

Calendar No. 522110TH 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, Mr. KENNEDY, Mr. BOND, Mrs. MURRAY, Ms. COLLINS, Mr. INOUE, Ms. CANTWELL, Mr. SANDERS, Mr. JOHNSON, Mr. WHITEHOUSE, Mr. BROWN, Mr. DURBIN, Mr. LUGAR, Mr. CARDIN, Mrs. LINCOLN, Mr. CASEY, Mr. HARKIN, Ms. MIKULSKI, and Mr. COLEMAN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

DECEMBER 5, 2007

Reported by Mr. KENNEDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

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”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

8 (1) Each year more than 4,000,000 babies born
9 in the United States are screened by State and pri-
10 vate laboratories to detect some conditions that may
11 threaten their long-term health.

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

19 (3) Approximately 4,000 infants born each year
20 are diagnosed with these detectable and treatable
21 disorders. If diagnosed early, these conditions can be
22 successfully managed or treated to prevent severe
23 and often lifelong health consequences.

24 (4) In 2004, the American College of Medical
25 Genetics (ACMG) completed a report commissioned

1 by the Department of Health and Human Services
 2 which recommended that every baby born in the
 3 United States be screened for 29 specific disorders,
 4 including certain metabolic conditions and hearing
 5 deficiencies.

6 (5) Currently only 11 States and the District of
 7 Columbia require infants to be screened for all 29 of
 8 these recommended disorders.

9 (6) Continuity, especially during a public health
 10 emergency, plays a critical role in the screening, di-
 11 agnosis, referral, and treatment of these disorders.
 12 Currently there is no national contingency plan for
 13 maintaining continuity of newborn screening systems
 14 following a public health emergency.

15 **SEC. 3. AMENDMENT TO TITLE III OF THE PUBLIC HEALTH**
 16 **SERVICE ACT.**

17 Part Q of title III of the Public Health Service Act
 18 (42 U.S.C. 280h et seq.) is amended by adding at the end
 19 the following:

20 **“SEC. 399Z-1. NEWBORN SCREENING.**

21 **“(a) AUTHORIZATION OF GRANT PROGRAMS.—**From
 22 funds appropriated under subsection (h), the Secretary,
 23 acting through the Administrator of the Health Resources
 24 and Services Administration (referred to in this section
 25 as the ‘Administrator’) and in consultation with the Advi-

1 sory Committee on Heritable Disorders in Newborns and
 2 Children (referred to in this section as the ‘Advisory Com-
 3 mittee’); shall award grants to eligible entities to enable
 4 such entities to assist in providing health care profes-
 5 sionals and newborn screening laboratory personnel
 6 with—

7 “(1) education in newborn screening; and

8 “(2) training in—

9 “(A) relevant and new technologies in new-
 10 born screening; and

11 “(B) congenital, genetic, and metabolic
 12 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 with respect to newborn screening;
21 and

22 “(ii) take all necessary steps to mini-
23 mize the duplication of the resources and
24 programs described in clause (i) and en-
25 sure that funding under this section will

1 supplement, not supplant, existing funding
2 for such activities.

3 “(d) COORDINATION.—The Secretary shall take all
4 necessary steps to coordinate programs funded with
5 grants received under this section and to coordinate with
6 existing newborn screening activities.

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

15 “(1) continuing medical education programs for
16 health care professionals and newborn screening lab-
17 oratory personnel in newborn screening;

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

21 “(3) models to evaluate the prevalence of, and
22 assess and communicate the risks of, congenital con-
23 ditions, including the prevalence and risk of some of
24 these conditions based on family history;

1 “(4) models to communicate effectively with
2 parents and families about—

3 “(A) the process and benefits of newborn
4 screening and the meaning of screening results,
5 including the possibility of false positive find-
6 ings;

7 “(B) how to use information gathered from
8 newborn screening;

9 “(C) the right of refusal of newborn
10 screening, if applicable; and

11 “(D) the potential need for followup care
12 after newborns are screened;

13 “(5) information and resources on coordinated
14 systems of followup care after newborns are
15 screened;

16 “(6) information on the disorders for which
17 States require and offer newborn screening and op-
18 tions for newborn screening relating to conditions in
19 addition to such disorders;

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

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

1 “(f) REPORTS TO CONGRESS.—

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

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

8 “(i) in promoting newborn screening
9 education, resources, and training for
10 health care professionals;

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

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

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

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

22 “(i) education and training in new-
23 born screening; and

24 “(ii) followup care after newborns are
25 screened.

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

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

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

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

15 “(1) a State or a political subdivision of a
16 State;

17 “(2) a consortium of 2 or more States or polit-
18 ical subdivisions of States;

19 “(3) a territory;

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

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

1 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
2 are authorized to be appropriated to carry out this sec-
3 tion—

4 “(1) \$5,000,000 for fiscal year 2008; and

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

7 **SEC. 4. IMPROVED NEWBORN AND CHILD SCREENING FOR**
8 **HERITABLE DISORDERS.**

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

11 (1) in subsection (e)(2)—

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

14 (B) by redesignating subparagraph (F) as
15 subparagraph (G); and

16 (C) by inserting after subparagraph (E)
17 the following:

18 “(F) an assurance that the entity has
19 adopted and implemented, is in the process of
20 adopting and implementing, or will use grant
21 amounts received under this section to adopt
22 and implement the guidelines and recommenda-
23 tions of the Advisory Committee on Heritable
24 Disorders in Newborns and Children established
25 under section 1111 (referred to in this section

1 as the ‘Advisory Committee’) that are adopted
 2 by the Secretary and in effect at the time the
 3 grant is awarded or renewed under this section,
 4 which shall include the screening of each new-
 5 born for the heritable disorders recommended
 6 by the Advisory Committee and adopted by the
 7 Secretary and the reporting of results; and”;
 8 and

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

14 **SEC. 5. EVALUATING THE EFFECTIVENESS OF NEWBORN-**
 15 **AND CHILD-SCREENING PROGRAMS.**

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

19 “(d) **AUTHORIZATION OF APPROPRIATIONS.**—There
 20 are authorized to be appropriated to carry out this section
 21 \$5,000,000 for fiscal year 2008 and such sums as may
 22 be necessary for each of the fiscal years 2009 through
 23 2012.”.

1 **SEC. 6. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
2 **IN NEWBORNS AND CHILDREN.**

3 Section 1111 of the Public Health Service Act (42
4 U.S.C. 300b-10) is amended—

5 (1) in subsection (b)—

6 (A) in paragraph (1), by inserting “and
7 grants awarded under section 399Z-1” before
8 the semicolon;

9 (B) by redesignating paragraph (3) as
10 paragraph (6);

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

13 (D) by inserting after paragraph (2) the
14 following:

15 “(3) make systematic evidence-based and peer-
16 reviewed recommendations that include the heritable
17 disorders for which all newborns should be screened,
18 including secondary conditions that may be identi-
19 fied as a result of the laboratory methods used for
20 screening;

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

25 “(5) consider ways to ensure that States attain
26 the capacity to screen for the conditions described in

1 paragraph (3), and include in such consideration the
2 results of grant funding under section 1109; and”;

3 (E) in paragraph (6) (as so redesignated
4 by subparagraph (A)), by striking the period at
5 the end and inserting “, which may include rec-
6 ommendations, advice, or information dealing
7 with—

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

13 “(B) implementation, monitoring, and
14 evaluation of newborn screening activities, in-
15 cluding diagnosis, screening, follow-up, and
16 treatment activities;

17 “(C) diagnostic and other technology used
18 in screening;

19 “(D) the availability and reporting of test-
20 ing for conditions for which there is no existing
21 treatment;

22 “(E) conditions not included in the rec-
23 ommended uniform screening panel that are
24 treatable with Food and Drug Administration-
25 approved products;

1 “(F) minimum standards and related poli-
2 cies and procedures used by State newborn
3 screening programs, such as language and ter-
4 minology used by State newborn screening pro-
5 grams to include standardization of case defini-
6 tions and names of disorders for which newborn
7 screening tests are performed;

8 “(G) quality assurance, oversight, and
9 evaluation of State newborn screening pro-
10 grams, including ensuring that tests and tech-
11 nologies used by each State meet established
12 standards for detecting and reporting positive
13 screening results;

14 “(H) public and provider awareness and
15 education;

16 “(I) the cost and effectiveness of newborn
17 screening and medical evaluation systems and
18 intervention programs conducted by State-based
19 programs;

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

22 “(K) coordination of surveillance activities,
23 including standardized data collection and re-
24 porting; harmonization of laboratory definitions
25 for heritable disorders and testing results; and

1 confirmatory testing and verification of positive
 2 results, in order to assess and enhance moni-
 3 toring of newborn diseases.”; and

4 (2) in subsection (c)(2)—

5 (A) by redesignating subparagraphs (E),
 6 (F) and (G) as subparagraphs (F), (H), and
 7 (I);

8 (B) by inserting after subparagraph (D)
 9 the following:

10 “(E) the Commissioner of the Food and
 11 Drug Administration;”; and

12 (C) by inserting after subparagraph (F),
 13 as so redesignated, the following:

14 “(G) individuals with expertise in ethics
 15 who have worked and published material in the
 16 area of newborn screening;”; and

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

18 “(d) DECISION ON RECOMMENDATIONS.—

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

23 “(2) PENDING RECOMMENDATIONS.—The Sec-
 24 retary shall adopt or reject any recommendation
 25 issued by the Advisory Committee that is pending on

1 the date of enactment of the Newborn Screening
 2 Saves Lives Act of 2007 by not later than 180 days
 3 after the date of enactment of such Act.

4 ~~“(3) DETERMINATIONS TO BE MADE PUBLIC.—~~

5 The Secretary shall publicize any determination on
 6 adopting or rejecting a recommendation of the Advi-
 7 sory Committee pursuant to this subsection, includ-
 8 ing the justification for the determination.

9 ~~“(e) ANNUAL REPORT.—Not later than 2 years after~~
 10 the date of enactment of the Newborn Screening Saves
 11 Lives Act of 2007, and each fiscal year thereafter, the Ad-
 12 visory Committee shall—

13 ~~“(1) publish a report on peer-reviewed newborn~~
 14 screening guidelines in the United States;

15 ~~“(2) submit such report to the appropriate com-~~
 16 mittees of Congress, the Secretary, and the State de-
 17 partments of health; and

18 ~~“(3) disseminate such report on as wide a basis~~
 19 as practicable, including through posting on the
 20 internet clearinghouse established under section
 21 1112.

22 ~~“(f) CONTINUATION OF OPERATION OF COM-~~
 23 MITTEE.—Notwithstanding section 14 of the Federal Ad-
 24 visory Committee Act (5 U.S.C. App.), the Advisory Com-
 25 mittee shall continue to operate during the 5-year period

1 beginning on the date of enactment of the Newborn
2 Screening Saves Lives Act of 2007.

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

6 “(1) \$1,000,000 for fiscal year 2008; and

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

9 **SEC. 7. INFORMATION CLEARINGHOUSE.**

10 Part A of title XI of the Public Health Service Act
11 (42 U.S.C. 300b–1 et seq.) is amended by adding at the
12 end the following:

13 **“SEC. 1112. CLEARINGHOUSE OF NEWBORN SCREENING IN-**
14 **FORMATION.**

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

24 “(1) enable parents and family members of
25 newborns, health professionals, industry representa-

1 tives, and other members of the public to increase
2 their awareness, knowledge, and understanding of
3 newborn screening;

4 “(2) increase awareness, knowledge, and under-
5 standing of newborn diseases and screening services
6 for individuals wanting to have children and expect-
7 ant families; and

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

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

16 “(1) is available on the Internet;

17 “(2) includes an interactive forum;

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

20 “(4) provides—

21 “(A) links to Government-sponsored, non-
22 profit, and other Internet websites of labora-
23 tories as determined appropriate by the Sec-
24 retary that have demonstrated expertise in new-
25 born screening that supply research-based infor-

1 mation on newborn screening tests currently
2 available throughout the United States;

3 “(B) information about newborn conditions
4 and screening services available in each State
5 from laboratories certified under subpart 2 of
6 part F of title III, including information about
7 supplemental screening that is available but not
8 required, in the State where the infant is born;

9 “(C) current research on both treatable
10 and not-yet treatable conditions for which new-
11 born screening tests are available;

12 “(D) the availability of Federal funding for
13 newborn and child screening for heritable dis-
14 orders including grants authorized under the
15 Newborn Screening Saves Lives Act of 2007;
16 and

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

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

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

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

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

4 **SEC. 8. LABORATORY QUALITY AND SURVEILLANCE.**

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 7, is
7 further amended by adding at the end the following:

8 **“SEC. 1113. LABORATORY QUALITY.**

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

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

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

23 “(b) ~~AUTHORIZATION OF APPROPRIATIONS.~~—For the
24 purpose of carrying out this section, there are authorized
25 to be appropriated \$5,000,000 for fiscal year 2008 and

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

3 **“SEC. 1114. SURVEILLANCE PROGRAMS FOR HERITABLE**
4 **DISORDERS SCREENING.**

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

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

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

23 “(3) to provide information and education to
24 the public on effective interventions for the preven-

1 tion of poor health outcomes resulting from such dis-
2 orders; and

3 “(4) to conduct research on and to promote the
4 prevention of poor health outcomes resulting from
5 such disorders, and secondary health conditions
6 among individuals with such disorders.

7 “(b) GRANTS AND CONTRACTS.—

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

12 “(2) SUPPLIES AND SERVICES IN LIEU OF
13 AWARD FUNDS.—

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

24 “(B) REDUCTION.—With respect to a re-
25 quest described in subparagraph (A), the Sec-

1 retary shall reduce the amount of payments
2 under the award involved by an amount equal
3 to the costs of detailing personnel and the fair
4 market value of any supplies, equipment, or
5 services provided by the Secretary. The Sec-
6 retary shall, for the payment of expenses in-
7 curred in complying with such request, expend
8 the amounts withheld.

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

17 “(e) REPORTS TO CONGRESS.—

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

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

24 “(B) containing an assessment of the ex-
25 tent to which various approaches of preventing

1 heritable disorders and secondary health condi-
2 tions among individuals with such disorders
3 have been effective;

4 “(C) describing the activities carried out
5 under this section;

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

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

20 “(F) containing any recommendations of
21 the Secretary regarding this section.

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 later
6 than 60 months after the date on which the
7 first grant funds are awarded under this sec-
8 tion.

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

15 “(e) **COORDINATION.**—

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

21 “(2) **PRIORITY IN GRANTS AND CONTRACTS.**—
22 In making grants and contracts under this section,
23 the Secretary shall give priority to entities that dem-
24 onstrate the ability to coordinate activities under a

1 grant or contract made under this section with exist-
 2 ing birth defects surveillance activities.

3 “(f) AUTHORIZATION OF APPROPRIATIONS.—For the
 4 purpose of carrying out this section, there are authorized
 5 to be appropriated \$15,000,000 for fiscal year 2008 and
 6 such sums as may be necessary for each of the fiscal years
 7 2009 through 2012.”.

8 **SEC. 9. GRANTS.**

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

12 **“SEC. 1115. GRANTS.**

13 “(a) AUTHORIZATION OF GRANT PROGRAM.—

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

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

1 “(B) enable such entities to establish,
2 maintain, and operate a system to assess and
3 coordinate treatment relating to congenital, ge-
4 netic, and metabolic disorders.

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

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

15 “(c) SELECTION OF GRANT RECIPIENTS.—

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

21 “(2) APPROVAL FACTORS.—

22 “(A) REQUIREMENTS.—An application
23 submitted under subsection (b) may not be ap-
24 proved by the Secretary unless the application
25 contains assurances that the eligible 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 and coordinated systems of followup
16 care with respect to newborn screening;
17 and

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

24 “(d) COORDINATION.—The Secretary shall take all
25 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.—

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

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

12 “(i) what newborn screening is and
13 how it is performed;

14 “(ii) who performs newborn screening;

15 “(iii) where newborn screening is per-
16 formed;

17 “(iv) the disorders for which the State
18 requires newborns to be screened;

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

23 “(vi) the meaning of various screening
24 results, including the possibility of false
25 positive and false negative findings;

1 “~~(vii)~~ the prevalence and risk of new-
2 born disorders, including the increased risk
3 of disorders that may stem from family
4 history;

5 “~~(viii)~~ coordinated systems of followup
6 care after newborns are screened; and

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

10 “~~(B)~~ for purposes of grants under sub-
11 section (a)(1)(B), to—

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

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

1 creased risk of a disorder on a screening
2 test;

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

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

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

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

25 “(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 “(e) 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.”.

10 **SECTION 1. SHORT TITLE.**

11 *This Act may be cited as the “Newborn Screening*
12 *Saves Lives Act of 2007”.*

13 **SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING FOR**
14 **HERITABLE DISORDER.**

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

17 *(1) by striking subsections (a), (b), and (c) and*
18 *inserting the following:*

19 “(a) AUTHORIZATION OF GRANT PROGRAM.—From
20 amounts appropriated under subsection (j), the Secretary,
21 acting through the Administrator of the Health Resources
22 and Services Administration (referred to in this section as
23 the ‘Administrator’) and in consultation with the Advisory
24 Committee on Heritable Disorders in Newborns and Chil-
25 dren (referred to in this section as the ‘Advisory Com-

1 *mittee*'), shall award grants to eligible entities to enable
 2 such entities—

3 “(1) to enhance, improve or expand the ability
 4 of State and local public health agencies to provide
 5 screening, counseling, or health care services to
 6 newborns and children having or at risk for heritable
 7 disorders;

8 “(2) to assist in providing health care profes-
 9 sionals and newborn screening laboratory personnel
 10 with education in newborn screening and training in
 11 relevant and new technologies in newborn screening
 12 and congenital, genetic, and metabolic disorders;

13 “(3) to develop and deliver educational programs
 14 (at appropriate literacy levels) about newborn screen-
 15 ing counseling, testing, follow-up, treatment, and spe-
 16 cialty services to parents, families, and patient advo-
 17 cacy and support groups; and

18 “(4) to establish, maintain, and operate a system
 19 to assess and coordinate treatment relating to con-
 20 genital, genetic, and metabolic disorders

21 “(b) *ELIGIBLE ENTITY*.—In this section, the term ‘eli-
 22 gible entity’ means—

23 “(1) a State or a political subdivision of a State;

24 “(2) a consortium of 2 or more States or polit-
 25 ical subdivisions of States;

1 “(3) a territory;

2 “(4) a health facility or program operated by or
3 pursuant to a contract with or grant from the Indian
4 Health Service; or

5 “(5) any other entity with appropriate expertise
6 in newborn screening, as determined by the Secretary.

7 “(c) APPROVAL FACTORS.—An application submitted
8 for a grant under subsection (a)(1) shall not be approved
9 by the Secretary unless the application contains assurances
10 that the eligible entity has adopted and implemented, is in
11 the process of adopting and implementing, or will use
12 amounts received under such grant to adopt and implement
13 the guidelines and recommendations of the Advisory Com-
14 mittee that are adopted by the Secretary and in effect at
15 the time the grant is awarded or renewed under this section,
16 which shall include the screening of each newborn for the
17 heritable disorders recommended by the Advisory Com-
18 mittee and adopted by the Secretary.”;

19 (2) by redesignating subsections (d) through (i)
20 as subsections (e) through (j), respectively;

21 (3) by inserting after subsection (c), the fol-
22 lowing:

23 “(d) COORDINATION.—The Secretary shall take all nec-
24 essary steps to coordinate programs funded with grants re-

1 *ceived under this section and to coordinate with existing*
 2 *newborn screening activities.”; and*

3 *(4) by striking subsection (j) (as so redesignated)*
 4 *and inserting the following:*

5 *“(j) AUTHORIZATION OF APPROPRIATIONS.—There is*
 6 *authorized to be appropriated—*

7 *“(1) to provide grants for the purpose of car-*
 8 *rying activities under section (a)(1), \$15,000,000 for*
 9 *fiscal year 2008; \$15,187,500 for fiscal year 2009,*
 10 *\$15,375,000 for fiscal year 2010, \$15,562,500 for fis-*
 11 *cal year 2011, and \$15,750,000 for fiscal year 2012;*
 12 *and*

13 *“(2) to provide grant for the purpose of carrying*
 14 *out activities under paragraphs (2), (3), and (4) of*
 15 *subsection (a), \$15,000,000 for fiscal year 2008,*
 16 *\$15,187,500 for fiscal year 2009, \$15,375,000 for fis-*
 17 *cal year 2010, \$15,562,500 for fiscal year 2011, and*
 18 *\$15,750,000 for fiscal year 2012.”.*

19 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**
 20 **AND CHILD SCREENING PROGRAMS.**

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

24 *“(d) AUTHORIZATION OF APPROPRIATIONS.—There*
 25 *are authorized to be appropriated to carry out this section*

1 \$5,000,000 for fiscal year 2008, \$5,062,500 for fiscal year
2 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal
3 year 2011, and \$5,250,000 for fiscal year 2012.”.

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

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

8 (1) in subsection (b)—

9 (A) by redesignating paragraph (3) as
10 paragraph (6);

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

13 (C) by inserting after paragraph (2) the fol-
14 lowing:

15 “(3) make systematic evidence-based and peer-re-
16 viewed recommendations that include the heritable
17 disorders that have the potential to significantly im-
18 pact public health for which all newborns should be
19 screened, including secondary conditions that may be
20 identified as a result of the laboratory methods used
21 for screening;

22 “(4) develop a model decision-matrix for new-
23 born screening expansion, including an evaluation of
24 the potential public health impact of such expansion,
25 and periodically update the recommended uniform

1 *screening panel, as appropriate, based on such deci-*
2 *sion-matrix;*

3 *“(5) consider ways to ensure that all States at-*
4 *tain the capacity to screen for the conditions de-*
5 *scribed in paragraph (3), and include in such consid-*
6 *eration the results of grant funding under section*
7 *1109; and”;*

8 *(E) in paragraph (6) (as so redesignated by*
9 *subparagraph (A)), by striking the period at the*
10 *end and inserting “, which may include rec-*
11 *ommendations, advice, or information dealing*
12 *with—*

13 *“(A) follow-up activities, including those*
14 *necessary to achieve rapid diagnosis in the short-*
15 *term, and those that ascertain long-term case*
16 *management outcomes and appropriate access to*
17 *related services;*

18 *“(B) implementation, monitoring, and eval-*
19 *uation of newborn screening activities, including*
20 *diagnosis, screening, follow-up, and treatment*
21 *activities;*

22 *“(C) diagnostic and other technology used*
23 *in screening;*

1 “(D) the availability and reporting of test-
2 ing for conditions for which there is no existing
3 treatment;

4 “(E) conditions not included in the rec-
5 ommended uniform screening panel that are
6 treatable with Food and Drug Administration-
7 approved products or other safe and effective
8 treatments, as determined by scientific evidence
9 and peer review;

10 “(F) minimum standards and related poli-
11 cies and procedures used by State newborn
12 screening programs, such as language and termi-
13 nology used by State newborn screening pro-
14 grams to include standardization of case defini-
15 tions and names of disorders for which newborn
16 screening tests are performed;

17 “(G) quality assurance, oversight, and eval-
18 uation of State newborn screening programs, in-
19 cluding ensuring that tests and technologies used
20 by each State meet established standards for de-
21 tecting and reporting positive screening results;

22 “(H) public and provider awareness and
23 education;

24 “(I) the cost and effectiveness of newborn
25 screening and medical evaluation systems and

1 *intervention programs conducted by State-based*
2 *programs;*

3 *“(J) identification of the causes of, public*
4 *health impacts of, and risk factors for heritable*
5 *disorders; and*

6 *“(K) coordination of surveillance activities,*
7 *including standardized data collection and re-*
8 *porting, harmonization of laboratory definitions*
9 *for heritable disorders and testing results, and*
10 *confirmatory testing and verification of positive*
11 *results, in order to assess and enhance moni-*
12 *toring of newborn diseases.”; and*

13 *(2) in subsection (c)(2)—*

14 *(A) by redesignating subparagraphs (E),*
15 *(F) and (G) as subparagraphs (F), (H), and (I);*

16 *(B) by inserting after subparagraph (D) the*
17 *following:*

18 *“(E) the Commissioner of the Food and*
19 *Drug Administration;”; and*

20 *(C) by inserting after subparagraph (F), as*
21 *so redesignated, the following:*

22 *“(G) individuals with expertise in ethics*
23 *and infectious diseases who have worked and*
24 *published material in the area of newborn*
25 *screening;”; and*

1 (3) *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 Saves*
11 *Lives Act of 2007 by not later than 180 days after*
12 *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, including*
17 *the justification for the determination.*

18 “(e) *ANNUAL REPORT.—Not later than 3 years after*
19 *the date of enactment of the Newborn Screening Saves Lives*
20 *Act of 2007, and each fiscal year thereafter, the Advisory*
21 *Committee shall—*

22 “(1) *publish a report on peer-reviewed newborn*
23 *screening guidelines, including follow-up and treat-*
24 *ment, in the United States;*

1 *istration (referred to in this part as the ‘Administrator’),*
2 *in consultation with the Director of the Centers for Disease*
3 *Control and Prevention and the Director of the National*
4 *Institutes of Health, shall establish and maintain a central*
5 *clearinghouse of current educational and family support*
6 *and services information, materials, resources, research,*
7 *and data on newborn screening to—*

8 “(1) *enable parents and family members of*
9 *newborns, health professionals, industry representa-*
10 *tives, and other members of the public to increase*
11 *their awareness, knowledge, and understanding of*
12 *newborn screening;*

13 “(2) *increase awareness, knowledge, and under-*
14 *standing of newborn diseases and screening services*
15 *for expectant individuals and families; and*

16 “(3) *maintain current data on quality indica-*
17 *tors to measure performance of newborn screening,*
18 *such as false-positive rates and other quality indica-*
19 *tors as determined by the Advisory Committee under*
20 *section 1111.*

21 “(b) *INTERNET AVAILABILITY.—The Secretary, acting*
22 *through the Administrator, shall ensure that the clearing-*
23 *house described under subsection (a)—*

24 “(1) *is available on the Internet;*

25 “(2) *includes an interactive forum;*

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

3 “(4) provides—

4 “(A) links to Government-sponsored, non-
5 profit, and other Internet websites of laboratories
6 that have demonstrated expertise in newborn
7 screening that supply research-based information
8 on newborn screening tests currently available
9 throughout the United States;

10 “(B) information about newborn conditions
11 and screening services available in each State
12 from laboratories certified under subpart 2 of
13 part F of title III, including information about
14 supplemental screening that is available but not
15 required, in the State where the infant is born;

16 “(C) current research on both treatable and
17 not-yet treatable conditions for which newborn
18 screening tests are available;

19 “(D) the availability of Federal funding for
20 newborn and child screening for heritable dis-
21 orders including grants authorized under the
22 Newborn Screening Saves Lives Act of 2007; and

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

1 “(c) *NONDUPLICATION.*—*In developing the clearing-*
 2 *house under this section, the Secretary shall ensure that*
 3 *such clearinghouse minimizes duplication and supplements,*
 4 *not supplants, existing information sharing efforts.*

5 “(d) *AUTHORIZATION OF APPROPRIATIONS.*—*There*
 6 *are authorized to be appropriated to carry out this section,*
 7 *\$2,500,000 for fiscal year 2008, \$2,531,250 for fiscal year*
 8 *2009, \$2,562,500 for fiscal year 2010, \$2,593,750 for fiscal*
 9 *year 2011, and \$2,625,000 for fiscal year 2012.”.*

10 **SEC. 6. LABORATORY QUALITY AND SURVEILLANCE.**

11 *Part A of title XI of the Public Health Service Act*
 12 *(42 U.S.C. 300b–1 et seq.), as amended by section 5, is fur-*
 13 *ther amended by adding at the end the following:*

14 **“SEC. 1113. LABORATORY QUALITY.**

15 “(a) *IN GENERAL.*—*The Secretary, acting through the*
 16 *Director of the Centers for Disease Control and Prevention*
 17 *and in consultation with the Advisory Committee on Heri-*
 18 *table Disorders in Newborns and Children established under*
 19 *section 1111, shall provide for—*

20 “(1) *quality assurance for laboratories involved*
 21 *in screening newborns and children for heritable dis-*
 22 *orders, including quality assurance for newborn-*
 23 *screening tests, performance evaluation services, and*
 24 *technical assistance and technology transfer to new-*

1 *born screening laboratories to ensure analytic validity*
2 *and utility of screening tests; and*

3 *“(2) appropriate quality control and other per-*
4 *formance test materials to evaluate the performance of*
5 *new screening tools.*

6 *“(b) AUTHORIZATION OF APPROPRIATIONS.—For the*
7 *purpose of carrying out this section, there are authorized*
8 *to be appropriated \$5,000,000 for fiscal year 2008,*
9 *\$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year*
10 *2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for*
11 *fiscal year 2012.*

12 **“SEC. 1114. SURVEILLANCE PROGRAMS FOR HERITABLE**
13 **DISORDERS SCREENING.**

14 *“(a) IN GENERAL.—The Secretary, acting through an*
15 *Interagency Group consisting of the Director of the Agency*
16 *for Healthcare Research and Quality, the Director of the*
17 *Centers for Disease Control and Prevention, the Adminis-*
18 *trator, and the Director of the National Institutes of Health,*
19 *shall build upon existing activities and infrastructure to*
20 *carry out programs—*

21 *“(1) to collect, analyze, and make available data*
22 *on the heritable disorders recommended by the Advi-*
23 *sory Committee on Heritable Disorders in Newborns*
24 *and Children established under section 1111, includ-*
25 *ing data on the incidence and prevalence of, as well*

1 *as poor health outcomes resulting from, such dis-*
2 *orders;*

3 “(2) *to identify regional centers for the conduct*
4 *of applied epidemiological research on effective inter-*
5 *ventions for such disorders for the prevention of poor*
6 *health outcomes;*

7 “(3) *to provide information and education to the*
8 *public on effective interventions for the prevention of*
9 *poor health outcomes resulting from such disorders;*
10 *and*

11 “(4) *to conduct research on and to promote the*
12 *prevention of poor health outcomes resulting from*
13 *such disorders, and secondary health conditions*
14 *among individuals with such disorders.*

15 “(b) *GRANTS AND CONTRACTS.—*

16 “(1) *IN GENERAL.—In carrying out subsection*
17 *(a), the Secretary may make grants to and enter into*
18 *contracts with public and nonprofit private entities.*

19 “(2) *SUPPLIES AND SERVICES IN LIEU OF*
20 *AWARD FUNDS.—*

21 “(A) *IN GENERAL.—Upon the request of a*
22 *recipient of an award of a grant or contract*
23 *under paragraph (1), the Secretary may, subject*
24 *to subparagraph (B), provide supplies, equip-*
25 *ment, and services for the purpose of aiding the*

1 *recipient in carrying out the purposes for which*
2 *the award is made and, for such purposes, may*
3 *detail to the recipient any officer or employee of*
4 *the Department of Health and Human Services.*

5 “(B) *REDUCTION.*—*With respect to a re-*
6 *quest described in subparagraph (A), the Sec-*
7 *retary shall reduce the amount of payments*
8 *under the award involved by an amount equal to*
9 *the costs of detailing personnel and the fair mar-*
10 *ket value of any supplies, equipment, or services*
11 *provided by the Secretary. The Secretary shall,*
12 *for the payment of expenses incurred in com-*
13 *plying with such request, expend the amounts*
14 *withheld.*

15 “(3) *APPLICATION FOR AWARD.*—*The Secretary*
16 *may make an award of a grant or contract under*
17 *paragraph (1) only if an application for the award*
18 *is submitted to the Secretary and the application is*
19 *in such form, is made in such manner, and contains*
20 *such agreements, assurances, and information as the*
21 *Secretary determines to be necessary to carry out the*
22 *purposes for which the award is to be made.*

23 “(c) *REPORTS TO CONGRESS.*—

1 “(1) *IN GENERAL.*—Subject to paragraph (2), the
2 Secretary shall submit to the relevant committees of
3 Congress reports—

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

7 “(B) containing an assessment of the extent
8 to which various approaches of preventing heri-
9 table disorders and secondary health conditions
10 among individuals with such disorders have been
11 effective;

12 “(C) describing the activities carried out
13 under this section;

14 “(D) containing information on the inci-
15 dence and prevalence of individuals living with
16 heritable disorders, information on the health
17 status of individuals with such disorders includ-
18 ing the extent to which such disorders have con-
19 tributed to the incidence and prevalence of infant
20 mortality, information on any health disparities
21 experienced by such individuals, and rec-
22 ommendations for improving the health and
23 wellness and quality of life of such individuals;

24 “(E) containing a summary of rec-
25 ommendations from all heritable disorders re-

1 *search conferences sponsored by the Centers for*
2 *Disease Control and Prevention or the National*
3 *Institutes of Health; and*

4 “(F) *containing any recommendations of*
5 *the Secretary regarding this section.*

6 “(2) *TIMING OF REPORTS.—The Secretary shall*
7 *submit—*

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

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

16 “(d) *COORDINATION.—*

17 “(1) *IN GENERAL.—In carrying out this section,*
18 *the Secretary shall coordinate, to the extent prac-*
19 *ticable, programs under this section with programs on*
20 *birth defects and developmental disabilities authorized*
21 *under section 317C.*

22 “(2) *PRIORITY IN GRANTS AND CONTRACTS.—In*
23 *making grants and contracts under this section, the*
24 *Secretary shall give priority to entities that dem-*
25 *onstrate the ability to coordinate activities under a*

1 “(2) the shipment of specimens to State newborn
2 screening laboratories;

3 “(3) the processing of specimens;

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

6 “(5) the diagnostic confirmation of positive
7 screening results;

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

10 “(7) educating families about newborn screening;
11 and

12 “(8) carrying out other activities determined ap-
13 propriate by the Secretary.

14 **“SEC. 1116. HUNTER KELLY RESEARCH PROGRAM.**

15 “(a) NEWBORN SCREENING ACTIVITIES.—

16 “(1) IN GENERAL.—The Secretary, in conjunc-
17 tion with the Director of the National Institutes of
18 Health and taking into consideration the rec-
19 ommendations of the Advisory Committee, may con-
20 tinue carrying out, coordinating, and expanding re-
21 search in newborn screening (to be known as ‘Hunter
22 Kelly Newborn Screening Research Program’) includ-
23 ing—

24 “(A) identifying, developing, and testing the
25 most promising new screening technologies, in

1 *order to improve already existing screening tests,*
 2 *increase the specificity of newborn screening, and*
 3 *expand the number of conditions for which*
 4 *screening tests are available;*

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

11 “(C) *other activities that would improve*
 12 *newborn screening, as identified by the Director.*

13 “(2) *ADDITIONAL NEWBORN CONDITION.—For*
 14 *purposes of this subsection, the term ‘additional new-*
 15 *born condition’ means any condition that is not one*
 16 *of the core conditions recommended by the Advisory*
 17 *Committee and adopted by the Secretary.*

18 “(b) *FUNDING.—In carrying out the research program*
 19 *under this section, the Secretary and the Director shall en-*
 20 *sure that entities receiving funding through the program*
 21 *will provide assurances, as practicable, that such entities*
 22 *will work in consultation with the appropriate State de-*
 23 *partments of health, and, as practicable, focus their research*
 24 *on screening technology not currently performed in the*
 25 *States in which the entities are located, and the conditions*

1 *on the uniform screening panel (or the standard test exist-*
2 *ing on the uniform screening panel).*

3 “(c) *REPORTS.*—*The Director is encouraged to include*
4 *information about the activities carried out under this sec-*
5 *tion in the biennial report required under section 403 of*
6 *the National Institutes of Health Reform Act of 2006. If*
7 *such information is included, the Director shall make such*
8 *information available to be included on the Internet Clear-*
9 *inghouse established under section 1112.*

10 “(d) *NONDUPLICATION.*—*In carrying out programs*
11 *under this section, the Secretary shall minimize duplication*
12 *and supplement, not supplant, existing efforts of the type*
13 *carried out under this section.*

14 “(e) *PEER REVIEW.*—*Nothing in this section shall be*
15 *construed to interfere with the scientific peer-review process*
16 *at the National Institutes of Health.”*

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110TH CONGRESS
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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.

DECEMBER 5, 2007

Reported with an amendment