

116TH CONGRESS  
1ST SESSION

# H. R. 2507

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IN THE SENATE OF THE UNITED STATES

JULY 25, 2019

Received; read twice and referred to the Committee on Health, Education,  
Labor, and Pensions

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## AN ACT

To amend the Public Health Service Act to reauthorize certain programs under part A of title XI of such Act relating to genetic diseases, and for other purposes.

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.**

2 This Act may be cited as the “Newborn Screening  
3 Saves Lives Reauthorization Act of 2019”.

**4 SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND  
5 FOLLOW-UP FOR HERITABLE DISORDERS.**

6 (a) PURPOSES.—Section 1109(a) of the Public  
7 Health Service Act (42 U.S.C. 300b–8(a)) is amended—  
8 (1) in paragraph (1), by striking “enhance, im-  
9 prove or” and inserting “facilitate, enhance, im-  
10 prove, or”;

11 (2) by amending paragraph (3) to read as fol-  
12 lows:

13 “(3) to develop, and deliver to parents, families,  
14 and patient advocacy and support groups, edu-  
15 cational programs that—

16 “(A) address newborn screening coun-  
17 seling, testing (including newborn screening  
18 pilot studies), follow-up, treatment, specialty  
19 services, and long-term care;

20 “(B) assess the target audience’s current  
21 knowledge, incorporate health communications  
22 strategies, and measure impact; and

23 “(C) are at appropriate literacy levels;”;  
24 and

25 (3) in paragraph (4)—

1 (A) by striking “followup” and inserting  
2 “follow-up”; and

3 (B) by inserting before the semicolon at  
4 the end the following: “, including re-engaging  
5 patients who have not received recommended  
6 follow-up services and supports”.

7 (b) APPROVAL FACTORS.—Section 1109(c) of the  
8 Public Health Service Act (42 U.S.C. 300b-8(c)) is  
9 amended—

10 (1) by striking “or will use” and inserting “will  
11 use”; and

## 16 SEC. 3. ADVISORY COMMITTEE ON HERITABLE DISORDERS

## IN NEWBORNS AND CHILDREN.

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

20 (1) in subsection (b)—

21 (A) in paragraph

22 adopt process improvements” after “take ap-  
23 propriate steps”;

24 (B) in paragraph (7) by striking “and” at  
25 the end;

1 (C) by redesignating paragraph (8) as  
2 paragraph (9);

3 (D) by inserting after paragraph (7) the  
4 following:

5                   “(8) develop, maintain, and publish on a pub-  
6                   licly accessible website consumer-friendly materials  
7                   detailing—

8                   “(A) the uniform screening panel nomina-  
9                   tion process, including data requirements,  
10                   standards, and the use of international data in  
11                   nomination submissions; and

12                             “(B) the process for obtaining technical as-  
13                             sistance for submitting nominations to the uni-  
14                             form screening panel and detailing the in-  
15                             stances in which the provision of technical as-  
16                             sistance would introduce a conflict of interest  
17                             for members of the Advisory Committee; and”;

18 (E) in paragraph (9), as redesignated—

19 (i) by redesignating subparagraphs  
20 (K) and (L) as subparagraphs (L) and  
21 (M), respectively; and

22 (ii) by inserting after subparagraph  
23 (J) the following:

24 " (K) the appropriate and recommended  
25 use of safe and effective genetic testing by

1        health care professionals in newborns and chil-  
2        dren with an initial diagnosis of a disease or  
3        condition characterized by a variety of genetic  
4        causes and manifestations;”; and  
5        (2) in subsection (g)—

10 SEC. 4. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-  
11 MATION.

12       Section 1112(c) of the Public Health Service Act (42  
13 U.S.C. 300b-11(c)) is amended by striking “and supple-  
14 ment, not supplant, existing information sharing efforts”  
15 and inserting “and complement other Federal newborn  
16 screening information sharing activities”.

## 17 SEC. 5. 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 subsection (a)—

21 (A) in paragraph 1

22 (i) by striking “performance evalua-  
23 tion services,” and inserting “development  
24 of new screening tests,”; and  
25 (ii) by striking “and” at the end;



1 the initial positive screen through diagnosis and  
2 long-term care management; and

3 “(2) by promoting data sharing linkages be-  
4 tween State newborn screening programs and State-  
5 based birth defects and developmental disabilities  
6 surveillance programs to help families connect with  
7 services to assist in evaluating long-term outcomes.”.

8 **SEC. 6. HUNTER KELLY RESEARCH PROGRAM.**

9 Section 1116 of the Public Health Service Act (42  
10 U.S.C. 300b-15) is amended—

11 (1) in subsection (a)(1)—

12 (A) by striking “may” and inserting  
13 “shall”; and

14 (B) in subparagraph (D)—

15 (i) by inserting “, or with a high prob-  
16 ability of being recommended by,” after  
17 “recommended by”; and

18 (ii) by striking “that screenings are  
19 ready for nationwide implementation” and  
20 inserting “that reliable newborn screening  
21 technologies are piloted and ready for  
22 use”; and

23 (2) in subsection (b) to read as follows:

24 “(b) FUNDING.—In carrying out the research pro-  
25 gram under this section, the Secretary and the Director

1 shall ensure that entities receiving funding through the  
2 program will provide assurances, as practicable, that such  
3 entities will work in consultation with State departments  
4 of health, as appropriate.”.

5 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS FOR NEW-**  
6 **BORN SCREENING PROGRAMS AND ACTIVI-**  
7 **TIES.**

8 Section 1117 of the Public Health Service Act (42  
9 U.S.C. 300b–16) is amended—

10 (1) in paragraph (1)—  
11 (A) by striking “\$11,900,000” and inserting  
12 “\$31,000,000”;  
13 (B) by striking “2015” and inserting  
14 “2020”; and  
15 (C) by striking “2019” and inserting  
16 “2024”; and  
17 (2) in paragraph (2)—  
18 (A) by striking “\$8,000,000” and inserting  
19 “\$29,650,000”;  
20 (B) by striking “2015” and inserting  
21 “2020”; and  
22 (C) by striking “2019” and inserting  
23 “2024”.

## 1 SEC. 8. INSTITUTIONAL REVIEW BOARDS; ETHICS GUID- 2 ANCE PROGRAM.

3 Section 12 of the Newborn Screening Saves Lives Re-  
4 authorization Act of 2014 (42 U.S.C. 289 note) is amend-  
5 ed to read as follows:

## 6 "SEC. 12. INSTITUTIONAL REVIEW BOARDS; ETHICS GUID- 7 ANCE PROGRAM.

8        “Research on nonidentified newborn dried blood spots  
9 shall be considered secondary research (as that term is  
10 defined in section 46.104(d)(4) of title 45, Code of Federal  
11 Regulations (or successor regulations)) with nonidentified  
12 biospecimens for purposes of federally funded research  
13 conducted pursuant to the Public Health Service Act (42  
14 U.S.C. 200 et seq.).”.

15 SEC. 9. NAM REPORT ON THE MODERNIZATION OF NEW-  
16 BORN SCREENING.

17 (a) STUDY.—Not later than 60 days after the date  
18 of the enactment of this Act, the Secretary of Health and  
19 Human Services shall seek to enter into an agreement  
20 with the National Academy of Medicine (in this section  
21 referred to as “NAM”) (or if NAM declines to enter into  
22 such an agreement, another appropriate entity) under  
23 which NAM, or such other appropriate entity, agrees to  
24 conduct a study on the following:

25 (1) The uniform screening panel review and  
26 recommendation processes to identify factors that

1 impact decisions to add new conditions to the uni-  
2 form screening panel, to describe challenges posed  
3 by newly nominated conditions, including low-inci-  
4 dence diseases, late onset variants, and new treat-  
5 ments without long-term efficacy data.

6 (2) The barriers that preclude States from add-  
7 ing new uniform screening panel conditions to their  
8 State screening panels with recommendations on re-  
9 sources needed to help States implement uniform  
10 screening panel recommendations.

11 (3) The current state of federally and privately  
12 funded newborn screening research with rec-  
13 commendations for optimizing the capacity of this re-  
14 search, including piloting multiple prospective condi-  
15 tions at once and addressing rare disease questions.

16 (4) New and emerging technologies that would  
17 permit screening for new categories of disorders, or  
18 would make current screening more effective, more  
19 efficient, or less expensive.

20 (5) Technological and other infrastructure  
21 needs to improve timeliness of diagnosis and short-  
22 and long-term follow-up for infants identified  
23 through newborn screening and improve public  
24 health surveillance.

14 (8) The impact on newborn morbidity and mor-  
15 tality in States that adopt newborn screening tests  
16 included on the uniform panel.

17 (b) PUBLIC STAKEHOLDER MEETING.—In the course  
18 of completing the study described in subsection (a), NAM  
19 or such other appropriate entity shall hold not less than  
20 one public meeting to obtain stakeholder input on the top-  
21 ics of such study.

22 (c) REPORT.—Not later than 18 months after the ef-  
23 fective date of the agreement under subsection (a), such  
24 agreement shall require NAM, or such other appropriate  
25 entity, to submit to the Secretary of Health and Human

## 1 Services and the appropriate committees of jurisdiction of

## 2 Congress a report containing—

3 (1) the results of the study conducted under  
4 subsection (a);

5 (2) recommendations to modernize the proc-  
6 esses described in subsection (a)(1); and

10 (d) AUTHORIZATION OF APPROPRIATIONS.—There is  
11 authorized to be appropriated \$2,000,000 for the period  
12 of fiscal years 2020 and 2021 to carry out this section.

Passed the House of Representatives July 24, 2019.

Attest:

CHERYL L. JOHNSON,

*Clerk.*