

## COMMITTEE PRINT

[SHOWING H.R. 1281, AS FAVORABLY FORWARDED BY THE SUBCOMMITTEE  
ON HEALTH ON FEBRUARY 27, 2014]

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 2014”.

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 and followup 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 and surveillance.
- 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. Authorization of appropriations.
- Sec. 11. Reports to Congress.

1 **SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND**  
2 **FOLLOWUP FOR 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

7 (1)—

8 (i) by striking “subsection (j)” and in-  
9 serting “section 1117”; and

10 (ii) by striking “and in consultation  
11 with the Advisory Committee” and insert-  
12 ing “and taking into consideration the ex-  
13 pertise of the Advisory Committee”;

14 (B) by amending paragraph (2) to read as  
15 follows:

16 “(2) to assist in providing health care profes-  
17 sionals and newborn screening laboratory personnel  
18 with education in newborn screening, counseling,  
19 and training in—

1           “(A) relevant and new technologies in new-  
2           born screening and congenital, genetic, and  
3           metabolic disorders;

4           “(B) the importance of the timeliness of  
5           collection, delivery, receipt, and screening of  
6           specimens; and

7           “(C) sharing of medical and diagnostic in-  
8           formation with providers and families;”;

9           (C) in paragraph (3), by striking “and” at  
10          the end;

11          (D) in paragraph (4)—

12           (i) by striking “treatment” and insert-  
13           ing “followup and treatment”; and

14           (ii) by striking the period and insert-  
15           ing “; and”; and

16          (E) by adding at the end the following:

17          “(5) to improve the timeliness of—

18           “(A) the collection, delivery, receipt, and  
19           screening of specimens; and

20           “(B) the diagnosis of heritable disorders in  
21           newborns.”;

22          (2) in subsection (c), by striking “application  
23          submitted for a grant under subsection (a)(1)” and  
24          inserting “application for a grant under this sec-  
25          tion”;

1           (3) in subsection (h), by striking “application  
2           submitted under subsection (c)(2)” each place it ap-  
3           pears and inserting “application for a grant under  
4           this section”; and

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

7 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**  
8                                   **AND CHILD SCREENING AND FOLLOWUP**  
9                                   **PROGRAMS.**

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

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

14           (2) in subsection (a), by striking “of screen-  
15           ing,” and inserting “, including with respect to time-  
16           liness, of screening, followup,”;

17           (3) in subsection (b)—

18                           (A) in paragraph (1)—

19                                   (i) by striking “counseling, testing”  
20                                   and inserting “treatment, counseling, test-  
21                                   ing, followup,”; and

22                                   (ii) by inserting before the semicolon  
23                                   the following: “, including, as appropriate,  
24                                   through the assessment of health and de-

1           velopment outcomes for such children  
2           through adolescence”;

3           (B) in paragraph (2)—

4                 (i) by striking “counseling, testing”  
5                 and inserting “treatment, counseling, test-  
6                 ing, followup,”;

7                 (ii) by striking “in accurately and reli-  
8                 ably” and inserting “in accurately and reli-  
9                 ably, and in a timely manner,”; and

10                (iii) by striking “or” at the end;

11           (C) in paragraph (3), by striking the pe-  
12           riod at the end and inserting a semicolon; and

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

14                “(4) methods that may be identified to improve  
15                quality in the diagnosis, treatment, and disease  
16                management of heritable disorders based on gaps in  
17                services or care; or

18                “(5) methods or best practices by which the eli-  
19                gible entities described in section 1109 can achieve  
20                in a timely manner—

21                    “(A) collection, delivery, receipt, and  
22                    screening of newborn screening specimens; and

23                    “(B) diagnosis of heritable disorders in  
24                    newborns.”; and

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

3 **SEC. 4. ADVISORY COMMITTEE ON HERITABLE DISORDERS**

4                                       **IN NEWBORNS AND CHILDREN.**

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

7                       (1) in subsection (b)—

8                               (A) by redesignating paragraphs (4)  
9                               through (6) as paragraphs (6) through (8), re-  
10                              spectively;

11                             (B) by inserting after paragraph (3), the  
12                             following:

13                            “(4) provide technical assistance, as appro-  
14                            prium, to individuals and organizations regarding  
15                            the submission of nominations to the uniform  
16                            screening panel, including prior to the submission of  
17                            such nominations;

18                            “(5) conduct, at its discretion, a preliminary re-  
19                            view of nominations to the uniform screening panel  
20                            for which, in its judgment, there is reasonable cer-  
21                            tainty that an effective treatment will be available  
22                            within 6 months and nomination criteria are other-  
23                            wise met;”;

1 (C) in paragraph (6) (as so redesignated),  
2 by inserting “, including the cost” after “public  
3 health impact”; and

4 (D) in paragraph (8) (as so redesignated)—

5  
6 (i) in subparagraph (A), by striking  
7 “achieve rapid diagnosis” and inserting  
8 “achieve best practices in rapid diagnosis  
9 and appropriate treatment”;

10 (ii) in subparagraph (D), by inserting  
11 before the semicolon “, including informa-  
12 tion on cost and incidence”;

13 (iii) in subparagraph (J), by striking  
14 “and” at the end;

15 (iv) in subparagraph (K), by striking  
16 the period and inserting “; and”; and

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

18 “(L) the timeliness of collection, delivery,  
19 receipt, and screening of specimens to be tested  
20 for heritable disorders in newborns in order to  
21 ensure rapid diagnosis and followup.”;

22 (2) in subsection (d)—

23 (A) in paragraph (1)—

24 (i) by striking “180” and inserting  
25 “120”; and

1                   (ii) by adding at the end the fol-  
2                   lowing: “If the Secretary is unable to make  
3                   a determination to adopt or reject such  
4                   recommendation within such 120-day pe-  
5                   riod, the Secretary shall notify the Advi-  
6                   sory Committee and the appropriate com-  
7                   mittees of Congress of such determination  
8                   together with an explanation for why the  
9                   Secretary was unable to comply within  
10                  such 120-day period, as well as a plan of  
11                  action for consideration of such pending  
12                  recommendation.”;

13                 (B) by striking paragraph (2);

14                 (C) by redesignating paragraph (3) as  
15                  paragraph (2); and

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

17                 “(3) DEADLINE FOR REVIEW.—For each nomi-  
18                  nation to the recommended uniform screening panel,  
19                  the Advisory Committee shall review and vote on the  
20                  nominated condition within 9 months of the date on  
21                  which the Advisory Committee referred the nomina-  
22                  tion to the condition review workgroup.”;

23                 (3) by redesignating subsections (f) and (g) as  
24                  subsections (g) and (h), respectively;



1           (4) by inserting after subsection (e) the fol-  
2           lowing new subsection:

3           “(f) MEETINGS.—The Advisory Committee shall  
4           meet at least 4 times each calendar year, or at the discre-  
5           tion of the Designated Federal Officer in consultation with  
6           the Chair.”;

7           (5) by amending subsection (g) (as so redesignig-  
8           nated) to read as follows:

9           “(g) CONTINUATION OF OPERATION OF COM-  
10          MITTEE.—

11           “(1) IN GENERAL.—Notwithstanding section 14  
12          of the Federal Advisory Committee Act, the Advi-  
13          sory Committee shall continue to operate through  
14          the end of fiscal year 2019.

15           “(2) CONTINUATION IF NOT REAUTHORIZED.—  
16          If at the end of fiscal year 2019 the duration of the  
17          Advisory Committee has not been extended by stat-  
18          ute, the Advisory Committee may be deemed, for  
19          purposes of the Federal Advisory Committee Act, an  
20          advisory committee established by the President or  
21          an officer of the Federal Government under section  
22          9(a) of such Act.”; and

23           (6) by striking subsection (h) (relating to au-  
24          thorization of appropriations), as redesignated by  
25          paragraph (3).

1 **SEC. 5. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-**  
2 **MATION.**

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

5 (1) in subsection (a)—

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

8 (B) in paragraph (3)—

9 (i) by striking “data” and inserting  
10 “information”; and

11 (ii) by striking the period at the end  
12 and inserting a semicolon; and

13 (C) by adding at the end the following new  
14 paragraphs:

15 “(4) maintain current information on the num-  
16 ber of conditions for which screening is conducted in  
17 each State; and

18 “(5) disseminate available evidence-based guide-  
19 lines related to diagnosis, counseling, and treatment  
20 with respect to conditions detected by newborn  
21 screening.”;

22 (2) in subsection (b)(4)(D), by striking “New-  
23 born Screening Saves Lives Act of 2008” and insert-  
24 ing “Newborn Screening Saves Lives Reauthoriza-  
25 tion Act of 2014”;

26 (3) in subsection (c)—

1 (A) by striking “developing the clearing-  
2 house” and inserting “carrying out activities”;  
3 and

4 (B) by striking “clearinghouse minimizes  
5 duplication and supplements, not supplants”  
6 and inserting “activities minimize duplication  
7 and supplement, not supplant”; and

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

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

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

13 (1) in the section heading, by inserting “**AND**  
14 **SURVEILLANCE**” before the period;

15 (2) in subsection (a)—

16 (A) in the matter preceding paragraph (1),  
17 by striking “and in consultation with the Advi-  
18 sory Committee” and inserting “and taking into  
19 consideration the expertise of the Advisory  
20 Committee”; and

21 (B) in paragraph (1), by inserting “timeli-  
22 ness for processing such tests,” after “newborn-  
23 screening tests,”; and

1           (3) by striking subsection (b) (relating to au-  
2           thorization of appropriations) and inserting the fol-  
3           lowing:

4           “(b) **SURVEILLANCE ACTIVITIES.**—The Secretary,  
5           acting through the Director of the Centers for Disease  
6           Control and Prevention, and taking into consideration the  
7           expertise of the Advisory Committee on Heritable Dis-  
8           orders in Newborns and Children established under sec-  
9           tion 1111, may provide, as appropriate, for the coordina-  
10          tion of surveillance activities, including—

11           “(1) through standardized data collection and  
12          reporting, as well as the use of electronic health  
13          records; and

14           “(2) by promoting data sharing regarding new-  
15          born screening with State-based birth defects and  
16          developmental disabilities monitoring programs.”.

17   **SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON**  
18                           **NEWBORN AND CHILD SCREENING.**

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

21           (1) in subsection (c), by striking “the Adminis-  
22          trator, the Director of the Agency for Healthcare  
23          Research and Quality,” and inserting “the Adminis-  
24          trator of the Health Resources and Services Admin-  
25          istration, the Director of the Agency for Healthcare

1 Research and Quality, the Commissioner of Food  
2 and Drugs,”; and

3 (2) by striking subsection (e) (relating to au-  
4 thorization of appropriations).

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—

9 (1) by striking “consortia” and inserting “con-  
10 sortium”; and

11 (2) by adding at the end the following: “The  
12 plan shall be updated as needed and at least every  
13 five years.”.

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

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

17 (1) in subsection (a)(1)—

18 (A) in subparagraph (B), by striking “;  
19 and” and inserting a semicolon;

20 (B) by redesignating subparagraph (C) as  
21 subparagraph (E); and

22 (C) by inserting after subparagraph (B)  
23 the following:

24 “(C) providing research findings and data  
25 for newborn conditions under review by the Ad-

1 advisory Committee on Heritable Disorders in  
2 Newborns and Children to be added to the rec-  
3 ommended uniform screening panel;

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

9 (2) in subsection (c), by striking “of the Na-  
10 tional Institutes of Health Reform Act of 2006”.

11 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

12 Part A of title XI of the Public Health Service Act  
13 (42 U.S.C. 300b–1 et seq.) is amended by adding at the  
14 end, the following:

15 **“SEC. 1117. 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, \$11,900,000 for each of fiscal years 2015  
21 through 2019; and

22 “(2) to carry out section 1113, \$7,000,000 for  
23 each of fiscal years 2015 through 2019.”.

1 **SEC. 11. REPORTS TO CONGRESS.**

2 (a) GAO REPORT ON TIMELINESS OF NEWBORN  
3 SCREENING.—

4 (1) IN GENERAL.—Not later than 2 years after  
5 the date of enactment of this Act, the Comptroller  
6 General of the United States shall submit a report  
7 to the Committee on Health, Education, Labor, and  
8 Pensions of the Senate and the Committee on En-  
9 ergy and Commerce of the House of Representatives  
10 concerning the timeliness of screening for heritable  
11 disorders in newborns.

12 (2) CONTENTS.—The report submitted under  
13 paragraph (1) shall include the following:

14 (A) An analysis of information regarding  
15 the timeliness of newborn screening, which may  
16 include the time elapsed from birth to specimen  
17 collection, specimen collection to receipt by lab-  
18 oratory, specimen receipt to reporting, reporting  
19 to followup testing, and followup testing to con-  
20 firmed diagnosis.

21 (B) A summary of any guidelines, rec-  
22 ommendations, or best practices available to  
23 States and health care providers intended to  
24 support a timely newborn screening system.

25 (C) An analysis of any barriers to main-  
26 taining a timely newborn screening system

1           which may exist and recommendations for ad-  
2           dressing such barriers.

3           (b) REPORT BY SECRETARY.—

4           (1) IN GENERAL.—The Secretary of Health and  
5           Human Services shall—

6                   (A) not later than 1 year after the date of  
7                   enactment of this Act, submit to the Committee  
8                   on Health, Education, Labor, and Pensions of  
9                   the Senate and the Committee on Energy and  
10                  Commerce of the House of Representatives a  
11                  report on activities related to—

12                           (i) newborn screening; and

13                           (ii) screening children who have or are  
14                          at risk for heritable disorders; and

15                  (B) not less than every 2 years, submit to  
16                  such committees an updated version of such re-  
17                  port.

18           (2) CONTENTS.—The report submitted under  
19           this subsection shall contain a description of—

20                   (A) the ongoing activities under sections  
21                   1109, 1110, and 1112 through 1115 of the  
22                   Public Health Service Act; and

23                   (B) the amounts expended on such activi-  
24                  ties.