grants and contracts under this section,
11 the Secretary shall give priority to entities that dem-
12 onstrate the ability to coordinate activities under a
13 grant or contract made under this section with exist-
14 ing birth defects surveillance activities.

15 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
16 purpose of carrying out this section, there are authorized
17 to be appropriated \$15,000,000 for fiscal year 2007 and
18 such sums as may be necessary for each of the fiscal years
19 2008 through 2011.”.

○