

110TH CONGRESS  
1ST SESSION

# S. 1858

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IN THE HOUSE OF REPRESENTATIVES

DECEMBER 17, 2007

Referred to the Committee on Energy and Commerce

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## AN ACT

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. IMPROVED NEWBORN AND CHILD SCREENING FOR**  
7 **HERITABLE DISORDER.**

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

10           (1) by striking subsections (a), (b), and (c) and  
11       inserting the following:

12       “(a) **AUTHORIZATION OF GRANT PROGRAM.**—From  
13 amounts appropriated under subsection (j), the Secretary,  
14 acting through the Administrator of the Health Resources  
15 and Services Administration (referred to in this section  
16 as the ‘Administrator’) and in consultation with the Advi-  
17 sory Committee on Heritable Disorders in Newborns and  
18 Children (referred to in this section as the ‘Advisory Com-  
19 mittee’), shall award grants to eligible entities to enable  
20 such entities—

21           “(1) to enhance, improve or expand the ability  
22       of State and local public health agencies to provide  
23       screening, counseling, or health care services to  
24       newborns and children having or at risk for heritable  
25       disorders;

1           “(2) to assist in providing health care profes-  
2           sionals and newborn screening laboratory personnel  
3           with education in newborn screening and training in  
4           relevant and new technologies in newborn screening  
5           and congenital, genetic, and metabolic disorders;

6           “(3) to develop and deliver educational pro-  
7           grams (at appropriate literacy levels) about newborn  
8           screening counseling, testing, follow-up, treatment,  
9           and specialty services to parents, families, and pa-  
10          tient advocacy and support groups; and

11          “(4) to establish, maintain, and operate a sys-  
12          tem to assess and coordinate treatment relating to  
13          congenital, genetic, and metabolic disorders.

14          “(b) ELIGIBLE ENTITY.—In this section, the term  
15          ‘eligible entity’ means—

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

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

20                 “(3) a territory;

21                 “(4) a health facility or program operated by or  
22                 pursuant to a contract with or grant from the In-  
23                 dian Health Service; or

1           “(5) any other entity with appropriate expertise  
2           in newborn screening, as determined by the Sec-  
3           retary.

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

16                 (2) by redesignating subsections (d) through (i)  
17                 as subsections (e) through (j), respectively;

18                 (3) by inserting after subsection (c), the fol-  
19                 lowing:

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.”; and

24                 (4) by striking subsection (j) (as so redesign-  
25                 ated) and inserting the following:

1 “(j) AUTHORIZATION OF APPROPRIATIONS.—There  
2 is authorized to be appropriated—

3 “(1) to provide grants for the purpose of car-  
4 rying activities under section (a)(1), \$15,000,000 for  
5 fiscal year 2008; \$15,187,500 for fiscal year 2009,  
6 \$15,375,000 for fiscal year 2010, \$15,562,500 for  
7 fiscal year 2011, and \$15,750,000 for fiscal year  
8 2012; and

9 “(2) to provide grant for the purpose of car-  
10 rying out activities under paragraphs (2), (3), and  
11 (4) of subsection (a), \$15,000,000 for fiscal year  
12 2008, \$15,187,500 for fiscal year 2009,  
13 \$15,375,000 for fiscal year 2010, \$15,562,500 for  
14 fiscal year 2011, and \$15,750,000 for fiscal year  
15 2012.”.

16 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**  
17 **AND CHILD SCREENING PROGRAMS.**

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

21 “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
22 are authorized to be appropriated to carry out this section  
23 \$5,000,000 for fiscal year 2008, \$5,062,500 for fiscal year  
24 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fis-  
25 cal year 2011, and \$5,250,000 for fiscal year 2012.”.

1 **SEC. 4. 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) by redesignating paragraph (3) as  
7 paragraph (6);

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

10 (C) by inserting after paragraph (2) the  
11 following:

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

19 “(4) develop a model decision-matrix for new-  
20 born screening expansion, including an evaluation of  
21 the potential public health impact of such expansion,  
22 and periodically update the recommended uniform  
23 screening panel, as appropriate, based on such deci-  
24 sion-matrix;

25 “(5) consider ways to ensure that all States at-  
26 tain the capacity to screen for the conditions de-

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

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

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

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

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

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

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

1 approved products or other safe and effective  
2 treatments, as determined by scientific evidence  
3 and peer review;

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

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

17 “(H) public and provider awareness and  
18 education;

19 “(I) the cost and effectiveness of newborn  
20 screening and medical evaluation systems and  
21 intervention programs conducted by State-based  
22 programs;

23 “(J) identification of the causes of, public  
24 health impacts of, and risk factors for heritable  
25 disorders; and

1           “(K) coordination of surveillance activities,  
2 including standardized data collection and re-  
3 porting, harmonization of laboratory definitions  
4 for heritable disorders and testing results, and  
5 confirmatory testing and verification of positive  
6 results, in order to assess and enhance moni-  
7 toring of newborn diseases.”; and

8 (2) in subsection (c)(2)—

9           (A) by redesignating subparagraphs (E),  
10 (F) and (G) as subparagraphs (F), (H), and  
11 (I);

12           (B) by inserting after subparagraph (D)  
13 the following:

14           “(E) the Commissioner of the Food and  
15 Drug Administration;”; and

16           (C) by inserting after subparagraph (F),  
17 as so redesignated, the following:

18           “(G) individuals with expertise in ethics  
19 and infectious diseases who have worked and  
20 published material in the area of newborn  
21 screening;”; and

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

23           “(d) DECISION ON RECOMMENDATIONS.—

24           “(1) IN GENERAL.—Not later than 180 days  
25 after the Advisory Committee issues a recommenda-

1       tion pursuant to this section, the Secretary shall  
2       adopt or reject such recommendation.

3               “(2) PENDING RECOMMENDATIONS.—The Sec-  
4       retary shall adopt or reject any recommendation  
5       issued by the Advisory Committee that is pending on  
6       the date of enactment of the Newborn Screening  
7       Saves Lives Act of 2007 by not later than 180 days  
8       after the date of enactment of such Act.

9               “(3) DETERMINATIONS TO BE MADE PUBLIC.—  
10      The Secretary shall publicize any determination on  
11      adopting or rejecting a recommendation of the Advi-  
12      sory Committee pursuant to this subsection, includ-  
13      ing the justification for the determination.

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

18              “(1) publish a report on peer-reviewed newborn  
19      screening guidelines, including follow-up and treat-  
20      ment, in the United States;

21              “(2) submit such report to the appropriate com-  
22      mittees of Congress, the Secretary, the Interagency  
23      Coordinating Committee established under Section  
24      1114, and the State departments of health; and



1 for Disease Control and Prevention and the Director of  
2 the National Institutes of Health, shall establish and  
3 maintain a central clearinghouse of current educational  
4 and family support and services information, materials, re-  
5 sources, research, and data on newborn screening to—

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

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

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

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

22           “(1) is available on the Internet;

23           “(2) includes an interactive forum;

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

1 “(4) provides—

2 “(A) links to Government-sponsored, non-  
3 profit, and other Internet websites of labora-  
4 tories that have demonstrated expertise in new-  
5 born screening that supply research-based infor-  
6 mation on newborn screening tests currently  
7 available throughout the United States;

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

14 “(C) current research on both treatable  
15 and not-yet treatable conditions for which new-  
16 born screening tests are available;

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

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

24 “(c) NONDUPLICATION.—In developing the clearing-  
25 house under this section, the Secretary shall ensure that

1 such clearinghouse minimizes duplication and supple-  
 2 ments, not supplants, existing information sharing efforts.

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

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

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 5, is  
 11 further amended by adding at the end the following:

12 **“SEC. 1113. LABORATORY QUALITY.**

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

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

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

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

10   **“SEC. 1114. INTERAGENCY COORDINATING COMMITTEE ON**  
11                                   **NEWBORN AND CHILD SCREENING.**

12           “(a) PURPOSE.—It is the purpose of this section to—

13                   “(1) assess existing activities and infrastruc-  
14                   ture, including activities on birth defects and devel-  
15                   opmental disabilities authorized under section 317C,  
16                   in order to make recommendations for programs to  
17                   collect, analyze, and make available data on the heri-  
18                   table disorders recommended by the Advisory Com-  
19                   mittee on Heritable Disorders in Newborns and  
20                   Children under section 1111, including data on the  
21                   incidence and prevalence of, as well as poor health  
22                   outcomes resulting from, such disorders; and

23                   “(2) make recommendations for the establish-  
24                   ment of regional centers for the conduct of applied  
25                   epidemiological research on effective interventions to

1 promote the prevention of poor health outcomes re-  
2 sulting from such disorders as well as providing in-  
3 formation and education to the public on such effec-  
4 tive interventions.

5 “(b) ESTABLISHMENT.—The Secretary shall estab-  
6 lish an Interagency Coordinating Committee on Newborn  
7 and Child Screening (referred to in this section as the  
8 ‘Interagency Coordinating Committee’) to carry out the  
9 purpose of this section.

10 “(c) COMPOSITION.—The Interagency Coordinating  
11 Committee shall be composed of the Director of the Cen-  
12 ters for Disease Control and Prevention, the Adminis-  
13 trator, the Director of the Agency for Healthcare Research  
14 and Quality, and the Director of the National Institutes  
15 of Health, or their designees.

16 “(d) ACTIVITIES.—The Interagency Coordinating  
17 Committee shall—

18 “(1) report to the Secretary and the appro-  
19 priate committees of Congress on its recommenda-  
20 tions related to the purpose described in subsection  
21 (a); and

22 “(2) carry out other activities determined ap-  
23 propriate by the Secretary.

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

1 to be appropriated \$1,000,000 for fiscal year 2008,  
2 \$1,012,500 for fiscal year 2009, \$1,025,000 for fiscal year  
3 2010, \$1,037,500 for fiscal year 2011, and \$1,050,000  
4 for fiscal year 2012.”.

5 **SEC. 7. CONTINGENCY PLANNING.**

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

9 **“SEC. 1115. NATIONAL CONTINGENCY PLAN FOR NEWBORN**  
10 **SCREENING.**

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

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

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

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

24 “(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. 1116. HUNTER KELLY RESEARCH PROGRAM.**

12          “(a) NEWBORN SCREENING ACTIVITIES.—

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

21           “(A) identifying, developing, and testing  
22          the most promising new screening technologies,  
23          in order to improve already existing screening  
24          tests, increase the specificity of newborn screen-

1           ing, and expand the number of conditions for  
2           which screening tests are available;

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

9           “(C) other activities that would improve  
10          newborn screening, as identified by the Direc-  
11          tor.

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

17          “(b) FUNDING.—In carrying out the research pro-  
18          gram under this section, the Secretary and the Director  
19          shall ensure that entities receiving funding through the  
20          program will provide assurances, as practicable, that such  
21          entities will work in consultation with the appropriate  
22          State departments of health, and, as practicable, focus  
23          their research on screening technology not currently per-  
24          formed in the States in which the entities are located, and

1 the conditions on the uniform screening panel (or the  
2 standard test existing on the uniform screening panel).

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

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

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

Passed the Senate December 13, 2007.

Attest:

NANCY ERICKSON,

*Secretary.*