

# Union Calendar No. 352

110TH CONGRESS  
2D SESSION

# H. R. 3825

[Report No. 110-570]

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.

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 15, 2007

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

APRIL 8, 2008

Additional sponsors: Mrs. MCCARTHY of New York, Ms. BALDWIN, Mr. RUSH, Ms. MATSUI, Mr. ROTHMAN, Ms. ESHOO, Mr. PEARCE, Mr. TOWNS, Mr. RAMSTAD, Mr. SCHIFF, Ms. SCHAKOWSKY, Mr. SPRATT, Mr. FATTAH, Mr. GORDON of Tennessee, Mr. McNULTY, Mr. PASTOR, Mr. LARSON of Connecticut, Mr. ARCURI, Mr. HINOJOSA, Mr. COHEN, Mr. LANGEVIN, Mr. ABERCROMBIE, Ms. DEGETTE, Mr. HIGGINS, Mr. SHAYS, Mr. ENGEL, Mr. GENE GREEN of Texas, Mrs. TAUSCHER, Mr. ALLEN, Mr. GRIJALVA, Mr. GONZALEZ, Ms. HERSETH SANDLIN, Mr. SIRES, Mr. BOUCHER, Mrs. CAPPS, Mr. BACA, Mrs. NAPOLITANO, Mr. ORTIZ, Mr. SALAZAR, Mr. LAMPSON, Ms. SOLIS, Ms. VELÁZQUEZ, Mr. RODRIGUEZ, Mr. CARDOZA, Mr. BECERRA, Mr. STARK, Ms. LORETTA SANCHEZ of California, Mr. CUELLAR, Mr. GUTIERREZ, Mr. SERRANO, Ms. LINDA T. SÁNCHEZ of California, Ms. DELAURO, Mrs. LOWEY, Ms. LEE, Mr. JACKSON of Illinois, Mr. KENNEDY, Mr. HONDA, Mr. RYAN of Ohio, Ms. WASSERMAN SCHULTZ, Ms. BERKLEY, Ms. RICHARDSON, Mr. HASTINGS of Florida, Mr. HINCHEY, Mr. BERRY, Mr. DUNCAN, Mr. BURGESS, Mr. FOSSELLA, Ms. PRYCE of Ohio, Mrs. CAPITO, Mr. MCHUGH, Mr. JOHNSON of Georgia, Mr. FILNER, Mr. DAVIS of Illinois, Ms. GRANGER, Mr. TIM MURPHY of Pennsylvania, Ms. HIRONO, Mr. MOORE of Kansas, and Mr. LEWIS of Georgia



1 *and Services Administration (referred to in this section as*  
2 *the ‘Administrator’) and in consultation with the Advisory*  
3 *Committee on Heritable Disorders in Newborns and Chil-*  
4 *dren (referred to in this section as the ‘Advisory Com-*  
5 *mittee’), shall award grants to eligible entities to enable*  
6 *such entities—*

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

12           “(2) to assist in providing health care profes-  
13          sionals and newborn screening laboratory personnel  
14          with education in newborn screening and training in  
15          relevant and new technologies in newborn screening  
16          and congenital, genetic, and metabolic disorders;

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

22           “(4) to establish, maintain, and operate a system  
23          to assess and coordinate treatment relating to con-  
24          genital, genetic, and metabolic disorders.

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

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

4                   “(2) a consortium of 2 or more States or polit-  
5 *ical subdivisions of States;*

6                   “(3) a territory;

7                   “(4) a health facility or program operated by or  
8 *pursuant to a contract with or grant from the Indian*  
9 *Health Service; or*

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

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

24                   (2) *by redesignating subsections (d) through (i)*  
25 *as subsections (e) through (j), respectively;*

1           (3) by inserting after subsection (c), the fol-  
2           lowing:

3           “(d) *COORDINATION.*—*The Secretary shall take all nec-*  
4           *essary steps to coordinate programs funded with grants re-*  
5           *ceived under this section and to coordinate with existing*  
6           *newborn screening activities.*”; and

7           (4) by striking subsection (j) (as so redesignated)  
8           and inserting the following:

9           “(j) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*  
10          *authorized to be appropriated—*

11           “(1) to provide grants for the purpose of car-  
12          rying out activities under subsection (a)(1),  
13          \$15,000,000 for fiscal year 2009, \$15,187,500 for fis-  
14          cal year 2010, \$15,375,000 for fiscal year 2011,  
15          \$15,562,500 for fiscal year 2012, and \$15,750,000 for  
16          fiscal year 2013; and

17           “(2) to provide grants for the purpose of car-  
18          rying out activities under paragraphs (2), (3), and  
19          (4) of subsection (a), \$15,000,000 for fiscal year 2009,  
20          \$15,187,500 for fiscal year 2010, \$15,375,000 for fis-  
21          cal year 2011, \$15,562,500 for fiscal year 2012, and  
22          \$15,750,000 for fiscal year 2013.”.

1 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**  
2 **AND CHILD SCREENING PROGRAMS.**

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

6 “(d) *AUTHORIZATION OF APPROPRIATIONS.—There*  
7 *are authorized to be appropriated to carry out this section*  
8 *\$5,000,000 for fiscal year 2009, \$5,062,500 for fiscal year*  
9 *2010, \$5,125,000 for fiscal year 2011, \$5,187,500 for fiscal*  
10 *year 2012, and \$5,250,000 for fiscal year 2013.”.*

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

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

15 *(1) in subsection (b)—*

16 *(A) by redesignating paragraph (3) as*  
17 *paragraph (6);*

18 *(B) in paragraph (2), by striking “and”*  
19 *after the semicolon;*

20 *(C) by inserting after paragraph (2) the fol-*  
21 *lowing:*

22 *“(3) make systematic evidence-based and peer-re-*  
23 *viewed recommendations that include the heritable*  
24 *disorders that have the potential to significantly im-*  
25 *pect public health for which all newborns should be*  
26 *screened, including secondary conditions that may be*

1       *identified as a result of the laboratory methods used*  
2       *for screening;*

3               “(4) develop a model decision-matrix for new-  
4       *born screening expansion, including an evaluation of*  
5       *the potential public health impact of such expansion,*  
6       *and periodically update the recommended uniform*  
7       *screening panel, as appropriate, based on such deci-*  
8       *sion-matrix;*

9               “(5) consider ways to ensure that all States at-  
10       *tain the capacity to screen for the conditions de-*  
11       *scribed in paragraph (3), and include in such consid-*  
12       *eration the results of grant funding under section*  
13       *1109; and”;*

14               (D) in paragraph (6) (as so redesignated by  
15       *subparagraph (A)), by striking the period at the*  
16       *end and inserting “, which may include rec-*  
17       *ommendations, advice, or information dealing*  
18       *with—*

19               “(A) follow-up activities, including those  
20       *necessary to achieve rapid diagnosis in the short-*  
21       *term, and those that ascertain long-term case*  
22       *management outcomes and appropriate access to*  
23       *related services;*

24               “(B) implementation, monitoring, and eval-  
25       *uation of newborn screening activities, including*

1           *diagnosis, screening, follow-up, and treatment*  
2           *activities;*

3           “(C) *diagnostic and other technology used*  
4           *in screening;*

5           “(D) *the availability and reporting of test-*  
6           *ing for conditions for which there is no existing*  
7           *treatment;*

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

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

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



1           “(H) public and provider awareness and  
2           education;

3           “(I) the cost and effectiveness of newborn  
4           screening and medical evaluation systems and  
5           intervention programs conducted by State-based  
6           programs;

7           “(J) identification of the causes of, public  
8           health impacts of, and risk factors for heritable  
9           disorders; and

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

17           (2) in subsection (c)(2)—

18           (A) by redesignating subparagraphs (E),  
19           (F), and (G) as subparagraphs (F), (H), and (I),  
20           respectively;

21           (B) by inserting after subparagraph (D) the  
22           following:

23           “(E) the Commissioner of the Food and  
24           Drug Administration;”; and

1           (C) by inserting after subparagraph (F), as  
2           so redesignated, the following:

3           “(G) individuals with expertise in ethics  
4           and infectious diseases who have worked and  
5           published material in the area of newborn  
6           screening;” and

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

8           “(d) *DECISION ON RECOMMENDATIONS.*—

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

13          “(2) *PENDING RECOMMENDATIONS.*—The Sec-  
14          retary shall adopt or reject any recommendation  
15          issued by the Advisory Committee that is pending on  
16          the date of enactment of the Newborn Screening Saves  
17          Lives Act of 2008 by not later than 180 days after  
18          the date of enactment of such Act.

19          “(3) *DETERMINATIONS TO BE MADE PUBLIC.*—  
20          The Secretary shall publicize any determination on  
21          adopting or rejecting a recommendation of the Advi-  
22          sory Committee pursuant to this subsection, including  
23          the justification for the determination.

24          “(e) *ANNUAL REPORT.*—Not later than 3 years after  
25          the date of enactment of the Newborn Screening Saves Lives

1 *Act of 2008, and each fiscal year thereafter, the Advisory*  
2 *Committee shall—*

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

6           “(2) *submit such report to the appropriate com-*  
7 *mittees of Congress, the Secretary, the Interagency*  
8 *Coordinating Committee established under Section*  
9 *1114, and the State departments of health; and*

10           “(3) *disseminate such report on as wide a basis*  
11 *as practicable, including through posting on the inter-*  
12 *net clearinghouse established under section 1112.*

13           “(f) *CONTINUATION OF OPERATION OF COMMITTEE.—*  
14 *Notwithstanding section 14 of the Federal Advisory Com-*  
15 *mittee Act (5 U.S.C. App.), the Advisory Committee shall*  
16 *continue to operate during the 5-year period beginning on*  
17 *the date of enactment of the Newborn Screening Saves Lives*  
18 *Act of 2008.*

19           “(g) *AUTHORIZATION OF APPROPRIATIONS.—There*  
20 *are authorized to be appropriated to carry out this section,*  
21 *\$1,000,000 for fiscal year 2009, \$1,012,500 for fiscal year*  
22 *2010, \$1,025,000 for fiscal year 2011, \$1,037,500 for fiscal*  
23 *year 2012, and \$1,050,000 for fiscal year 2013.”.*

1 **SEC. 5. INFORMATION CLEARINGHOUSE.**

2 *Part A of title XI of the Public Health Service Act*  
3 *(42 U.S.C. 300b–1 et seq.) is amended by adding at the*  
4 *end the following:*

5 **“SEC. 1112. CLEARINGHOUSE OF NEWBORN SCREENING IN-**  
6 **FORMATION.**

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

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

21 *“(2) increase awareness, knowledge, and under-*  
22 *standing of newborn diseases and screening services*  
23 *for expectant individuals and families; and*

24 *“(3) maintain current data on quality indica-*  
25 *tors to measure performance of newborn screening,*  
26 *such as false-positive rates and other quality indica-*

1        *tors as determined by the Advisory Committee under*  
2        *section 1111.*

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

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

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

8                “(3) *is updated on a regular basis, but not less*  
9        *than quarterly; and*

10               “(4) *provides—*

11                        “(A) *links to Government-sponsored, non-*  
12                        *profit, and other Internet websites of laboratories*  
13                        *that have demonstrated expertise in newborn*  
14                        *screening that supply research-based information*  
15                        *on newborn screening tests currently available*  
16                        *throughout the United States;*

17                        “(B) *information about newborn conditions*  
18                        *and screening services available in each State*  
19                        *from laboratories certified under subpart 2 of*  
20                        *part F of title III, including information about*  
21                        *supplemental screening that is available but not*  
22                        *required, in the State where the infant is born;*

23                        “(C) *current research on both treatable and*  
24                        *not-yet treatable conditions for which newborn*  
25                        *screening tests are available;*

1           “(D) the availability of Federal funding for  
2           newborn and child screening for heritable dis-  
3           orders including grants authorized under the  
4           Newborn Screening Saves Lives Act of 2008; and

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

7           “(c) NONDUPLICATION.—In developing the clearing-  
8           house under this section, the Secretary shall ensure that  
9           such clearinghouse minimizes duplication and supplements,  
10          not supplants, existing information sharing efforts.

11          “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
12          are authorized to be appropriated to carry out this section,  
13          \$2,500,000 for fiscal year 2009, \$2,531,250 for fiscal year  
14          2010, \$2,562,500 for fiscal year 2011, \$2,593,750 for fiscal  
15          year 2012, and \$2,625,000 for fiscal year 2013.”.

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

17          Part A of title XI of the Public Health Service Act  
18          (42 U.S.C. 300b–1 et seq.), as amended by section 5, is fur-  
19          ther amended by adding at the end the following:

20          **“SEC. 1113. LABORATORY QUALITY.**

21          “(a) IN GENERAL.—The Secretary, acting through the  
22          Director of the Centers for Disease Control and Prevention  
23          and in consultation with the Advisory Committee on Heri-  
24          table Disorders in Newborns and Children established under  
25          section 1111, shall provide for—



1        *mittee on Heritable Disorders in Newborns and Chil-*  
2        *dren under section 1111, including data on the inci-*  
3        *dence and prevalence of, as well as poor health out-*  
4        *comes resulting from, such disorders; and*

5            *“(2) make recommendations for the establishment*  
6        *of regional centers for the conduct of applied epide-*  
7        *miological research on effective interventions to pro-*  
8        *mote the prevention of poor health outcomes resulting*  
9        *from such disorders as well as providing information*  
10       *and education to the public on such effective interven-*  
11       *tions.*

12        *“(b) ESTABLISHMENT.—The Secretary shall establish*  
13       *an Interagency Coordinating Committee on Newborn and*  
14       *Child Screening (referred to in this section as the ‘Inter-*  
15       *agency Coordinating Committee’) to carry out the purpose*  
16       *of this section.*

17        *“(c) COMPOSITION.—The Interagency Coordinating*  
18       *Committee shall be composed of the Director of the Centers*  
19       *for Disease Control and Prevention, the Administrator, the*  
20       *Director of the Agency for Healthcare Research and Qual-*  
21       *ity, and the Director of the National Institutes of Health,*  
22       *or their designees.*

23        *“(d) ACTIVITIES.—The Interagency Coordinating*  
24       *Committee shall—*





1       “(b) *CONTENTS.*—*The contingency plan developed*  
2 *under subsection (a) shall include a plan for—*

3               “(1) *the collection and transport of specimens;*

4               “(2) *the shipment of specimens to State newborn*  
5 *screening laboratories;*

6               “(3) *the processing of specimens;*

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

9               “(5) *the diagnostic confirmation of positive*  
10 *screening results;*

11               “(6) *ensuring the availability of treatment and*  
12 *management resources;*

13               “(7) *educating families about newborn screening;*  
14 *and*

15               “(8) *carrying out other activities determined ap-*  
16 *propriate by the Secretary.*

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

18       “(a) *NEWBORN SCREENING ACTIVITIES.*—

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

1 *Kelly Newborn Screening Research Program*’) includ-  
2 *ing—*

3 “(A) *identifying, developing, and testing the*  
4 *most promising new screening technologies, in*  
5 *order to improve already existing screening tests,*  
6 *increase the specificity of newborn screening, and*  
7 *expand the number of conditions for which*  
8 *screening tests are available;*

9 “(B) *experimental treatments and disease*  
10 *management strategies for additional newborn*  
11 *conditions, and other genetic, metabolic, hor-*  
12 *monal, or functional conditions that can be de-*  
13 *tected through newborn screening for which*  
14 *treatment is not yet available; and*

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

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

22 “(b) *FUNDING.—In carrying out the research program*  
23 *under this section, the Secretary and the Director shall en-*  
24 *sure that entities receiving funding through the program*  
25 *will provide assurances, as practicable, that such entities*

1 *will work in consultation with the appropriate State de-*  
2 *partments of health, and, as practicable, focus their research*  
3 *on screening technology not currently performed in the*  
4 *States in which the entities are located, and the conditions*  
5 *on the uniform screening panel (or the standard test exist-*  
6 *ing on the uniform screening panel).*

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

14       “(d) *NONDUPLICATION.*—*In carrying out programs*  
15 *under this section, the Secretary shall minimize duplication*  
16 *and supplement, not supplant, existing efforts of the type*  
17 *carried out under this section.*

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



Union Calendar No. 352

110<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

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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.

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APRIL 8, 2008

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed