

Calendar No. 282113TH CONGRESS
1ST SESSION**S. 1417**

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

IN THE SENATE OF THE UNITED STATES

AUGUST 1, 2013

Mrs. HAGAN (for herself, Mr. HATCH, Mr. ENZI, Mr. CASEY, Ms. COLLINS, Mr. SCHUMER, Mr. COCHRAN, Mr. BENNET, Ms. CANTWELL, Mr. DONNELLY, Mr. MURPHY, Mr. SCHATZ, Mr. FRANKEN, Mr. HARKIN, and Mr. WICKER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

DECEMBER 19, 2013

Reported by Mr. HARKIN, with an amendment

[Strike out all after the enacting clause and insert the part printed in *italic*]**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,*

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.
- 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.

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 (1),
 13 by striking “and in consultation with the Advi-
 14 sory Committee” and inserting “and taking into
 15 consideration the recommendations of the Advi-
 16 sory Committee”;

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

1 (C) in paragraph (4), by striking “treat-
 2 ment” and inserting “follow-up and treatment”;
 3 (2) in subsection (h), by striking “subsection
 4 (e)(2)” each place that such appears and inserting
 5 “subsection (e)”; and
 6 (3) by striking subsection (j) (relating to au-
 7 thorization of appropriations).

8 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**
 9 **AND CHILD SCREENING AND FOLLOW-UP**
 10 **PROGRAMS.**

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

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

15 (2) in subsection (a), by inserting “follow-up,”
 16 after “the effectiveness of screening,”;

17 (3) in subsection (b)—

18 (A) in paragraph (1), by inserting “ascer-
 19 tainment, treatment,” after “the effectiveness
 20 of screening, counseling,”;

21 (B) in paragraph (2)—

22 (i) by inserting “ascertainment, treat-
 23 ment,” after “the effectiveness of screen-
 24 ing, counseling,”; and

25 (ii) by striking “or” at the end;

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

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

4 “(4) the availability and effectiveness of follow-
5 up care for newborns and their families after screen-
6 ing and diagnosis;

7 “(5) the costs and effectiveness of newborn
8 screening, evaluation and intervention programs, and
9 surveillance systems conducted by State-based pro-
10 grams in order to answer issues of importance to
11 State and national policymakers;

12 “(6) the effectiveness of newborn screening fol-
13 low-up and intervention programs through the as-
14 sessment of the health and development of children
15 at school age and as young adults;

16 “(7) the level of data sharing regarding new-
17 born screening with State-based birth defects and
18 developmental disabilities monitoring programs;

19 “(8) the coordination of surveillance activities,
20 including—

21 “(A) standardized data collection and re-
22 porting; and

23 “(B) use of electronic health records;

24 “(9) the facilitation of quality improvement in
25 treatment and disease management based on gaps in

1 services or care identified by longitudinal tracking
2 systems; and

3 “(10) the utilization of data from longitudinal
4 tracking systems to support the development and
5 evaluation of evidence-based guidelines for diagnosis,
6 treatment, and disease management.”; and

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

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

10 **IN NEWBORNS AND CHILDREN.**

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

13 (1) in subsection (b)—

14 (A) in paragraph (4), by striking “public
15 health impact” and inserting “public health im-
16 pact, including the cost”; and

17 (B) in paragraph (6)—

18 (i) in subparagraph (A), by striking
19 “achieve rapid diagnosis” and inserting
20 “achieve best practices in rapid diagnosis
21 and appropriate treatment”;

22 (ii) in subparagraph (D), by inserting
23 before the semicolon “, including informa-
24 tion on cost and incidence”;

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

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

5 (2) in subsection (d)—

6 (A) in paragraph (1), by striking “180”
7 and inserting “60”;

8 (B) in paragraph (2), by striking “New-
9 born Screening Saves Lives Act of 2008” and
10 insert “Newborn Screening Saves Lives Reau-
11 thorization Act of 2013”; and

12 (C) by adding at the end the following:

13 “(4) PRIORITY REVIEW.—

14 “(A) IN GENERAL.—For each nomination
15 to the recommended uniform screening panel
16 that meets the criteria of subparagraph (B), the
17 Advisory Committee on Heritable Disorders in
18 Newborns and Children shall provide a priority
19 review as described in this paragraph and sub-
20 ject to the deadlines in subparagraph (C).

21 “(B) CRITERIA FOR PRIORITY REVIEW.—

22 The Advisory Committee on Heritable Dis-
23 orders in Newborns and Children shall provide
24 a priority review with respect to a nomination

1 to the recommended uniform screening panel
2 that meets each of the following criteria:

3 “(i) A human drug application, as de-
4 fined in section 735(1) of the Federal
5 Food, Drug, and Cosmetic Act (21 U.S.C.
6 379g(1)), has been submitted to the Sec-
7 retary for treatment of such disease or
8 condition.

9 “(ii) The application described in
10 clause (i) has been granted priority review
11 or has received fast track or breakthrough
12 therapy designations by the Secretary as
13 described in section 529(a)(1) of the Fed-
14 eral Food, Drug, and Cosmetic Act (21
15 U.S.C. 360ff(a)(1)).

16 “(C) DEADLINES FOR PRIORITY RE-
17 VIEW.—The Advisory Committee on Heritable
18 Disorders in Newborns and Children shall vote
19 on the nominated condition that is under pri-
20 ority review within 8 months of the later of—

21 “(i) the date on which the Advisory
22 Committee refers the nomination to the
23 condition review workgroup; or

24 “(ii) the date of the approval, by the
25 Food and Drug Administration, of the

1 treatment associated with the nomination
2 to the recommended uniform screening
3 panel.

4 “(D) FAILURE TO ACT.—If the Secretary
5 fails to act on a recommendation within the
6 time period provided for in paragraph (1), the
7 Secretary shall adopt the recommendation and
8 include the screening recommended by the Advi-
9 sory Committee on Heritable Disorders in
10 Newborns and Children in the recommended
11 uniform screening panel.

12 “(E) OTHER REVIEWS.—For each nomina-
13 tion to the recommended uniform screening
14 panel that does not meet the criteria of sub-
15 paragraph (B), the Advisory Committee on
16 Heritable Disorders in Newborns and Children
17 shall provide for a review and vote on the nomi-
18 nated condition that is under review within 10
19 months of the date on which the Advisory Com-
20 mittee referred the nomination to the condition
21 review workgroup.”;

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

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

1 “(f) MEETINGS.—The Advisory Committee shall
 2 meet at least 4 times each calendar year with at least 2
 3 meetings in person.”; 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) disseminate available evidence-informed
 22 guidelines related to diagnosis, counseling, and
 23 treatment with respect to conditions detected by
 24 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 (e), 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. AUTHORIZATION OF APPROPRIATIONS.**

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

9 **“SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR**
 10 **NEWBORN SCREENING PROGRAMS AND AC-**
 11 **TIVITIES.**

12 “There are authorized to be appropriated—

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

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

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

19 (a) *SHORT TITLE.*—*This Act may be cited as the*
 20 *“Newborn Screening Saves Lives Reauthorization Act of*
 21 *2013”.*

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

Sec. 1. Short title; table of contents.

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

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

1 **SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND**
 2 **FOLLOW-UP 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) in paragraph (2), by striking “screen-*
 15 *ing and training” and inserting “screening,*
 16 *counseling, and training”;*

17 *(C) in paragraph (3), by striking “and” at*
 18 *the end;*

19 *(D) in paragraph (4)—*

20 *(i) by striking “treatment” and insert-*
 21 *ing “follow-up and treatment”; and*

1 (ii) by striking the period and insert-
2 ing “; and”; and

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

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

7 (2) in subsection (h), by striking “subsection
8 (c)(2)” each place that such appears and inserting
9 “subsection (c)”; and

10 (3) by striking subsection (j) (relating to author-
11 ization of appropriations).

12 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**
13 **AND CHILD SCREENING AND FOLLOW-UP**
14 **PROGRAMS.**

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

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

19 (2) in subsection (a), by striking “of screening,”
20 and inserting “, including with respect to timeliness,
21 of screening, follow-up,”;

22 (3) in subsection (b)—

23 (A) in paragraph (1)—

1 (i) by striking “counseling, testing”
2 and inserting “treatment, counseling, test-
3 ing, follow-up,”; and

4 (ii) by inserting before the semicolon
5 the following: “, including, as appropriate,
6 through the assessment of health and devel-
7 opment outcomes for such children through
8 adolescence”;

9 (B) in paragraph (2)—

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

13 (ii) by striking “or” at the end;

14 (C) in paragraph (3), by striking the period
15 at the end and inserting a semicolon; and

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

17 “(4) methods that may be identified to improve
18 quality in the diagnosis, treatment, and disease man-
19 agement of heritable disorders based on gaps in serv-
20 ices or care; or

21 “(5) methods or best practices by which the eligi-
22 ble entities described in section 1109 can achieve the
23 timely collection, delivery, receipt, and screening of
24 newborn screening specimens, and the timely diag-
25 nosis of heritable disorders in newborns.”; and

1 (4) by striking subsection (d) (relating to author-
2 ization 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 (5) through (7), re-
10 spectively;

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

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

18 (C) in paragraph (5) (as so redesignated),
19 by inserting “, including the cost” after “public
20 health impact”; and

21 (D) in paragraph (7) (as so redesignated)—

22 (i) in subparagraph (A), by striking
23 “achieve rapid diagnosis” and inserting
24 “achieve best practices in rapid diagnosis
25 and appropriate treatment”;

1 (ii) in subparagraph (D), by inserting
2 before the semicolon “, including informa-
3 tion on cost and incidence”;

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

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

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

9 “(L) the timely collection, delivery, receipt,
10 and screening of specimens to be tested for heri-
11 table disorders in newborns in order to ensure
12 rapid diagnosis and follow-up.”;

13 (2) in subsection (d)—

14 (A) in paragraph (1)—

15 (i) by striking “180” and inserting
16 “120”; and

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

18 “If the Secretary is unable to make a deter-
19 mination to adopt or reject such rec-
20 ommendation within such 120-day period,
21 the Secretary shall notify the Advisory
22 Committee and the appropriate committees
23 of Congress of such determination together
24 with an explanation for why the Secretary
25 was unable to comply within such 120-day

1 *period, as well as a plan of action for con-*
 2 *sideration of such pending recommenda-*
 3 *tions.”;*

4 *(B) by striking paragraph (2);*

5 *(C) by redesignating paragraph (3) as*
 6 *paragraph (2); and*

7 *(D) by adding at the end the following:*

8 *“(3) DEADLINE FOR REVIEW.—For each nomina-*
 9 *tion to the recommended uniform screening panel, the*
 10 *Advisory Committee on Heritable Disorders in*
 11 *Newborns and Children shall review and vote on the*
 12 *nominated condition within 9 months of the date on*
 13 *which the Advisory Committee referred the nomina-*
 14 *tion to the condition review workgroup.”;*

15 *(3) by redesignating subsections (f) and (g) as*
 16 *subsections (g) and (h), respectively;*

17 *(4) by inserting after subsection (e) the following*
 18 *new subsection:*

19 *“(f) MEETINGS.—The Advisory Committee shall meet*
 20 *at least 4 times each calendar year, or as subject to the*
 21 *discretion of the Designated Federal Officer in consultation*
 22 *with the Chair.”;*

23 *(5) in subsection (g) (as so redesignated), by*
 24 *striking “Newborn Screening Saves Lives Act of*

1 2008” and inserting “Newborn Screening Saves Lives
2 Reauthorization Act of 2013”; and

3 (6) by striking subsection (h) (relating to author-
4 ization of appropriations), as redesignated by para-
5 graph (3).

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

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

10 (1) in subsection (a)—

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

13 (B) in paragraph (3)—

14 (i) by striking “data” and inserting
15 “information”; and

16 (ii) by striking the period at the end
17 and inserting a semicolon; and

18 (C) by adding at the end the following new
19 paragraphs:

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

23 “(5) disseminate available evidence-based guide-
24 lines related to diagnosis, counseling, and treatment

1 *with respect to conditions detected by newborn screen-*
 2 *ing.”;*

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

7 (3) *in subsection (c)—*

8 (A) *by striking “developing the clearing-*
 9 *house” and inserting “carrying out activities”;*
 10 *and*

11 (B) *by striking “clearinghouse minimizes”*
 12 *and inserting “activities minimize”;* *and*

13 (4) *by striking subsection (d) (relating to author-*
 14 *ization of appropriations).*

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

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

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

20 (2) *in subsection (a)—*

21 (A) *by striking the subsection enumerator*
 22 *and heading;*

23 (B) *in the matter preceding paragraph (1),*
 24 *by striking “and in consultation with the Advi-*
 25 *sory Committee” and inserting “and taking into*

1 *consideration the expertise of the Advisory Com-*
2 *mittee”;*

3 *(C) in paragraph (1)—*

4 *(i) by inserting “timeliness for proc-*
5 *essing such tests,” after “newborn screening*
6 *tests”; and*

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

8 *(D) in paragraph (2), by striking the pe-*
9 *riod and inserting “; and”; and*

10 *(3) by striking subsection (b) (relating to author-*
11 *ization of appropriations) and inserting the fol-*
12 *lowing:*

13 *“(b) SURVEILLANCE ACTIVITIES.—The Secretary, act-*
14 *ing through the Director of the Centers for Disease Control*
15 *and Prevention, and taking into consideration the expertise*
16 *of the Advisory Committee on Heritable Disorders in*
17 *Newborns and Children established under section 1111, may*
18 *provide, as appropriate, for the coordination of surveillance*
19 *activities, including—*

20 *“(1) through standardized data collection and re-*
21 *porting, as well as the use of electronic health records;*
22 *and*

23 *“(2) by promoting data sharing regarding new-*
24 *born screening with State-based birth defects and de-*
25 *velopmental disabilities monitoring programs.”.*

1 **SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON**
2 **NEWBORN AND CHILD SCREENING.**

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

5 *(1) in subsection (c), by striking “the Adminis-*
6 *trator, the Director of the Agency for Healthcare Re-*
7 *search and Quality” and inserting “the Adminis-*
8 *trator of the Health Resources and Services Adminis-*
9 *tration, the Director of the Agency for Healthcare Re-*
10 *search and Quality, the Commissioner of Food and*
11 *Drugs,”; and*

12 *(2) by striking subsection (e) (relating to author-*
13 *ization of appropriations).*

14 **SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN**
15 **SCREENING.**

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

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

21 *Section 1116(a)(1) of the Public Health Service Act*
22 *(42 U.S.C. 300b–15(a)(1)) is amended—*

23 *(1) in subparagraph (B), by striking “; and”*
24 *and inserting a semicolon;*

25 *(2) by redesignating subparagraph (C) as sub-*
26 *paragraph (E); and*

1 (3) by inserting after subparagraph (B) the fol-
2 lowing:

3 “(C) by providing research findings and
4 data for newborn conditions under review by the
5 Advisory Committee on Heritable Disorders in
6 Newborns and Children to be added to the rec-
7 ommended uniform screening panel;

8 “(D) conducting pilot studies on conditions
9 recommended by the Advisory Committee on
10 Heritable Disorders in Newborns and Children
11 to ensure that screenings are ready for nation-
12 wide implementation; and”.

13 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

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

16 **“SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR**
17 **NEWBORN SCREENING PROGRAMS AND AC-**
18 **TIVITIES.**

19 “There are authorized to be appropriated—

20 “(1) to carry out sections 1109, 1110, 1111, and
21 1112, \$18,334,000 for each of fiscal years 2014
22 through 2018; and

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

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 to*
7 *the Committee on Health, Education, Labor and Pen-*
8 *sions of the Senate and the Committee on Energy and*
9 *Commerce of the House of Representatives concerning*
10 *the timeliness of screening for heritable disorders in*
11 *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 follow-up testing, and follow-up 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 sup-*
24 *port 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 *ressing 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 the Newborn Screening Saves Lives*
8 *Reauthorization Act of 2013, submit to the Com-*
9 *mittee on Health, Education, Labor and Pen-*
10 *sions of the Senate and the Committee on En-*
11 *ergy and Commerce of the House of Representa-*
12 *tives a report on activities related to—*

13 **(i)** *newborn screening; and*

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

16 **(B)** *not less than every 2 years, shall submit*
17 *to such committees an updated version of such*
18 *report.*

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

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

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

Calendar No. 282

113TH CONGRESS
1ST Session
S. 1417

A BILL

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

DECEMBER 19, 2013

Reported with an amendment