

113TH CONGRESS
2^D SESSION

H. R. 1281

IN THE SENATE OF THE UNITED STATES

JUNE 25, 2014

Received

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 2014”.

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 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.

7 **SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND**
8 **FOLLOWUP 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) by amending paragraph (2) to read as
2 follows:

3 “(2) to assist in providing health care profes-
4 sionals and newborn screening laboratory personnel
5 with education in newborn screening, counseling,
6 and training in—

7 “(A) relevant and new technologies in new-
8 born screening and congenital, genetic, and
9 metabolic disorders;

10 “(B) the importance of the timeliness of
11 collection, delivery, receipt, and screening of
12 specimens; and

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

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

17 (D) in paragraph (4)—

18 (i) by striking “treatment” and insert-
19 ing “followup and treatment”; and

20 (ii) by striking the period and insert-
21 ing “; and”; and

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

23 “(5) to improve the timeliness of—

24 “(A) the collection, delivery, receipt, and
25 screening of specimens; and

1 “(B) the diagnosis of heritable disorders in
2 newborns.”;

3 (2) in subsection (c), by striking “application
4 submitted for a grant under subsection (a)(1)” and
5 inserting “application for a grant under this sec-
6 tion”;

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

11 (4) by striking subsection (j) (relating to au-
12 thorization of appropriations).

13 **SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN**
14 **AND CHILD SCREENING AND FOLLOWUP**
15 **PROGRAMS.**

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

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

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

23 (3) in subsection (b)—

24 (A) in paragraph (1)—

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

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

9 (B) in paragraph (2)—

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

13 (ii) by inserting “in a timely manner”
14 after “in newborns and children”; and

15 (iii) by striking “or” at the end;

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

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

19 “(4) methods that may be identified to improve
20 quality in the diagnosis, treatment, and disease
21 management of heritable disorders based on gaps in
22 services or care; or

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

1 “(A) collection, delivery, receipt, and
2 screening of newborn screening specimens; and

3 “(B) diagnosis of heritable disorders in
4 newborns.”; and

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

7 **SEC. 4. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
8 **IN NEWBORNS AND CHILDREN.**

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

11 (1) in subsection (b)—

12 (A) by redesignating paragraphs (4)
13 through (6) as paragraphs (6) through (8), re-
14 spectively;

15 (B) by inserting after paragraph (3), the
16 following:

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

22 “(5) take appropriate steps, at its discretion, to
23 prepare for the review of nominations prior to their
24 submission, including for conditions for which a
25 screening method has been validated but other nomi-

1 nation criteria are not yet met, in order to facilitate
2 timely action by the Advisory Committee once such
3 submission has been received by the Committee;”;

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

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

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

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

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

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

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

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

25 (2) in subsection (d)—

1 (A) in paragraph (1)—

2 (i) by striking “180” and inserting
3 “120”; and

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

16 (B) by striking paragraph (2);

17 (C) by redesignating paragraph (3) as
18 paragraph (2); and

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

20 “(3) DEADLINE FOR REVIEW.—For each condi-
21 tion nominated to be added to the recommended uni-
22 form screening panel in accordance with the require-
23 ments of this section, the Advisory Committee shall
24 review and vote on the nominated condition within
25 9 months of the date on which the Advisory Com-

1 mittee referred the nominated condition to the con-
2 dition review workgroup.”;

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

5 (4) by inserting after subsection (e) the fol-
6 lowing new subsection:

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

11 (5) by amending subsection (g) (as so redesign-
12 nated) to read as follows:

13 “(g) CONTINUATION OF OPERATION OF COM-
14 MITTEE.—

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

19 “(2) CONTINUATION IF NOT REAUTHORIZED.—
20 If at the end of fiscal year 2019 the duration of the
21 Advisory Committee has not been extended by stat-
22 ute, the Advisory Committee may be deemed, for
23 purposes of the Federal Advisory Committee Act, an
24 advisory committee established by the President or

1 an officer of the Federal Government under section
2 9(a) of such Act.”; and

3 (6) by striking subsection (h) (relating to au-
4 thorization of appropriations), as redesignated by
5 paragraph (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” at
12 the end;

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
2 screening.”;

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 Reauthoriza-
6 tion Act of 2014”;

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 duplication and supplements, not supplants”
13 and inserting “activities minimize duplication
14 and supplement, not supplant”; and

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

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

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

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

22 (2) in subsection (a)—

23 (A) 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
2 Committee”; and

3 (B) in paragraph (1), by inserting “timeli-
4 ness for processing such tests,” after “newborn-
5 screening tests,”; and

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

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

16 “(1) through standardized data collection and
17 reporting, as well as the use of electronic health
18 records; and

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

22 **SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON**
23 **NEWBORN AND CHILD SCREENING.**

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

1 (1) in subsection (c), by striking “the Adminis-
2 trator, the Director of the Agency for Healthcare
3 Research and Quality,” and inserting “the Adminis-
4 trator of the Health Resources and Services Admin-
5 istration, the Director of the Agency for Healthcare
6 Research and Quality, the Commissioner of Food
7 and Drugs,”; and

8 (2) by striking subsection (e) (relating to au-
9 thorization of appropriations).

10 **SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN**
11 **SCREENING.**

12 Section 1115(a) of the Public Health Service Act (42
13 U.S.C. 300b–14(a)) is amended—

14 (1) by striking “consortia” and inserting “con-
15 sortium”; and

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

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

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

22 (1) in subsection (a)(1)—

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

1 (B) by redesignating subparagraph (C) as
2 subparagraph (E); and

3 (C) by inserting after subparagraph (B)
4 the following:

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

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

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

17 **SEC. 10. AUTHORIZATION OF APPROPRIATIONS.**

18 Part A of title XI of the Public Health Service Act
19 (42 U.S.C. 300b–1 et seq.) is amended by adding at the
20 end, the following:

21 **“SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR**
22 **NEWBORN SCREENING PROGRAMS AND AC-**
23 **TIVITIES.**

24 “There are authorized to be appropriated—

1 “(1) to carry out sections 1109, 1110, 1111,
2 and 1112, \$11,900,000 for each of fiscal years 2015
3 through 2019; and

4 “(2) to carry out section 1113, \$8,000,000 for
5 each of fiscal years 2015 through 2019.”.

6 **SEC. 11. REPORTS TO CONGRESS.**

7 (a) GAO REPORT ON TIMELINESS OF NEWBORN
8 SCREENING.—

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

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

19 (A) An analysis of information regarding
20 the timeliness of newborn screening, which may
21 include the time elapsed from birth to specimen
22 collection, specimen collection to receipt by lab-
23 oratory, specimen receipt to reporting, reporting
24 to followup testing, and followup testing to con-
25 firmed diagnosis.

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

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

9 (b) REPORT BY SECRETARY.—

10 (1) IN GENERAL.—The Secretary of Health and
11 Human Services shall—

12 (A) not later than 1 year after the date of
13 enactment of this Act, submit to the Committee
14 on Health, Education, Labor, and Pensions of
15 the Senate and the Committee on Energy and
16 Commerce of the House of Representatives a
17 report on activities related to—

18 (i) newborn screening; and

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

21 (B) not less than every 2 years, submit to
22 such committees an updated version of such re-
23 port.

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

