

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

# S. 1417

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## AN ACT

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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

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

5 (b) TABLE OF CONTENTS.—The table of contents of  
6 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Improved newborn and child screening and follow-up for heritable disorders.

Sec. 3. Evaluating the effectiveness of newborn and child screening and follow-up 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

7 **SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND**  
8 **FOLLOW-UP FOR HERITABLE DISORDERS.**

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

11 (1) in subsection (a)—

12 (A) in the matter preceding paragraph

13 (1)—

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

16 (ii) by striking “and in consultation  
17 with the Advisory Committee” and insert-  
18 ing “and taking into consideration the ex-  
19 pertise of the Advisory Committee”;

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

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

6 (D) in paragraph (4)—

7 (i) by striking “treatment” and insert-  
8 ing “follow-up and treatment”; and

9 (ii) by striking the period and insert-  
10 ing “; and”; and

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

12 “(5) to improve the timely collection, delivery,  
13 receipt, and screening of specimens, and the timely  
14 diagnosis of heritable disorders in newborns.”;

15 (2) in subsection (h), by striking “subsection  
16 (c)(2)” each place that such appears and inserting  
17 “subsection (e)”; and

18 (3) by striking subsection (j) (relating to au-  
19 thorization of appropriations).

20 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**  
21 **AND CHILD SCREENING AND FOLLOW-UP**  
22 **PROGRAMS.**

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

1 (1) in the section heading, by inserting “**AND**  
2 **FOLLOW-UP**” after “**CHILD SCREENING**”;

3 (2) in subsection (a), by striking “of screen-  
4 ing,” and inserting “, including with respect to time-  
5 liness, of screening, follow-up,”;

6 (3) in subsection (b)—

7 (A) in paragraph (1)—

8 (i) by striking “counseling, testing”  
9 and inserting “treatment, counseling, test-  
10 ing, follow-up,”; and

11 (ii) by inserting before the semicolon  
12 the following: “, including, as appropriate,  
13 through the assessment of health and de-  
14 velopment outcomes for such children  
15 through adolescence”;

16 (B) in paragraph (2)—

17 (i) by striking “counseling, testing”  
18 and inserting “treatment, counseling, test-  
19 ing, follow-up,”; and

20 (ii) by striking “or” at the end;

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

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

24 “(4) methods that may be identified to improve  
25 quality in the diagnosis, treatment, and disease

1 management of heritable disorders based on gaps in  
2 services or care; or

3 “(5) methods or best practices by which the eli-  
4 gible entities described in section 1109 can achieve  
5 the timely collection, delivery, receipt, and screening  
6 of newborn screening specimens, and the timely di-  
7 agnosis of heritable disorders in newborns.”; and

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

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

11 **IN NEWBORNS AND CHILDREN.**

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

14 (1) in subsection (b)—

15 (A) by redesignating paragraphs (4)  
16 through (6) as paragraphs (5) through (7), re-  
17 spectively;

18 (B) by inserting after paragraph (3), the  
19 following:

20 “(4) provide technical assistance, as appro-  
21 priate, to individuals and organizations regarding  
22 the submission of nominations to the uniform  
23 screening panel, including prior to the submission of  
24 such nominations;”;

1 (C) in paragraph (5) (as so redesignated),  
2 by inserting “, including the cost” after “public  
3 health impact”; and

4 (D) in paragraph (7) (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 timely collection, delivery, receipt,  
19 and screening of specimens to be tested for  
20 heritable disorders in newborns in order to en-  
21 sure rapid diagnosis and follow-up.”;

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          recommendations.”;

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 on Heritable Disorders in  
20          Newborns and Children shall review and vote on the  
21          nominated condition within 9 months of the date on  
22          which the Advisory Committee referred the nomina-  
23          tion to the condition review workgroup.”;

24          (3) by redesignating subsections (f) and (g) as  
25          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 as subject  
5 to the discretion of the Designated Federal Officer in con-  
6 sultation with the Chair.”;

7           (5) in subsection (g) (as so redesignated), by  
8 striking “Newborn Screening Saves Lives Act of  
9 2008” and inserting “Newborn Screening Saves  
10 Lives Reauthorization Act of 2013”; and

11           (6) by striking subsection (h) (relating to au-  
12 thorization of appropriations), as redesignated by  
13 paragraph (3).

14 **SEC. 5. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-**  
15 **MATION.**

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

18           (1) in subsection (a)—

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

21                   (B) in paragraph (3)—

22                           (i) by striking “data” and inserting  
23 “information”; and

24                           (ii) by striking the period at the end  
25 and inserting a semicolon; and



1 (C) by adding at the end the following new  
2 paragraphs:

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

6 “(5) disseminate available evidence-based guide-  
7 lines related to diagnosis, counseling, and treatment  
8 with respect to conditions detected by newborn  
9 screening.”;

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

14 (3) in subsection (c)—

15 (A) by striking “developing the clearing-  
16 house” and inserting “carrying out activities”;  
17 and

18 (B) by striking “clearinghouse minimizes”  
19 and inserting “activities minimize”; and

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

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

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

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

3 (2) in subsection (a)—

4 (A) by striking the subsection enumerator  
5 and heading;

6 (B) 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 expertise of the Advisory  
10 Committee”;

11 (C) in paragraph (1)—

12 (i) by inserting “timeliness for proc-  
13 essing such tests,” after “newborn screen-  
14 ing tests”; and

15 (ii) by striking “and” at the end; and

16 (D) in paragraph (2), by striking the pe-  
17 riod and inserting “; and”; and

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

21 “(b) **SURVEILLANCE ACTIVITIES.**—The Secretary,  
22 acting through the Director of the Centers for Disease  
23 Control and Prevention, and taking into consideration the  
24 expertise of the Advisory Committee on Heritable Dis-  
25 orders in Newborns and Children established under sec-

1 tion 1111, may provide, as appropriate, for the coordina-  
2 tion of surveillance activities, including—

3 “(1) through standardized data collection and  
4 reporting, as well as the use of electronic health  
5 records; and

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

9 **SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON**  
10 **NEWBORN AND CHILD SCREENING.**

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

13 (1) in subsection (c), by striking “the Adminis-  
14 trator, the Director of the Agency for Healthcare  
15 Research and Quality” and inserting “the Adminis-  
16 trator of the Health Resources and Services Admin-  
17 istration, the Director of the Agency for Healthcare  
18 Research and Quality, the Commissioner of Food  
19 and Drugs,”; and

20 (2) by striking subsection (e) (relating to au-  
21 thorization of appropriations).

22 **SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN**  
23 **SCREENING.**

24 Section 1115(a) of the Public Health Service Act (42  
25 U.S.C. 300b–14(a)) is amended by adding at the end the

1 following: “The plan shall be updated as needed and at  
2 least every five years.”.

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

4 Section 1116(a)(1) of the Public Health Service Act  
5 (42 U.S.C. 300b–15(a)(1)) is amended—

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

8 (2) by redesignating subparagraph (C) as sub-  
9 paragraph (E); and

10 (3) by inserting after subparagraph (B) the fol-  
11 lowing:

12 “(C) by providing research findings and  
13 data for newborn conditions under review by  
14 the Advisory Committee on Heritable Disorders  
15 in Newborns and Children to be added to the  
16 recommended uniform screening panel;

17 “(D) conducting pilot studies on conditions  
18 recommended by the Advisory Committee on  
19 Heritable Disorders in Newborns and Children  
20 to ensure that screenings are ready for nation-  
21 wide implementation; and”.

22 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

23 Part A of title XI of the Public Health Service Act  
24 is amended by adding at the end, the following:

1 **“SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR**  
2 **NEWBORN SCREENING PROGRAMS AND AC-**  
3 **TIVITIES.**

4 “There are authorized to be appropriated—

5 “(1) to carry out sections 1109, 1110, 1111,  
6 and 1112, \$18,334,000 for each of fiscal years 2014  
7 through 2018; and

8 “(2) to carry out section 1113, \$7,500,000 for  
9 each of fiscal years 2014 through 2018.”.

10 **SEC. 11. REPORTS TO CONGRESS.**

11 (a) **GAO REPORT ON TIMELINESS OF NEWBORN**  
12 **SCREENING.—**

13 (1) **IN GENERAL.—**Not later than 2 years after  
14 the date of enactment of this Act, the Comptroller  
15 General of the United States shall submit a report  
16 to the Committee on Health, Education, Labor and  
17 Pensions of the Senate and the Committee on En-  
18 ergy and Commerce of the House of Representatives  
19 concerning the timeliness of screening for heritable  
20 disorders in newborns.

21 (2) **CONTENTS.—**The report submitted under  
22 paragraph (1) shall include the following:

23 (A) An analysis of information regarding  
24 the timeliness of newborn screening, which may  
25 include the time elapsed from birth to specimen  
26 collection, specimen collection to receipt by lab-

1 oratory, specimen receipt to reporting, reporting  
2 to follow-up testing, and follow-up testing to  
3 confirmed diagnosis.

4 (B) A summary of any guidelines, rec-  
5 ommendations, or best practices available to  
6 States and health care providers intended to  
7 support a timely newborn screening system.

8 (C) An analysis of any barriers to main-  
9 taining a timely newborn screening system  
10 which may exist and recommendations for ad-  
11 dressing such barriers.

12 (b) REPORT BY SECRETARY.—

13 (1) IN GENERAL.—The Secretary of Health and  
14 Human Services shall—

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

22 (i) newborn screening; and

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

1           (B) not less than every 2 years, shall sub-  
2           mit to such committees an updated version of  
3           such report.

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

6           (A) the ongoing activities under sections  
7           1109, 1110, and 1112 through 1115 of the  
8           Public Health Service Act; and

9           (B) the amounts expended on such activi-  
10          ties.

Passed the Senate January 29, 2014.

Attest:

*Secretary.*

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

**S. 1417**

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**AN ACT**

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