

110TH CONGRESS  
1ST SESSION

# 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.

---

## IN THE SENATE OF THE UNITED STATES

JULY 23, 2007

Mr. DODD (for himself, Mr. HATCH, Mrs. CLINTON, and Mr. KENNEDY) 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. 399Z-1. NEWBORN SCREENING.**

16           “(a) AUTHORIZATION OF GRANT PROGRAMS.—From  
17 funds appropriated under subsection (h), the Secretary,  
18 acting through the Administrator of the Health Resources  
19 and Services Administration (referred to in this section  
20 as the ‘Administrator’) and in consultation with the Advi-  
21 sory Committee on Heritable Disorders in Newborns and  
22 Children (referred to in this section as the ‘Advisory Com-  
23 mittee’), shall award grants to eligible entities to enable  
24 such entities to assist in providing health care profes-

1 sionals and newborn screening laboratory personnel  
2 with—

3 “(1) education in newborn screening; and

4 “(2) training in—

5 “(A) relevant and new technologies in new-  
6 born screening; and

7 “(B) congenital, genetic, and metabolic  
8 disorders.

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

14 “(c) SELECTION OF GRANT RECIPIENTS.—

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

20 “(2) APPROVAL FACTORS.—

21 “(A) REQUIREMENTS FOR APPROVAL.—An  
22 application submitted under subsection (b) may  
23 not be approved by the Secretary unless the ap-  
24 plication contains assurances that the eligible  
25 entity—

1           “(i) will use grant funds only for the  
2           purposes specified in the approved applica-  
3           tion and in accordance with the require-  
4           ments of this section; and

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

10          “(B) EXISTING PROGRAMS.—Prior to  
11          awarding a grant under this section, the Sec-  
12          retary shall—

13               “(i) conduct an assessment of existing  
14               educational resources and training pro-  
15               grams with respect to newborn screening;  
16               and

17               “(ii) take all necessary steps to mini-  
18               mize the duplication of the resources and  
19               programs described in clause (i) and en-  
20               sure that funding under this section will  
21               supplement, not supplant, existing funding  
22               for such activities.

23          “(d) COORDINATION.—The Secretary shall take all  
24          necessary steps to coordinate programs funded with

1 grants received under this section and to coordinate with  
2 existing newborn screening activities.

3 “(e) USE OF GRANT FUNDS.—An eligible entity that  
4 receives a grant under subsection (a)(1) may use the grant  
5 funds to work with appropriate medical schools, nursing  
6 schools, schools of public health, schools of genetic coun-  
7 seling, internal education programs in State agencies, non-  
8 governmental organizations, and professional organiza-  
9 tions and societies to develop and deliver education and  
10 training programs that include—

11 “(1) continuing medical education programs for  
12 health care professionals and newborn screening lab-  
13 oratory personnel in newborn screening;

14 “(2) education, technical assistance, and train-  
15 ing on new discoveries in newborn screening and the  
16 use of any related technology;

17 “(3) models to evaluate the prevalence of, and  
18 assess and communicate the risks of, congenital con-  
19 ditions, including the prevalence and risk of some of  
20 these conditions based on family history;

21 “(4) models to communicate effectively with  
22 parents and families about—

23 “(A) the process and benefits of newborn  
24 screening and the meaning of screening results,

1 including the possibility of false positive find-  
2 ings;

3 “(B) how to use information gathered from  
4 newborn screening;

5 “(C) the right of refusal of newborn  
6 screening, if applicable; and

7 “(D) the potential need for followup care  
8 after newborns are screened;

9 “(5) information and resources on coordinated  
10 systems of followup care after newborns are  
11 screened;

12 “(6) information on the disorders for which  
13 States require and offer newborn screening and op-  
14 tions for newborn screening relating to conditions in  
15 addition to such disorders;

16 “(7) information on additional newborn screen-  
17 ing that may not be required by the State, but that  
18 may be available from other sources; and

19 “(8) other items to carry out the purpose de-  
20 scribed in subsection (a)(1) as determined appro-  
21 priate by the Secretary.

22 “(f) REPORTS TO CONGRESS.—

23 “(1) IN GENERAL.—Subject to paragraph (2),  
24 the Secretary shall submit to the relevant commit-  
25 tees of Congress reports—

1           “(A) evaluating the effectiveness and the  
2 impact of the grants awarded under this sec-  
3 tion—

4                   “(i) in promoting newborn screening  
5 education, resources, and training for  
6 health care professionals;

7                   “(ii) on the successful diagnosis and  
8 treatment of congenital, genetic, and meta-  
9 bolic disorders; and

10                  “(iii) on the continued development of  
11 coordinated systems of followup care after  
12 newborns are screened;

13           “(B) describing and evaluating the effec-  
14 tiveness of the activities carried out with grant  
15 funds received under this section; and

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

18                   “(i) education and training in new-  
19 born screening; and

20                   “(ii) followup care after newborns are  
21 screened.

22           “(2) TIMING OF REPORTS.—The Secretary shall  
23 submit—

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



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

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

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

11 “(1) a State or a political subdivision of a  
12 State;

13 “(2) a consortium of 2 or more States or polit-  
14 ical subdivisions of States;

15 “(3) a territory;

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

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

20 “(h) AUTHORIZATION OF APPROPRIATIONS.—There  
21 are authorized to be appropriated to carry out this sec-  
22 tion—

23 “(1) \$5,000,000 for fiscal year 2008; and

24 “(2) such sums as may be necessary for each  
25 of fiscal years 2009 through 2012.”.

1 **SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR**  
2 **HERITABLE DISORDERS.**

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

5 (1) in subsection (c)(2)—

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

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

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

12 “(F) an assurance that the entity has  
13 adopted and implemented, is in the process of  
14 adopting and implementing, or will use grant  
15 amounts received under this section to adopt  
16 and implement the guidelines and recommenda-  
17 tions of the Advisory Committee on Heritable  
18 Disorders in Newborns and Children established  
19 under section 1111 (referred to in this section  
20 as the ‘Advisory Committee’) that are adopted  
21 by the Secretary and in effect at the time the  
22 grant is awarded or renewed under this section,  
23 which shall include the screening of each new-  
24 born for the heritable disorders recommended  
25 by the Advisory Committee and adopted by the

1 Secretary and the reporting of results; and”;  
2 and

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

8 **SEC. 5. EVALUATING THE EFFECTIVENESS OF NEWBORN-**  
9 **AND CHILD-SCREENING PROGRAMS.**

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

13 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
14 are authorized to be appropriated to carry out this section  
15 \$5,000,000 for fiscal year 2008 and such sums as may  
16 be necessary for each of the fiscal years 2009 through  
17 2012.”.

18 **SEC. 6. ADVISORY COMMITTEE ON HERITABLE DISORDERS**  
19 **IN NEWBORNS AND CHILDREN.**

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

22 (1) in subsection (b)—

23 (A) in paragraph (1), by inserting “and  
24 grants awarded under section 399Z–1” before  
25 the semicolon;

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

3 (C) in paragraph (2), by striking “and”  
4 after the semicolon;

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

7 “(3) make systematic evidence-based and peer-  
8 reviewed recommendations that include the heritable  
9 disorders for which all newborns should be screened,  
10 including secondary conditions that may be identi-  
11 fied as a result of the laboratory methods used for  
12 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 as appropriate, based on such decision-matrix;

17 “(5) consider ways to ensure that States attain  
18 the capacity to screen for the conditions described in  
19 paragraph (3), and include in such consideration the  
20 results of grant funding under section 1109; and”;

21 (E) in paragraph (6) (as so redesignated  
22 by subparagraph (A)), by striking the period at  
23 the end and inserting “, which may include rec-  
24 ommendations, advice, or information dealing  
25 with—

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

6           “(B) implementation, monitoring, and  
7 evaluation of newborn screening activities, in-  
8 cluding diagnosis, screening, follow-up, and  
9 treatment activities;

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

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

15           “(E) conditions not included in the rec-  
16 ommended uniform screening panel that are  
17 treatable with Food and Drug Administration-  
18 approved products;

19           “(F) minimum standards and related poli-  
20 cies and procedures used by State newborn  
21 screening programs, such as language and ter-  
22 minology used by State newborn screening pro-  
23 grams to include standardization of case defini-  
24 tions and names of disorders for which newborn  
25 screening tests are performed;

1           “(G) quality assurance, oversight, and  
2           evaluation of State newborn screening pro-  
3           grams, including ensuring that tests and tech-  
4           nologies used by each State meet established  
5           standards for detecting and reporting positive  
6           screening results;

7           “(H) public and provider awareness and  
8           education;

9           “(I) the cost and effectiveness of newborn  
10          screening and medical evaluation systems and  
11          intervention programs conducted by State-based  
12          programs;

13          “(J) identification of the causes of, and  
14          risk factors for heritable disorders; and

15          “(K) coordination of surveillance activities,  
16          including standardized data collection and re-  
17          porting, harmonization of laboratory definitions  
18          for heritable disorders and testing results, and  
19          confirmatory testing and verification of positive  
20          results, in order to assess and enhance moni-  
21          toring of newborn diseases.”; and

22          (2) in subsection (c)(2)—

23                 (A) by redesignating subparagraphs (E),  
24                 (F) and (G) as subparagraphs (F), (H), and  
25                 (I);

1 (B) by inserting after subparagraph (D)  
2 the following:

3 “(E) the Commissioner of the Food and  
4 Drug Administration;”; and

5 (C) by inserting after subparagraph (F),  
6 as so redesignated, the following:

7 “(G) individuals with expertise in ethics  
8 who have worked and published material in the  
9 area of newborn screening;”; and

10 (3) by adding at the end the following:

11 “(d) DECISION ON RECOMMENDATIONS.—

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

16 “(2) PENDING RECOMMENDATIONS.—The Sec-  
17 retary shall adopt or reject any recommendation  
18 issued by the Advisory Committee that is pending on  
19 the date of enactment of the Newborn Screening  
20 Saves Lives Act of 2007 by not later than 180 days  
21 after the date of enactment of such Act.

22 “(3) DETERMINATIONS TO BE MADE PUBLIC.—  
23 The Secretary shall publicize any determination on  
24 adopting or rejecting a recommendation of the Advi-

1 sory Committee pursuant to this subsection, includ-  
2 ing the justification for the determination.

3 “(e) ANNUAL REPORT.—Not later than 2 years after  
4 the date of enactment of the Newborn Screening Saves  
5 Lives Act of 2007, and each fiscal year thereafter, the Ad-  
6 visory Committee shall—

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

9 “(2) submit such report to the appropriate com-  
10 mittees of Congress, the Secretary, and the State de-  
11 partments of health; and

12 “(3) disseminate such report on as wide a basis  
13 as practicable, including through posting on the  
14 internet clearinghouse established under section  
15 1112.

16 “(f) CONTINUATION OF OPERATION OF COM-  
17 MITTEE.—Notwithstanding section 14 of the Federal Ad-  
18 visory Committee Act (5 U.S.C. App.), the Advisory Com-  
19 mittee shall continue to operate during the 5-year period  
20 beginning on the date of enactment of the Newborn  
21 Screening Saves Lives Act of 2007.

22 “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
23 are authorized to be appropriated to carry out this sec-  
24 tion—

25 “(1) \$1,000,000 for fiscal year 2008; and



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

3 **SEC. 7. INFORMATION CLEARINGHOUSE.**

4           Part A of title XI of the Public Health Service Act  
5 (42 U.S.C. 300b–1 et seq.) is amended by adding at the  
6 end the following:

7 **“SEC. 1112. CLEARINGHOUSE OF NEWBORN SCREENING IN-**  
8 **FORMATION.**

9           “(a) IN GENERAL.—The Secretary, acting through  
10 the Administrator of the Health Resources and Services  
11 Administration (referred to in this part as the ‘Adminis-  
12 trator’), in consultation with the Director of the Centers  
13 for Disease Control and Prevention and the Director of  
14 the National Institutes of Health, shall establish and  
15 maintain a central clearinghouse of current educational  
16 and family support and services information, materials, re-  
17 sources, research, and data on newborn screening to—

18           “(1) enable parents and family members of  
19 newborns, health professionals, industry representa-  
20 tives, and other members of the public to increase  
21 their awareness, knowledge, and understanding of  
22 newborn screening;

23           “(2) increase awareness, knowledge, and under-  
24 standing of newborn diseases and screening services

1 for individuals wanting to have children and expect-  
2 ant families; and

3 “(3) develop and maintain current data on  
4 quality indicators to measure performance of new-  
5 born screening, such as false-positive rates and other  
6 quality indicators as determined by the Advisory  
7 Committee under section 1111.

8 “(b) INTERNET AVAILABILITY.—The Secretary, act-  
9 ing through the Administrator, shall ensure that the clear-  
10 inghouse described under subsection (a)—

11 “(1) is available on the Internet;

12 “(2) includes an interactive forum;

13 “(3) is updated on a regular basis, but not less  
14 than quarterly; and

15 “(4) provides—

16 “(A) links to Government-sponsored, non-  
17 profit, and other Internet websites of labora-  
18 tories as determined appropriate by the Sec-  
19 retary that have demonstrated expertise in new-  
20 born screening that supply research-based infor-  
21 mation on newborn screening tests currently  
22 available throughout the United States;

23 “(B) information about newborn conditions  
24 and screening services available in each State  
25 from laboratories certified under subpart 2 of

1 part F of title III, including information about  
2 supplemental screening that is available but not  
3 required, in the State where the infant is born;

4 “(C) current research on both treatable  
5 and not-yet treatable conditions for which new-  
6 born screening tests are available;

7 “(D) the availability of Federal funding for  
8 newborn and child screening for heritable dis-  
9 orders including grants authorized under the  
10 Newborn Screening Saves Lives Act of 2007;  
11 and

12 “(E) other relevant information as deter-  
13 mined appropriate by the Secretary.

14 “(c) NONDUPLICATION.—In developing the clearing-  
15 house under this section, the Secretary shall ensure that  
16 such clearinghouse minimizes duplication and supple-  
17 ments, not supplants, existing information sharing efforts.

18 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
19 are authorized to be appropriated to carry out this sec-  
20 tion—

21 “(1) \$2,500,000 for fiscal year 2008; and

22 “(2) such sums as may be necessary for each  
23 of the fiscal years 2009 through 2012.”.

1 **SEC. 8. 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.), as amended by section 7, is  
4 further amended by adding at the end the following:

5 **“SEC. 1113. 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. 1114. SURVEILLANCE PROGRAMS FOR HERITABLE**  
2 **DISORDERS SCREENING.**

3 “(a) IN GENERAL.—The Secretary, acting through  
4 an Interagency Group consisting of the Director of the  
5 Agency for Healthcare Research and Quality, the Director  
6 of the Centers for Disease Control and Prevention, the Ad-  
7 ministrator, and the Director of the National Institutes  
8 of Health, shall build upon existing activities and infra-  
9 structure to carry out programs—

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

17 “(2) to operate regional centers for the conduct  
18 of applied epidemiological research on effective inter-  
19 ventions for such disorders for the prevention of  
20 poor health outcomes;

21 “(3) to provide information and education to  
22 the public on effective interventions for the preven-  
23 tion of poor health outcomes resulting from such dis-  
24 orders; and

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

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

3 “(b) GRANTS AND CONTRACTS.—

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

8 “(2) SUPPLIES AND SERVICES IN LIEU OF  
9 AWARD FUNDS.—

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

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

1 services provided by the Secretary. The Sec-  
2 retary shall, for the payment of expenses in-  
3 curred in complying with such request, expend  
4 the amounts withheld.

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

13 “(c) REPORTS TO CONGRESS.—

14 “(1) IN GENERAL.—Subject to paragraph (2),  
15 the Secretary shall submit to the relevant commit-  
16 tees of Congress reports—

17 “(A) containing information under para-  
18 graph (1) that is specific to various racial, eth-  
19 nic, and socioeconomic groups;

20 “(B) containing an assessment of the ex-  
21 tent to which various approaches of preventing  
22 heritable disorders and secondary health condi-  
23 tions among individuals with such disorders  
24 have been effective;

1           “(C) describing the activities carried out  
2 under this section;

3           “(D) containing information on the inci-  
4 dence and prevalence of individuals living with  
5 heritable disorders, information on the health  
6 status of individuals with such disorders includ-  
7 ing the extent to which such disorders have con-  
8 tributed to the incidence and prevalence of in-  
9 fant mortality, information on any health dis-  
10 parities experienced by such individuals, and  
11 recommendations for improving the health and  
12 wellness and quality of life of such individuals;

13           “(E) containing a summary of rec-  
14 ommendations from all heritable disorders re-  
15 search conferences sponsored by the Centers for  
16 Disease Control and Prevention; and

17           “(F) containing any recommendations of  
18 the Secretary regarding this section.

19           “(2) TIMING OF REPORTS.—The Secretary shall  
20 submit—

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



1           “(B) a subsequent report that includes the  
2           information described in paragraph 1, not later  
3           than 60 months after the date on which the  
4           first grant funds are awarded under this sec-  
5           tion.

6           “(d) APPLICABILITY OF PRIVACY LAWS.—The provi-  
7           sions of this section shall be subject to the requirements  
8           of section 552a of title 5, United States Code. All Federal  
9           laws relating to the privacy of information shall apply to  
10          the data and information that is collected under this sec-  
11          tion.

12          “(e) COORDINATION.—

13                 “(1) IN GENERAL.—In carrying out this sec-  
14                 tion, the Secretary shall coordinate, to the extent  
15                 practicable, programs under this section with pro-  
16                 grams on birth defects and developmental disabilities  
17                 authorized under section 317C.

18                 “(2) PRIORITY IN GRANTS AND CONTRACTS.—  
19                 In making grants and contracts under this section,  
20                 the Secretary shall give priority to entities that dem-  
21                 onstrate the ability to coordinate activities under a  
22                 grant or contract made under this section with exist-  
23                 ing birth defects surveillance activities.

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

1 to be appropriated \$15,000,000 for fiscal year 2008 and  
2 such sums as may be necessary for each of the fiscal years  
3 2009 through 2012.”.

4 **SEC. 9. GRANTS.**

5 Part A of title XI of the Public Health Service Act  
6 (42 U.S.C. 300b–1 et seq.), as amended by section 8, is  
7 further amended by adding at the end the following:

8 **“SEC. 1115. GRANTS.**

9 “(a) AUTHORIZATION OF GRANT PROGRAM.—

10 “(1) IN GENERAL.—From funds appropriated  
11 under subsection (h), the Secretary, acting through  
12 the Administrator and in consultation with the Advi-  
13 sory Committee, shall award grants to eligible enti-  
14 ties to—

15 “(A) enable such entities to develop and  
16 deliver educational programs about newborn  
17 screening to parents, families, and patient advo-  
18 cacy and support groups, such educational ma-  
19 terials accompanying such educational pro-  
20 grams to be provided at appropriate literacy  
21 levels; and

22 “(B) enable such entities to establish,  
23 maintain, and operate a system to assess and  
24 coordinate treatment relating to congenital, ge-  
25 netic, and metabolic disorders.

1           “(2) AWARENESS OF THE AVAILABILITY OF  
2 PROGRAMS.—To the extent practicable, the Sec-  
3 retary shall make relevant health care providers  
4 aware of the availability of the educational programs  
5 supported pursuant to paragraph (1).

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

11          “(c) SELECTION OF GRANT RECIPIENTS.—

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

17           “(2) APPROVAL FACTORS.—

18           “(A) REQUIREMENTS.—An application  
19 submitted under subsection (b) may not be ap-  
20 proved by the Secretary unless the application  
21 contains assurances that the eligible entity—

22                   “(i) will use grant funds only for the  
23 purposes specified in the approved applica-  
24 tion and in accordance with the require-  
25 ments of this section; and

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

6           “(B) EXISTING PROGRAMS.—Prior to  
7           awarding a grant under this section, the Sec-  
8           retary shall—

9                   “(i) conduct an assessment of existing  
10                  educational resources and training pro-  
11                  grams and coordinated systems of followup  
12                  care with respect to newborn screening;  
13                  and

14                   “(ii) take all necessary steps to mini-  
15                  mize the duplication of the resources and  
16                  programs described in clause (i) and en-  
17                  sure that funding under this section will  
18                  supplement, not supplant, existing funding  
19                  for such activities.

20           “(d) COORDINATION.—The Secretary shall take all  
21           necessary steps to coordinate programs funded with  
22           grants received under this section and to coordinate with  
23           existing newborn screening activities.

24           “(e) USE OF GRANT FUNDS.—

1           “(1) IN GENERAL.—An eligible entity that re-  
2           ceives a grant under this section may use the grant  
3           funds—

4           “(A) for purposes of grants under sub-  
5           section (a)(1)(A), to develop and deliver to par-  
6           ents, families, and patient advocacy and sup-  
7           port groups, educational programs about new-  
8           born screening that include information on—

9           “(i) what newborn screening is and  
10          how it is performed;

11          “(ii) who performs newborn screening;

12          “(iii) where newborn screening is per-  
13          formed;

14          “(iv) the disorders for which the State  
15          requires newborns to be screened;

16          “(v) different options for newborn  
17          screening for disorders other than those in-  
18          cluded by the State in the mandated new-  
19          born screening program;

20          “(vi) the meaning of various screening  
21          results, including the possibility of false  
22          positive and false negative findings;

23          “(vii) the prevalence and risk of new-  
24          born disorders, including the increased risk

1 of disorders that may stem from family  
2 history;

3 “(viii) coordinated systems of followup  
4 care after newborns are screened; and

5 “(ix) other items to carry out the pur-  
6 pose described in subsection (a)(1) as de-  
7 termined appropriate by the Secretary; and

8 “(B) for purposes of grants under sub-  
9 section (a)(1)(B), to—

10 “(i) expand on existing procedures  
11 and systems, where appropriate and avail-  
12 able, for the timely reporting of newborn  
13 screening results to individuals, families,  
14 primary care physicians, and appropriate  
15 subspecialists such as in congenital, ge-  
16 netic, and metabolic disorders;

17 “(ii) coordinate ongoing followup  
18 treatment with individuals, families, pri-  
19 mary care physicians, and appropriate sub-  
20 specialists such as in congenital, genetic,  
21 and metabolic disorders after a newborn  
22 receives an indication of the presence or in-  
23 creased risk of a disorder on a screening  
24 test;

1           “(iii) ensure the seamless integration  
2 of confirmatory testing, tertiary care med-  
3 ical services, comprehensive genetic serv-  
4 ices including genetic counseling, and in-  
5 formation about Food and Drug Adminis-  
6 tration-approved treatments as well as ac-  
7 cess to developing therapies by participa-  
8 tion in approved clinical trials involving the  
9 primary health care of the infant;

10           “(iv) analyze data, if appropriate and  
11 available, collected from newborn  
12 screenings to identify populations at risk  
13 for disorders affecting newborns, examine  
14 and respond to health concerns, recognize  
15 and address relevant environmental, behav-  
16 ioral, socioeconomic, demographic, and  
17 other relevant risk factors;

18           “(v) collect, analyze and report data  
19 on the costs, benefits and effectiveness of  
20 such tests; and

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

23           “(f) REPORTS TO CONGRESS.—

1           “(1) IN GENERAL.—Subject to paragraph (2),  
2           the Secretary shall submit to the relevant commit-  
3           tees 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, State, and local 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                   “(i) a subsequent report that includes  
11                   the information described in paragraph  
12                   (1), not later than 60 months after the  
13                   date on which the first grant funds are  
14                   awarded under this section.

15                   “(g) ELIGIBLE ENTITY.—In this section, the term  
16 ‘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

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

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

3               “(1) \$10,000,000 for fiscal year 2008; and

4               “(2) such sums as may be necessary for each  
5 of fiscal years 2009 through 2012.”.

6 **SEC. 10. CONTINGENCY PLANNING.**

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

10 **“SEC. 1116. NATIONAL CONTINGENCY PLAN FOR NEWBORN  
11                               SCREENING.**

12       “(a) IN GENERAL.—Not later than 180 days after  
13 the date of enactment of this section, the Secretary, acting  
14 through the Director of the Centers for Disease Control  
15 and Prevention and in consultation with the Administrator  
16 and State departments of health (or related agencies),  
17 shall develop a national contingency plan for newborn  
18 screening for use by a State, region, or consortia of States  
19 in the event of a public health emergency.

20       “(b) CONTENTS.—The contingency plan developed  
21 under subsection (a) shall include a plan for—

22               “(1) the collection and transport of specimens;

23               “(2) the shipment of specimens to State new-  
24 born screening laboratories;

25               “(3) the processing of specimens;

1           “(4) the reporting of screening results to physi-  
2           cians and families;

3           “(5) the diagnostic confirmation of positive  
4           screening results;

5           “(6) ensuring the availability of treatment and  
6           management resources;

7           “(7) educating families about newborn screen-  
8           ing; and

9           “(8) carrying out other activities determined  
10          appropriate by the Secretary.

11 **“SEC. 1117. HUNTER KELLY RESEARCH PROGRAM.**

12          “(a) ADDITIONAL NEWBORN SCREENING TESTS  
13          GRANTS.—

14               “(1) IN GENERAL.—The Secretary, in conjunc-  
15               tion with the Director of the National Institutes of  
16               Health and taking into consideration the rec-  
17               ommendations of the Advisory Committee, shall es-  
18               tablish a research program (to be known as ‘Hunter  
19               Kelly Newborn Screening Research Program’) by ex-  
20               panding, carrying out, and coordinating research  
21               in—

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

1 ease and Insulin Dependent Diabetes Mellitus,  
2 and Turner Syndrome, increase the specificity  
3 of newborn screening, and expand the number  
4 of conditions for which screening tests are  
5 available;

6 “(B) experimental treatments and disease  
7 management strategies for additional newborn  
8 conditions, and other genetic, metabolic, hor-  
9 monal and/or functional conditions that can be  
10 detected through newborn screening for which  
11 treatment is not yet available; and

12 “(C) other activities that would improve  
13 newborn screening, as identified by the Direc-  
14 tor.

15 “(2) ADDITIONAL NEWBORN CONDITION.—For  
16 purposes of this subsection, the term ‘additional  
17 newborn condition’ means any condition that is not  
18 one of the core conditions designated by the Advi-  
19 sory Committee.

20 “(b) FUNDING.—In carrying out the research pro-  
21 gram under this section, the Secretary and the Director  
22 shall ensure that entities receiving funding through the  
23 program will provide assurances, as practicable, that such  
24 entities will work in consultation with the appropriate  
25 State departments of health, and, as practicable, focus

1 their research on screening technology not currently per-  
2 formed in the States in which the entities are located, and  
3 the conditions on the uniform screening panel (or the  
4 standard test existing on the uniform screening panel).

5 “(c) MONITORING AND RESULTS.—The Director  
6 shall—

7 “(1) monitor and report on the activities result-  
8 ing from any funding distributed under this section;  
9 and

10 “(2) on an annual basis—

11 “(A) publish and disseminate the results of  
12 such monitoring on as wide a basis as is prac-  
13 ticable, which may include incorporation of  
14 these results in other newborn screening reports  
15 and posting on the Internet Clearinghouse es-  
16 tablished under section 1112;

17 “(B) submit to the relevant committees of  
18 Congress the results of such evaluation, which  
19 may include incorporation of such results in  
20 other newborn screening reports being sub-  
21 mitted to Congress.

22 “(d) NONDUPLICATION.—In carrying out programs  
23 under this section, the Secretary shall minimize duplica-  
24 tion and supplement, not supplant, existing efforts of the  
25 type carried out under this section.

1       “(e) PEER REVIEW.—Nothing in this section shall be  
2 construed to interfere with the scientific peer-review pro-  
3 cess at the National Institutes of Health.

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

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

8               “(2) such sums as may be necessary for fiscal  
9 years 2009 through 2012.”.

○