

113TH 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 and Mr. HATCH) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 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.

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 (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 “follow-up and treatment”;

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

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

1 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**
2 **AND CHILD SCREENING AND FOLLOW-UP**
3 **PROGRAMS.**

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

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

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

10 (3) in subsection (b)—

11 (A) in paragraph (1), by inserting “ascertain-
12 tainment, treatment,” after “the effectiveness
13 of screening, counseling,”;

14 (B) in paragraph (2)—

15 (i) by inserting “ascertainment, treat-
16 ment,” after “the effectiveness of screen-
17 ing, counseling,”; and

18 (ii) by striking “or” at the end;

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

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

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

25 “(5) the costs and effectiveness of newborn
26 screening, evaluation and intervention programs, and

1 surveillance systems conducted by State-based pro-
2 grams in order to answer issues of importance to
3 State and national policymakers;

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

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

11 “(8) the coordination of surveillance activities,
12 including—

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

15 “(B) use of electronic health records;

16 “(9) the facilitation of quality improvement in
17 treatment and disease management based on gaps in
18 services or care identified by longitudinal tracking
19 systems; and

20 “(10) the utilization of data from longitudinal
21 tracking systems to support the development and
22 evaluation of evidence-based guidelines for diagnosis,
23 treatment, and disease management.”; and

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

1 **SEC. 4. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
2 **IN NEWBORNS AND CHILDREN.**

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

5 (1) in subsection (b)—

6 (A) in paragraph (4), by striking “public
7 health impact” and inserting “public health im-
8 pact, including the cost”; and

9 (B) in paragraph (6)—

10 (i) in subparagraph (A), by striking
11 “achieve rapid diagnosis” and inserting
12 “achieve best practices in rapid diagnosis
13 and appropriate treatment”;

14 (ii) in subparagraph (D), by inserting
15 before the semicolon “, including informa-
16 tion on cost and incidence”;

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

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

21 (2) in subsection (d)—

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

24 (B) in paragraph (2), by striking “New-
25 born Screening Saves Lives Act of 2008” and

1 insert “Newborn Screening Saves Lives Reau-
2 thorization Act of 2013”; and

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

4 “(4) PRIORITY REVIEW.—

5 “(A) IN GENERAL.—For each nomination
6 to the recommended uniform screening panel
7 that meets the criteria of subparagraph (B), the
8 Advisory Committee on Heritable Disorders in
9 Newborns and Children shall provide a priority
10 review as described in this paragraph and sub-
11 ject to the deadlines in subparagraph (C).

12 “(B) CRITERIA FOR PRIORITY REVIEW.—
13 The Advisory Committee on Heritable Dis-
14 orders in Newborns and Children shall provide
15 a priority review with respect to a nomination
16 to the recommended uniform screening panel
17 that meets each of the following criteria:

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

24 “(ii) The application described in
25 clause (i) has been granted priority review

1 or has received fast track or breakthrough
2 therapy designations by the Secretary as
3 described in section 529(a)(1) of the Fed-
4 eral Food, Drug, and Cosmetic Act (21
5 U.S.C. 360ff(a)(1)).

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

11 “(i) the date on which the Advisory
12 Committee refers the nomination to the
13 condition review workgroup; or

14 “(ii) the date of the approval, by the
15 Food and Drug Administration, of the
16 treatment associated with the nomination
17 to the recommended uniform screening
18 panel.

19 “(D) FAILURE TO ACT.—If the Secretary
20 fails to act on a recommendation within the
21 time period provided for in paragraph (1), the
22 Secretary shall adopt the recommendation and
23 include the screening recommended by the Advi-
24 sory Committee on Heritable Disorders in

1 Newborns and Children in the recommended
2 uniform screening panel.

3 “(E) OTHER REVIEWS.—For each nomina-
4 tion to the recommended uniform screening
5 panel that does not meet the criteria of sub-
6 paragraph (B), the Advisory Committee on
7 Heritable Disorders in Newborns and Children
8 shall provide for a review and vote on the nomi-
9 nated condition that is under review within 10
10 months of the date on which the Advisory Com-
11 mittee referred the nomination to the condition
12 review workgroup.”;

13 (3) by redesignating subsections (f) and (g) as
14 subsections (g) and (h), respectively;

15 (4) by inserting after subsection (e) the fol-
16 lowing new subsection:

17 “(f) MEETINGS.—The Advisory Committee shall
18 meet at least 4 times each calendar year with at least 2
19 meetings in person.”; and

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

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), by striking the pe-
9 riod at the end and inserting a semicolon; and

10 (C) by adding at the end the following new
11 paragraphs:

12 “(4) maintain current data on the number of
13 conditions for which screening is conducted in each
14 State; and

15 “(5) disseminate available evidence-informed
16 guidelines related to diagnosis, counseling, and
17 treatment with respect to conditions detected by
18 newborn screening.”;

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

23 (3) by striking subsection (d) (relating to au-
24 thorization of appropriations).

1 **SEC. 6. LABORATORY QUALITY.**

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

4 (1) in subsection (a)—

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

7 (B) by striking “and in consultation with
8 the Advisory Committee” and inserting “and
9 taking into consideration the recommendations
10 of the Advisory Committee”; and

11 (2) by striking subsection (b) (relating to au-
12 thorization of appropriations).

13 **SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON**
14 **NEWBORN AND CHILD SCREENING.**

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

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

24 (2) by striking subsection (e) (relating to au-
25 thorization of appropriations) and inserting the fol-
26 lowing:

1 “(e) REPORT TO CONGRESS.—

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

3 “(A) not later than 1 year after the date
4 of enactment of the Newborn Screening Saves
5 Lives Reauthorization Act of 2013, submit to
6 the Health, Education, Labor, and Pensions
7 Committee of the Senate and the Energy and
8 Commerce Committee of the House of Rep-
9 resentatives a report on activities related to—

10 “(i) newborn screening; and

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

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

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

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

20 “(B) the amounts expended on such imple-
21 mentation.”.

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) providing research and data for new-
13 born conditions under review by the Advisory
14 Committee on Heritable Disorders in Newborns
15 and Children to be added to the recommended
16 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.”.

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