

Union Calendar No.

116TH CONGRESS
1ST SESSION

H. R. 2507

[Report No. 116-]

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.

IN THE HOUSE OF REPRESENTATIVES

MAY 2, 2019

Ms. ROYBAL-ALLARD (for herself, Mr. SIMPSON, Ms. CLARK of Massachusetts, and Ms. HERRERA BEUTLER) introduced the following bill; which was referred to the Committee on Energy and Commerce

JULY --, 2019

Reported with an amendment, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

[Strike out all after the enacting clause and insert the part printed in italics]

[For text of introduced bill, see copy of bill as introduced on May 2, 2019]

A BILL

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,*

3 **SECTION 1. SHORT TITLE.**

4 *This Act may be cited as the “Newborn Screening*
5 *Saves Lives Reauthorization Act of 2019”.*

6 **SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING AND**
7 **FOLLOW-UP FOR HERITABLE DISORDERS.**

8 *(a) PURPOSES.—Section 1109(a) of the Public Health*
9 *Service Act (42 U.S.C. 300b–8(a)) is amended—*

10 *(1) in paragraph (1), by striking “enhance, im-*
11 *prove or” and inserting “facilitate, enhance, improve,*
12 *or”;*

13 *(2) by amending paragraph (3) to read as fol-*
14 *lows:*

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

18 *“(A) address newborn screening counseling,*
19 *testing (including newborn screening pilot stud-*
20 *ies), follow-up, treatment, specialty services, and*
21 *long-term care;*

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

1 “(C) are at appropriate literacy levels;”;

2 and

3 (3) in paragraph (4)—

4 (A) by striking “followup” and inserting
5 “follow-up”; and

6 (B) by inserting before the semicolon at the
7 end the following: “, including re-engaging pa-
8 tients who have not received recommended follow-
9 up services and supports”.

10 (b) *APPROVAL FACTORS*.—Section 1109(c) of the Pub-
11 lic Health Service Act (42 U.S.C. 300b–8(c)) is amended—

12 (1) by striking “or will use” and inserting “will
13 use”; and

14 (2) by inserting “, or will use amounts received
15 under such grant to enhance capacity and infrastruc-
16 ture to facilitate the adoption of,” before “the guide-
17 lines and recommendations”.

18 **SEC. 3. ADVISORY COMMITTEE ON HERITABLE DISORDERS**

19 **IN NEWBORNS AND CHILDREN.**

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

22 (1) in subsection (b)—

23 (A) in paragraph (5), by inserting “and
24 adopt process improvements” after “take appro-
25 priate steps”;

1 (B) in paragraph (7) by striking “and” at
2 the end;

3 (C) by redesignating paragraph (8) as
4 paragraph (9);

5 (D) by inserting after paragraph (7) the fol-
6 lowing:

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

10 “(A) the uniform screening panel nomina-
11 tion process, including data requirements, stand-
12 ards, and the use of international data in nomi-
13 nation submissions; and

14 “(B) the process for obtaining technical as-
15 sistance for submitting nominations to the uni-
16 form screening panel and detailing the instances
17 in which the provision of technical assistance
18 would introduce a conflict of interest for mem-
19 bers of the Advisory Committee; and”;

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

21 (i) by redesignating subparagraphs (K)
22 and (L) as subparagraphs (L) and (M), re-
23 spectively; and

24 (ii) by inserting after subparagraph
25 (J) the following:

1 “(K) the appropriate and recommended use
2 of safe and effective genetic testing by health care
3 professionals in newborns and children with an
4 initial diagnosis of a disease or condition char-
5 acterized by a variety of genetic causes and
6 manifestations;” and

7 (2) in subsection (g)—

8 (A) in paragraph (1) by striking “2019”
9 and inserting “2024”; and

10 (B) in paragraph (2) by striking “2019”
11 and inserting “2024”.

12 **SEC. 4. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-**
13 **MATION.**

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

19 **SEC. 5. LABORATORY QUALITY AND SURVEILLANCE.**

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

22 (1) in subsection (a)—

23 (A) in paragraph (1)—

1 (i) by striking “performance evalua-
2 tion services,” and inserting “development
3 of new screening tests,”; and

4 (ii) by striking “and” at the end;
5 (B) in paragraph (2)—

6 (i) by striking “performance test mate-
7 rials” and inserting “test performance ma-
8 terials”; and

9 (ii) by striking the period at the end
10 and inserting “; and”; and

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

12 “(3) performance evaluation services to enhance
13 disease detection, including the development of tools,
14 resources, and infrastructure to improve data anal-
15 ysis, test result interpretation, data harmonization,
16 and dissemination of laboratory best practices.”; and

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

18 “(b) *SURVEILLANCE ACTIVITIES.*—*The Secretary, act-*
19 *ing through the Director of the Centers for Disease Control*
20 *and Prevention, and taking into consideration the expertise*
21 *of the Advisory Committee on Heritable Disorders in*
22 *Newborns and Children established under section 1111,*
23 *shall provide for the coordination of national surveillance*
24 *activities, including—*

1 “(1) *standardizing data collection and reporting*
2 *through the use of electronic and other forms of health*
3 *records to achieve real-time data for tracking and*
4 *monitoring the newborn screening system, from the*
5 *initial positive screen through diagnosis and long-*
6 *term care management; and*

7 “(2) *by promoting data sharing linkages between*
8 *State newborn screening programs and State-based*
9 *birth defects and developmental disabilities surveil-*
10 *lance programs to help families connect with services*
11 *to assist in evaluating long-term outcomes.”.*

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

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

15 *(1) in subsection (a)(1)—*

16 *(A) by striking “may” and inserting*
17 *“shall”; and*

18 *(B) in subparagraph (D)—*

19 *(i) by inserting “, or with a high prob-*
20 *ability of being recommended by,” after*
21 *“recommended by”; and*

22 *(ii) by striking “that screenings are*
23 *ready for nationwide implementation” and*
24 *inserting “that reliable newborn screening*

1 *technologies are evaluated and ready for*
2 *use”; and*

3 *(2) in subsection (b) to read as follows:*

4 “(b) *FUNDING.—In carrying out the research program*
5 *under this section, the Secretary and the Director—*

6 *“(1) shall ensure that entities receiving funding*
7 *through the program will provide assurances, as prac-*
8 *ticable, that such entities will work in consultation*
9 *with the appropriate State departments of health; and*

10 *“(2) may accept, use, and dispose of donations*
11 *and bequests from private for-profit and non-profit*
12 *entities, in accordance with Federal law.”.*

13 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS FOR NEW-**
14 **BORN SCREENING PROGRAMS AND ACTIVI-**
15 **TIES.**

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

18 *(1) in paragraph (1)—*

19 *(A) by striking “\$11,900,000” and inserting*
20 *“\$31,000,000”;*

21 *(B) by striking “2015” and inserting*
22 *“2020”; and*

23 *(C) by striking “2019” and inserting*
24 *“2024”; and*

25 *(2) in paragraph (2)—*

1 (A) by striking “\$8,000,000” and inserting
2 “\$29,650,000”;
3 (B) by striking “2015” and inserting
4 “2020”; and
5 (C) by striking “2019” and inserting
6 “2024”.

7 **SEC. 8. INSTITUTIONAL REVIEW BOARDS; ETHICS GUID-**
8 **ANCE PROGRAM.**

9 Section 12 of the Newborn Screening Saves Lives Re-
10 authorization Act of 2014 (42 U.S.C. 289 note) is amended
11 to read as follows:

12 **“SEC. 12. INSTITUTIONAL REVIEW BOARDS; ETHICS GUID-**
13 **ANCE PROGRAM.**

14 “Research on nonidentified newborn dried blood spots
15 shall be considered secondary research (as that term is de-
16 fined in part 4 of section 46.104 of title 45, Code of Federal
17 Regulations) with nonidentified biospecimens for purposes
18 of federally funded research conducted pursuant to the Pub-
19 lic Health Service Act (42 U.S.C. 200 et seq.).”

20 **SEC. 9. NAM REPORT ON THE MODERNIZATION OF NEW-**
21 **BORN SCREENING.**

22 (a) *STUDY.*—Not later than 60 days after the date of
23 the enactment of this Act, the Secretary of Health and
24 Human Services shall seek to enter into an agreement with
25 the National Academy of Medicine (in this section referred

1 to as “NAM”) (or if NAM declines to enter into such an
2 agreement, another appropriate entity) under which NAM,
3 or such other appropriate entity, agrees to conduct a study
4 on the following:

5 (1) *The uniform screening panel review and rec-*
6 *ommendation processes to identify factors that impact*
7 *decisions to add new conditions to the uniform screen-*
8 *ing panel, to describe challenges posed by newly nom-*
9 *inated conditions, including low-incidence diseases,*
10 *late onset variants, and new treatments without long-*
11 *term efficacy data.*

12 (2) *The barriers that preclude States from add-*
13 *ing new uniform screening panel conditions to their*
14 *State screening panels with recommendations on re-*
15 *sources needed to help States implement uniform*
16 *screening panel recommendations.*

17 (3) *The current state of federally and privately*
18 *funded newborn screening research with recommenda-*
19 *tions for optimizing the capacity of this research, in-*
20 *cluding piloting multiple prospective conditions at*
21 *once and addressing rare disease questions.*

22 (4) *New and emerging technologies that would*
23 *permit screening for new categories of disorders, or*
24 *would make current screening more effective, more ef-*
25 *ficent, or less expensive.*

1 (5) *Technological and other infrastructure needs*
2 *to improve timeliness of diagnosis and short- and*
3 *long-term follow-up for infants identified through*
4 *newborn screening and improve public health surveil-*
5 *lance.*

6 (6) *Current and future communication and edu-*
7 *cational needs for priority stakeholders and the public*
8 *to promote understanding and knowledge of a mod-*
9 *ernized newborn screening system with an emphasis*
10 *on evolving communication channels and messaging.*

11 (7) *The extent to which newborn screening yields*
12 *better data on the disease prevalence for screened con-*
13 *ditions and improves long-term outcomes for those*
14 *identified through newborn screening, including exist-*
15 *ing systems supporting such data collection and rec-*
16 *ommendations for systems that would allow for im-*
17 *proved data collection.*

18 (8) *The impact on newborn morbidity and mor-*
19 *tality in States that adopt newborn screening tests in-*
20 *cluded on the uniform panel.*

21 (b) *PUBLIC STAKEHOLDER MEETING.*—*In the course*
22 *of completing the study described in subsection (a), NAM*
23 *or such other appropriate entity shall hold not less than*
24 *one public meeting to obtain stakeholder input on the topics*
25 *of such study.*

1 (c) *REPORT.*—Not later than 18 months after the effec-
2 *tive date of the agreement under subsection (a), such agree-*
3 *ment shall require NAM, or such other appropriate entity,*
4 *to submit to the Secretary of Health and Human Services*
5 *and the appropriate committees of jurisdiction of Congress*
6 *a report containing—*

7 (1) *the results of the study conducted under sub-*
8 *section (a);*

9 (2) *recommendations to modernize the processes*
10 *described in subsection (a)(1); and*

11 (3) *recommendations for such legislative and ad-*
12 *ministrative action as NAM, or such other appro-*
13 *priate entity, determines appropriate.*

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