

113TH CONGRESS  
1ST SESSION

# H. R. 1281

To amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 20, 2013

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

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## A BILL

To amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.

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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Newborn Screening Saves Lives Reauthorization Act of  
6 2013”.

7 (b) **TABLE OF CONTENTS.**—The table of contents of  
8 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Improved newborn and child screening for heritable disorders.

Sec. 3. Evaluating the effectiveness of newborn and child screening and followup programs.

Sec. 4. Advisory committee on heritable disorders in newborns and children.

Sec. 5. Clearinghouse of Newborn Screening Information.

Sec. 6. Laboratory quality.

Sec. 7. Interagency Coordinating Committee on Newborn and Child Screening.

Sec. 8. National contingency plan for newborn screening.

Sec. 9. Hunter Kelly Research Program.

Sec. 10. Newborn screening surveillance, followup, and applied research.

Sec. 11. Authorization of appropriations.

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

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

5 (1) in subsection (a)—

6 (A) in the matter preceding paragraph (1),  
7 by striking “and in consultation with the Advi-  
8 sory Committee” and inserting “and taking into  
9 consideration the recommendations of the Advi-  
10 sory Committee”;

11 (B) in paragraph (2), by striking “screen-  
12 ing and training” and inserting “screening,  
13 counseling, and training”; and

14 (C) in paragraph (4), by striking “treat-  
15 ment” and inserting “followup and treatment”;

16 (2) in subsection (b)—

17 (A) in paragraph (4), by striking “or” at  
18 the end;

19 (B) by redesignating paragraph (5) as  
20 paragraph (7); and

21 (C) by inserting after paragraph (4) the  
22 following:

- 1           “(5) a health professional organization;  
2           “(6) an early childhood health system; or”; and  
3           (3) by striking subsection (j) (relating to au-  
4           thorization of appropriations).

5 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**  
6                   **AND CHILD SCREENING AND FOLLOWUP**  
7                   **PROGRAMS.**

8           Section 1110 of the Public Health Service Act (42  
9 U.S.C. 300b-9) is amended—

10           (1) in the section heading, by inserting “**AND**  
11           **FOLLOWUP**” after “**CHILD SCREENING**”;

12           (2) in subsection (a), by inserting “followup,”  
13           after “the effectiveness of screening,”;

14           (3) in subsection (b)—

15                   (A) in paragraph (1), by inserting “ascertain-  
16                   ment, treatment,” after “the effectiveness  
17                   of screening, counseling,”;

18                   (B) in paragraph (2)—

19                           (i) by inserting “ascertainment, treat-  
20                           ment,” after “the effectiveness of screen-  
21                           ing, counseling,”; and

22                           (ii) by striking “or” at the end;

23                   (C) in paragraph (3), by striking the pe-  
24                   riod at the end and inserting “; or”; and

25                   (D) by adding at the end the following:

1 “(4) the availability and effectiveness of treat-  
2 ment and followup care for newborns and their fami-  
3 lies after screening and diagnosis.”; and

4 (4) by striking subsection (d) (relating to au-  
5 thorization of appropriations).

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) in paragraph (4), by striking “public  
12 health impact” and inserting “public health im-  
13 pact and cost”; and

14 (B) in paragraph (6)—

15 (i) in subparagraph (A), by striking  
16 “achieve rapid diagnosis” and inserting  
17 “achieve best practices in rapid diagnosis  
18 and appropriate treatment”; and

19 (ii) in subparagraph (D), by inserting  
20 before the semicolon “, including informa-  
21 tion on cost and incidence”;

22 (2) by redesignating subsections (f) and (g) as  
23 subsections (g) and (h), respectively;

24 (3) by inserting after subsection (e) the fol-  
25 lowing new subsection:

1 “(f) MEETINGS.—The Advisory Committee shall  
2 meet in person at least twice each year.”;

3 (4) by amending subsection (g), as redesignated  
4 by paragraph (2), to read as follows:

5 “(g) CONTINUATION OF OPERATION OF COM-  
6 MITTEE.—

7 “(1) IN GENERAL.—Notwithstanding section 14  
8 of the Federal Advisory Committee Act (5 U.S.C.  
9 App.), the Advisory Committee shall continue to op-  
10 erate for the period beginning on the date of enact-  
11 ment of the Newborn Screening Saves Lives Reau-  
12 thorization Act of 2013 and concluding at the end  
13 of the fifth fiscal year which begins after such date.

14 “(2) CONTINUATION IF NOT REAUTHORIZED.—  
15 If at the end of the fifth fiscal year described in  
16 paragraph (1) the duration of the Advisory Com-  
17 mittee has not been extended by statute—

18 “(A) the Advisory Committee may be con-  
19 sidered, for the purposes of the Federal Advi-  
20 sory Committee Act, to be an advisory com-  
21 mittee established by the President or an officer  
22 of the Federal Government under section 9(a)  
23 of such Act; and

1           “(B) the Secretary may renew the Advi-  
2           sory Committee under section 14(a)(1)(A) of  
3           such Act.”; and

4           (5) by striking subsection (h) (relating to au-  
5           thorization of appropriations), as redesignated by  
6           paragraph (2).

7   **SEC. 5. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-**  
8           **MATION.**

9           Section 1112 of the Public Health Service Act (42  
10          U.S.C. 300b–11) is amended—

11           (1) in subsection (a)—

12                   (A) in paragraph (2), by striking “; and”  
13                   and inserting a semicolon;

14                   (B) in paragraph (3), by striking the pe-  
15                   riod at the end and inserting a semicolon; and

16                   (C) by adding at the end the following new  
17                   paragraphs:

18                   “(4) maintain current data on the number of  
19                   conditions for which screening is conducted in each  
20                   State; and

21                   “(5) establish or disseminate guidelines for  
22                   services and personnel necessary for followup, diag-  
23                   nosis, counseling, and treatment with respect to con-  
24                   ditions detected by newborn screening.”;

1           (2) in subsection (b)(4)(D), by striking “New-  
2       born Screening Saves Lives Act of 2008” and insert-  
3       ing “Newborn Screening Saves Lives Reauthoriza-  
4       tion Act of 2013”; and

5           (3) by striking subsection (d) (relating to au-  
6       thorization of appropriations).

7       **SEC. 6. LABORATORY QUALITY.**

8       Section 1113 of the Public Health Service Act (42  
9       U.S.C. 300b–12) is amended—

10           (1) in subsection (a)—

11               (A) by striking the subsection enumerator  
12               and heading; and

13               (B) by striking “and in consultation with  
14               the Advisory Committee” and inserting “and  
15               taking into consideration the recommendations  
16               of the Advisory Committee”; and

17           (2) by striking subsection (b) (relating to au-  
18       thorization of appropriations).

19       **SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON**  
20               **NEWBORN AND CHILD SCREENING.**

21       Section 1114 of the Public Health Service Act (42  
22       U.S.C. 300b–13) is amended—

23           (1) in subsection (c), by striking “the Adminis-  
24       trator, the Director of the Agency for Healthcare  
25       Research and Quality” and inserting “the Adminis-

1       trator of the Health Resources and Services Admin-  
2       istration, the Director of the Agency for Healthcare  
3       Research and Quality, the Commissioner of Food  
4       and Drugs,”; and

5               (2) by striking subsection (e) (relating to au-  
6       thorization of appropriations) and inserting the fol-  
7       lowing:

8       “(e) REPORT TO CONGRESS.—

9               “(1) IN GENERAL.—The Secretary shall—

10               “(A) not later than 1 year after the date  
11       of enactment of the Newborn Screening Saves  
12       Lives Reauthorization Act of 2013, submit to  
13       the Health, Education, Labor, and Pensions  
14       Committee of the Senate and the Energy and  
15       Commerce Committee of the House of Rep-  
16       resentatives a report on activities related to—

17               “(i) newborn screening; and

18               “(ii) screening children who have or  
19       are at risk for heritable disorders; and

20               “(B) not less than every 2 years, shall sub-  
21       mit to such committees an updated version of  
22       such report.

23               “(2) CONTENTS.—The report submitted under  
24       subsection (a) shall contain a description of—



1           “(A) the implementation of sections 1111  
2           through 1116B, including this section; and

3           “(B) the amounts expended on such imple-  
4           mentation.”.

5 **SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN**  
6 **SCREENING.**

7           Section 1115(a) of the Public Health Service Act (42  
8 U.S.C. 300b–14(a)) is amended by adding at the end the  
9 following: “The plan shall be updated as needed and at  
10 least every five years.”.

11 **SEC. 9. HUNTER KELLY RESEARCH PROGRAM.**

12           Section 1116(a)(1) of the Public Health Service Act  
13 (42 U.S.C. 300b–15(a)(1)) is amended—

14           (1) in subparagraph (B), by striking “; and”  
15           and inserting a semicolon;

16           (2) by redesignating subparagraph (C) as sub-  
17           paragraph (E); and

18           (3) by inserting after subparagraph (B) the fol-  
19           lowing:

20           “(C) providing research and data for new-  
21           born conditions under review by the Advisory  
22           Committee on Heritable Disorders in Newborns  
23           and Children to be added to the Recommended  
24           Uniform Screening Panel;

1           “(D) conducting pilot studies on conditions  
2           recommended by the Advisory Committee on  
3           Heritable Disorders in Newborns and Children  
4           to ensure that screenings are ready for nation-  
5           wide implementation; and”.

6 **SEC. 10. NEWBORN SCREENING SURVEILLANCE, FOL-**  
7           **LOWUP, AND APPLIED RESEARCH.**

8           The Public Health Service Act is amended by insert-  
9           ing after section 1116 of such Act (42 U.S.C. 300b-15)  
10          the following:

11 **“SEC. 1116A. NEWBORN SCREENING SURVEILLANCE, FOL-**  
12           **LOWUP, AND APPLIED RESEARCH.**

13           “(a) IN GENERAL.—The Secretary, acting through  
14           the Director of the Centers for Disease Control and Pre-  
15           vention, shall award grants to, or enter into cooperative  
16           agreements with, eligible entities to develop longitudinal  
17           followup and tracking programs for newborn screening.

18           “(b) PROGRAM.—Longitudinal followup and tracking  
19           programs developed through a grant under subsection (a)  
20           shall incorporate standardized procedures for data man-  
21           agement and program effectiveness and costs, such as—

22                   “(1) studying the costs and effectiveness of  
23                   newborn screening, evaluation and intervention pro-  
24                   grams, and surveillance systems conducted by State-

1 based programs in order to answer issues of impor-  
2 tance to State and national policymakers;

3 “(2) studying the effectiveness of newborn  
4 screening followup and intervention programs by as-  
5 sessing the health and development of children at  
6 school age and as young adults;

7 “(3) promoting the sharing of data regarding  
8 newborn screening with State-based birth defects  
9 and developmental disabilities monitoring programs;

10 “(4) ensuring coordination of surveillance ac-  
11 tivities, including—

12 “(A) standardized data collection and re-  
13 porting; and

14 “(B) use of electronic health records;

15 “(5) facilitating quality improvement in treat-  
16 ment and disease management based on gaps in  
17 services or care identified by longitudinal tracking  
18 systems; and

19 “(6) utilizing data from longitudinal tracking  
20 systems to support the development and evaluation  
21 of evidence-based guidelines for diagnosis, treatment,  
22 and disease management.

23 “(c) ELIGIBLE ENTITY.—In this section, the term  
24 ‘eligible entity’ means—

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

3           “(2) a consortium of 2 or more States or sub-  
4 divisions described in paragraph (1);

5           “(3) a health facility or program operated by or  
6 pursuant to a contract with, or a grant from, the In-  
7 dian Health Service; or

8           “(4) any other entity with appropriate expertise  
9 in newborn screening, as determined by the Sec-  
10 retary.”.

11 **SEC. 11. AUTHORIZATION OF APPROPRIATIONS.**

12       The Public Health Service Act is amended by insert-  
13 ing after section 1116A of such Act, as added by section  
14 10 of this Act, the following:

15 **“SEC. 1116B. AUTHORIZATION OF APPROPRIATIONS FOR**  
16 **NEWBORN SCREENING PROGRAMS AND AC-**  
17 **TIVITIES.**

18       “There are authorized to be appropriated—

19           “(1) to carry out sections 1109, 1110, 1111,  
20 and 1112, \$13,334,000 for each of fiscal years 2014  
21 through 2018;

22           “(2) to carry out section 1113, \$7,500,000 for  
23 each of fiscal years 2014 through 2018; and

1           “(3) to carry out section 1116A, \$5,000,000 for  
2           each of fiscal years 2014 through 2018.”.

○