

116TH CONGRESS
1ST SESSION

S. 2158

To improve certain programs of the Department of Health and Human Services with respect to heritable disorders.

IN THE SENATE OF THE UNITED STATES

JULY 18, 2019

Ms. HASSAN (for herself and Mr. GARDNER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To improve certain programs of the Department of Health and Human Services with respect to heritable disorders.

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.**

4 This Act may be cited as the “The Newborn Screen-
5 ing Saves Lives Reauthorization Act of 2019”.

6 **SEC. 2. AMENDMENTS.**

7 (a) IMPROVED NEWBORN AND CHILD SCREENING
8 FOR HERITABLE DISORDERS.—Section 1109(a)(3) of the
9 Public Health Service Act (42 U.S.C. 300b–8(a)(3)) is
10 amended—

1 (1) by striking “develop and deliver educational
2 programs (at appropriate literacy levels)” and in-
3 serting “develop, deliver, and assess the impact of
4 educational programs (with varying levels of infor-
5 mation and at appropriate literacy levels)”; and

6 (2) by striking “and specialty services” and in-
7 serting “specialty services, research-related pilot
8 studies, and long-term care”.

9 (b) EXTENSION OF ADVISORY COMMITTEE ON HERI-
10 TABLE DISORDERS IN NEWBORNS AND CHILDREN.—Sec-
11 tion 1111(g) of the Public Health Service Act (42 U.S.C.
12 300b–10(g)) is amended by striking “2019” each place
13 it appears and inserting “2024”.

14 (c) TECHNICAL AMENDMENTS.—Title XI of the Pub-
15 lic Health Service Act (42 U.S.C. 300b–1 et seq.) is
16 amended—

17 (1) in the section heading of section 1110, by
18 striking “**FOLLOWUP**” and inserting “**FOLLOW-**
19 **UP**”;

20 (2) in sections 1109, 1110, and 1111, by strik-
21 ing “followup” each place such term appears and in-
22 serting “follow-up”; and

23 (3) in paragraphs (1) and (2) of section
24 1110(b), by inserting “(including long-term follow-
25 up)” before “, or specialty”.

1 (d) CLEARINGHOUSE OF NEWBORN SCREENING IN-
2 FORMATION.—Subsection (c) of section 1112 of the Public
3 Health Service Act (42 U.S.C. 300b–11) is amended to
4 read as follows:

5 “(c) NONDUPLICATION.—In carrying out activities
6 under this section, the Secretary shall ensure that such
7 activities minimize duplication and complement other ex-
8 isting Federal newborn screening-related information-
9 sharing activities.”.

10 (e) LABORATORY QUALITY AND SURVEILLANCE.—
11 Section 1113 of the Public Health Service Act (42 U.S.C.
12 300b–12) is amended—

13 (1) in subsection (a)—

14 (A) in paragraph (1)—

15 (i) by striking “performance evalua-
16 tion services” and inserting “development
17 of new screening tests”; and

18 (ii) by striking “; and” and inserting
19 a semicolon;

20 (B) in paragraph (2)—

21 (i) by striking “performance test ma-
22 terials” and inserting “test performance
23 materials”; and

24 (ii) by striking the period and insert-
25 ing “; and”; and

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

2 “(3) performance evaluation services to enhance
3 disease detection, including the development of tools
4 and resources to improve data analysis, interpreta-
5 tion of test results, and dissemination of laboratory
6 best practices.”; and

7 (2) in subsection (b)—

8 (A) in paragraph (1), by striking “; and”
9 and inserting a semicolon;

10 (B) in paragraph (2), by striking the pe-
11 riod and inserting “; and”; and

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

13 “(3) by assisting States, as appropriate, in as-
14 sassing and conducting long-term follow-up and as-
15 sassing long-term outcomes.”.

16 (f) HUNTER KELLY RESEARCH PROGRAM.—Section
17 1116(a)(1)(D) of the Public Health Service Act (42
18 U.S.C. 300b–15(a)(1)(D)) is amended—

19 (1) by inserting “, or with a high probability of
20 being recommend by,” after “recommended by”; and

21 (2) by striking “to ensure that screenings are
22 ready for nationwide implementation” and inserting
23 “, which may include those conditions that have
24 been nominated pursuant to section 1111, to ensure

1 that screening technologies are piloted and ready for
2 implementation”.

3 (g) AUTHORIZATION OF APPROPRIATIONS.—Section
4 1117 of the Public Health Service Act (42 U.S.C. 300b–
5 16) is amended—

6 (1) in paragraph (1), by striking “\$11,900,000
7 for each of fiscal years 2015 through 2019” and in-
8 serting “\$16,383,000 for each of fiscal years 2020
9 through 2024”; and

10 (2) in paragraph (2), by striking “\$8,000,000
11 for each of fiscal years 2015 through 2019” and in-
12 serting “\$17,250,000 for each of fiscal years 2020
13 through 2024”.

14 (h) TECHNICAL ASSISTANCE.—The Secretary shall
15 publish on the internet website of the Department of
16 Health and Human Services, information regarding the
17 process for obtaining technical assistance for submitting
18 nominations to the recommended uniform screening panel.

19 (i) REPORT ON THE MODERNIZATION OF NEWBORN
20 SCREENING.—

21 (1) IN GENERAL.—The Secretary of Health and
22 Human Services shall, directly or through a con-
23 tract, conduct an assessment of each of the fol-
24 lowing:

1 (A) The uniform screening panel review
2 and recommendation processes, including an as-
3 sessment of factors that impact decisions to add
4 new conditions to the uniform screening panel
5 and challenges associated with newly nominated
6 conditions, including rare diseases with late
7 onset variants.

8 (B) Strategies to support implementation
9 of uniform screening panel recommendations.

10 (C) Opportunities to improve newborn
11 screening research, such as piloting the screen-
12 ing of multiple conditions in a single test and
13 optimizing the capacity for such research.

14 (D) Technologies that would improve
15 screening, including technologies that identify
16 multiple, related disorders in a single test.

17 (E) Methods to improve public health sur-
18 veillance, timeliness of diagnosis, and short- and
19 long-term follow-up for infants identified
20 through newborn screening.

21 (F) Strategies to improve communication
22 with the public and stakeholders in order to
23 promote understanding and knowledge of the
24 newborn screening system.

1 (G) The quality of data on disease preva-
2 lence for screened conditions.

3 (H) The effect of newborn screening on the
4 outcomes of those identified as newborns
5 through such screenings.

6 (2) REPORT.—Not later than 2 years after the
7 date of enactment of this Act, the Secretary of
8 Health and Human Services shall submit, to the
9 Committee on Health, Education, Labor, and Pen-
10 sions of the Senate and the Committee on Energy
11 and Commerce of the House of Representatives, a
12 report containing the results of the assessment and
13 recommendations to improve processes described in
14 paragraph (1).

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