

**AMENDMENT IN THE NATURE OF A SUBSTITUTE  
TO H.R. 3825  
OFFERED BY MR. PALLONE OF NEW JERSEY**

Strike all after the enacting clause and insert the following:

**1 SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Newborn Screening  
3 Saves Lives Act of 2008”.

**4 SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING FOR  
5 HERITABLE DISORDER.**

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

8 (1) by striking subsections (a), (b), and (c) and  
9 inserting the following:

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

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

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

11           “(3) to develop and deliver educational pro-  
12 grams (at appropriate literacy levels) about newborn  
13 screening counseling, testing, follow-up, treatment,  
14 and specialty services to parents, families, and pa-  
15 tient advocacy and support groups; and

16           “(4) to establish, maintain, and operate a sys-  
17 tem to assess and coordinate treatment relating to  
18 congenital, genetic, and metabolic disorders.

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

21           “(1) a State or a political subdivision of a  
22 State;

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

25           “(3) a territory;

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

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

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 assur-  
10          ances that the eligible entity has adopted and imple-  
11          mented, is in the process of adopting and implementing,  
12          or will use amounts received under such grant to adopt  
13          and implement the guidelines and recommendations of the  
14          Advisory Committee that are adopted by the Secretary  
15          and in effect at the time the grant is awarded or renewed  
16          under this section, which shall include the screening of  
17          each newborn for the heritable disorders recommended by  
18          the Advisory Committee 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  
24           necessary steps to coordinate programs funded with

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

3 (4) by striking subsection (j) (as so redesign-  
4 nated) and inserting the following:

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

7 “(1) to provide grants for the purpose of car-  
8 rying out activities under subsection (a)(1),  
9 \$15,000,000 for fiscal year 2009, \$15,187,500 for  
10 fiscal year 2010, \$15,375,000 for fiscal year 2011,  
11 \$15,562,500 for fiscal year 2012, and \$15,750,000  
12 for fiscal year 2013; and

13 “(2) to provide grants for the purpose of car-  
14 rying out activities under paragraphs (2), (3), and  
15 (4) of subsection (a), \$15,000,000 for fiscal year  
16 2009, \$15,187,500 for fiscal year 2010,  
17 \$15,375,000 for fiscal year 2011, \$15,562,500 for  
18 fiscal year 2012, and \$15,750,000 for fiscal year  
19 2013.”.

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

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

1       “(d) AUTHORIZATION OF APPROPRIATIONS.—There  
2 are authorized to be appropriated to carry out this section  
3 \$5,000,000 for fiscal year 2009, \$5,062,500 for fiscal year  
4 2010, \$5,125,000 for fiscal year 2011, \$5,187,500 for fis-  
5 cal year 2012, and \$5,250,000 for fiscal year 2013.”.

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

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

10           (1) in subsection (b)—

11                   (A) by redesignating paragraph (3) as  
12 paragraph (6);

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

15                   (C) by inserting after paragraph (2) the  
16 following:

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

24                   “(4) develop a model decision-matrix for new-  
25 born screening expansion, including an evaluation of

1 the potential public health impact of such expansion,  
2 and periodically update the recommended uniform  
3 screening panel, as appropriate, based on such deci-  
4 sion-matrix;

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

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

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

20 “(B) implementation, monitoring, and  
21 evaluation of newborn screening activities, in-  
22 cluding diagnosis, screening, follow-up, and  
23 treatment activities;

24 “(C) diagnostic and other technology used  
25 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 ter-  
13          minology 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  
18          evaluation of State newborn screening pro-  
19          grams, including ensuring that tests and tech-  
20          nologies used by each State meet established  
21          standards for detecting and reporting positive  
22          screening results;

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

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

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

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

15 (2) in subsection (c)(2)—

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

19           (B) by inserting after subparagraph (D)  
20 the following:

21           “(E) the Commissioner of the Food and  
22 Drug Administration;”; and

23           (C) by inserting after subparagraph (F),  
24 as so redesignated, the following:

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

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

6           “(d) DECISION ON RECOMMENDATIONS.—

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

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

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

22          “(e) ANNUAL REPORT.—Not later than 3 years after  
23          the date of enactment of the Newborn Screening Saves  
24          Lives Act of 2008, and each fiscal year thereafter, the Ad-  
25          visory Committee shall—

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

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

8           “(3) disseminate such report on as wide a basis  
9           as practicable, including through posting on the  
10          internet clearinghouse established under section  
11          1112.

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

18          “(g) AUTHORIZATION OF APPROPRIATIONS.—There  
19          are authorized to be appropriated to carry out this section,  
20          \$1,000,000 for fiscal year 2009, \$1,012,500 for fiscal year  
21          2010, \$1,025,000 for fiscal year 2011, \$1,037,500 for fis-  
22          cal 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  
8 the Administrator of the Health Resources and Services  
9 Administration (referred to in this part as the ‘Adminis-  
10 trator’), in consultation with the Director of the Centers  
11 for Disease Control and Prevention and the Director of  
12 the National Institutes of Health, shall establish and  
13 maintain a central clearinghouse of current educational  
14 and family support and services information, materials, re-  
15 sources, research, 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, act-  
4       ing through the Administrator, shall ensure that the clear-  
5       inghouse 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 labora-  
13                      tories that have demonstrated expertise in new-  
14                      born screening that supply research-based infor-  
15                      mation on newborn screening tests currently  
16                      available 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  
24                      and not-yet treatable conditions for which new-  
25                      born 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;  
5           and

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

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

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

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

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

21          **“SEC. 1113. LABORATORY QUALITY.**

22          “(a) IN GENERAL.—The Secretary, acting through  
23          the Director of the Centers for Disease Control and Pre-  
24          vention and in consultation with the Advisory Committee

1 on Heritable Disorders in Newborns and Children estab-  
2 lished under section 1111, shall provide for—

3 “(1) quality assurance for laboratories involved  
4 in screening newborns and children for heritable dis-  
5 orders, including quality assurance for newborn-  
6 screening tests, performance evaluation services, and  
7 technical assistance and technology transfer to new-  
8 born screening laboratories to ensure analytic valid-  
9 ity and utility of screening tests; and

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

13 “(b) AUTHORIZATION OF APPROPRIATIONS.—For the  
14 purpose of carrying out this section, there are authorized  
15 to be appropriated \$5,000,000 for fiscal year 2009,  
16 \$5,062,500 for fiscal year 2010, \$5,125,000 for fiscal year  
17 2011, \$5,187,500 for fiscal year 2012, and \$5,250,000  
18 for fiscal year 2013.

19 **“SEC. 1114. INTERAGENCY COORDINATING COMMITTEE ON**  
20 **NEWBORN AND CHILD SCREENING.**

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

22 “(1) assess existing activities and infrastruc-  
23 ture, including activities on birth defects and devel-  
24 opmental disabilities authorized under section 317C,  
25 in order to make recommendations for programs to

1 collect, analyze, and make available data on the heri-  
2 table disorders recommended by the Advisory Com-  
3 mittee on Heritable Disorders in Newborns and  
4 Children under section 1111, including data on the  
5 incidence and prevalence of, as well as poor health  
6 outcomes resulting from, such disorders; and

7 “(2) make recommendations for the establish-  
8 ment of regional centers for the conduct of applied  
9 epidemiological research on effective interventions to  
10 promote the prevention of poor health outcomes re-  
11 sulting from such disorders as well as providing in-  
12 formation and education to the public on such effec-  
13 tive interventions.

14 “(b) ESTABLISHMENT.—The Secretary shall estab-  
15 lish an Interagency Coordinating Committee on Newborn  
16 and Child Screening (referred to in this section as the  
17 ‘Interagency Coordinating Committee’) to carry out the  
18 purpose of this section.

19 “(c) COMPOSITION.—The Interagency Coordinating  
20 Committee shall be composed of the Director of the Cen-  
21 ters for Disease Control and Prevention, the Adminis-  
22 trator, the Director of the Agency for Healthcare Research  
23 and Quality, and the Director of the National Institutes  
24 of Health, or their designees.

1 “(d) ACTIVITIES.—The Interagency Coordinating  
2 Committee shall—

3 “(1) report to the Secretary and the appro-  
4 priate committees of Congress on its recommenda-  
5 tions related to the purpose described in subsection  
6 (a); and

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

9 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the  
10 purpose of carrying out this section, there are authorized  
11 to be appropriated \$1,000,000 for fiscal year 2009,  
12 \$1,012,500 for fiscal year 2010, \$1,025,000 for fiscal year  
13 2011, \$1,037,500 for fiscal year 2012, and \$1,050,000  
14 for fiscal year 2013.”.

15 **SEC. 7. CONTINGENCY PLANNING.**

16 Part A of title XI of the Public Health Service Act  
17 (42 U.S.C. 300b–1 et seq.), as amended by section 6, is  
18 further amended by adding at the end the following:

19 **“SEC. 1115. NATIONAL CONTINGENCY PLAN FOR NEWBORN**  
20 **SCREENING.**

21 “(a) IN GENERAL.—Not later than 180 days after  
22 the date of enactment of this section, the Secretary, acting  
23 through the Director of the Centers for Disease Control  
24 and Prevention and in consultation with the Administrator  
25 and State departments of health (or related agencies),

1 shall develop a national contingency plan for newborn  
2 screening for use by a State, region, or consortia of States  
3 in the event of a public health emergency.

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

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

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

9 “(3) the processing of specimens;

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

12 “(5) the diagnostic confirmation of positive  
13 screening results;

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

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

18 “(8) carrying out other activities determined  
19 appropriate by the Secretary.

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

21 “(a) NEWBORN SCREENING ACTIVITIES.—

22 “(1) IN GENERAL.—The Secretary, in conjunc-  
23 tion with the Director of the National Institutes of  
24 Health and taking into consideration the rec-  
25 ommendations of the Advisory Committee, may con-

1       tinue carrying out, coordinating, and expanding re-  
2       search in newborn screening (to be known as  
3       ‘Hunter Kelly Newborn Screening Research Pro-  
4       gram’) including—

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

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

17             “(C) other activities that would improve  
18             newborn screening, as identified by the Direc-  
19             tor.

20             “(2) ADDITIONAL NEWBORN CONDITION.—For  
21             purposes of this subsection, the term ‘additional  
22             newborn condition’ means any condition that is not  
23             one of the core conditions recommended by the Advi-  
24             sory Committee and adopted by the Secretary.

1       “(b) FUNDING.—In carrying out the research pro-  
2 gram under this section, the Secretary and the Director  
3 shall ensure that entities receiving funding through the  
4 program will provide assurances, as practicable, that such  
5 entities will work in consultation with the appropriate  
6 State departments of health, and, as practicable, focus  
7 their research on screening technology not currently per-  
8 formed in the States in which the entities are located, and  
9 the conditions on the uniform screening panel (or the  
10 standard test existing on the uniform screening panel).

11       “(c) REPORTS.—The Director is encouraged to in-  
12 clude information about the activities carried out under  
13 this section in the biennial report required under section  
14 403 of the National Institutes of Health Reform Act of  
15 2006. If such information is included, the Director shall  
16 make such information available to be included on the  
17 Internet Clearinghouse established under section 1112.

18       “(d) NONDUPLICATION.—In carrying out programs  
19 under this section, the Secretary shall minimize duplica-  
20 tion and supplement, not supplant, existing efforts of the  
21 type carried out under this section.

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