

116TH CONGRESS
1ST SESSION

H. R. 2507

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

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 Section 1109(a)(3) of the Public Health Service Act
9 (42 U.S.C. 300b–8(a)(3)) is amended to read as follows:

1 “(3) to develop and deliver educational pro-
2 grams (at appropriate literacy levels) about newborn
3 screening counseling, testing, follow-up, treatment,
4 specialty services, and long-term care to parents,
5 families, and patient advocacy and support groups
6 that assess the target audience’s current knowledge,
7 incorporate health communications strategies, and
8 measure impact;”.

9 **SEC. 3. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
10 **IN NEWBORNS AND CHILDREN.**

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

13 (1) in subsection (b)—

14 (A) in paragraph (7) by striking “and” at
15 the end;

16 (B) by redesignating paragraph (8) as
17 paragraph (9); and

18 (C) by inserting after paragraph (7) the
19 following:

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

23 “(A) the uniform screening panel nomina-
24 tion process, including data requirements,

1 standards, and the use of international data in
2 nomination submissions; and

3 “(B) the process for obtaining technical as-
4 sistance for submitting nominations to the uni-
5 form screening panel and detailing the in-
6 stances in which the provision of technical as-
7 sistance would introduce a conflict of interest
8 for members of the Advisory Committee; and”;
9 and

10 (2) in subsection (g)—

11 (A) in paragraph (1) by striking “2019”
12 and inserting “2024”; and

13 (B) in paragraph (2) by striking “2019”
14 and inserting “2024”.

15 **SEC. 4. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-**
16 **MATION.**

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

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

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

25 (1) in subsection (a)—

1 (A) in paragraph (1)—

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

5 (ii) by striking “and” at the end;

6 (B) in paragraph (2)—

7 (i) by striking “performance test ma-
8 terials” and inserting “test performance
9 materials”; and

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

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

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

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

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

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

7 “(2) by promoting data sharing linkages be-
8 tween State newborn screening programs and State-
9 based birth defects and developmental disabilities
10 surveillance programs to help families connect with
11 services 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 pro-
5 gram under this section, the Secretary and the Director—

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

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

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

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

19 (1) in paragraph (1)—

20 (A) by striking “\$11,900,000” and insert-
21 ing “\$31,000,000”;

22 (B) by striking “2015” and inserting
23 “2020”; and

24 (C) by striking “2019” and inserting
25 “2024”; and

1 (2) in paragraph (2)—

2 (A) by striking “\$8,000,000” and inserting
3 “\$29,650,000”;

4 (B) by striking “2015” and inserting
5 “2020”; and

6 (C) by striking “2019” and inserting
7 “2024”.

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

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

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

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

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

23 (a) STUDY.—Not later than 60 days after the date
24 of the enactment of this Act, the Secretary of Health and
25 Human Services shall seek to enter into an agreement

1 with the National Academy of Medicine (in this section
2 referred to as “NAM”) (or if NAM declines to enter into
3 such an agreement, another appropriate entity) under
4 which NAM, or such other appropriate entity, agrees to
5 conduct a study on the following:

6 (1) The uniform screening panel review and
7 recommendation processes to identify factors that
8 impact decisions to add new conditions to the uni-
9 form screening panel, to describe challenges posed
10 by newly nominated conditions, including low-inci-
11 dence diseases, late onset variants, and new treat-
12 ments without long-term efficacy data.

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

18 (3) The current state of federally and privately
19 funded newborn screening research with rec-
20 ommendations for optimizing the capacity of this re-
21 search, including piloting multiple prospective condi-
22 tions at once and addressing rare disease questions.

23 (4) New and emerging technologies that would
24 permit screening for new categories of disorders, or

1 would make current screening more effective, more
2 efficient, or less expensive.

3 (5) Technological and other infrastructure
4 needs to improve timeliness of diagnosis and short-
5 and long-term follow-up for infants identified
6 through newborn screening and improve public
7 health surveillance.

8 (6) Current and future communication and edu-
9 cational needs for priority stakeholders and the pub-
10 lic to promote understanding and knowledge of a
11 modernized newborn screening system with an em-
12 phasis on evolving communication channels and mes-
13 saging.

14 (7) The extent to which newborn screening
15 yields better data on the disease prevalence for
16 screened conditions and improves long-term out-
17 comes for those identified through newborn screen-
18 ing, including existing systems supporting such data
19 collection and recommendations for systems that
20 would allow for improved data collection.

21 (b) REPORT.—Not later than 18 months after the ef-
22 fective date of the agreement under subsection (a), such
23 agreement shall require NAM, or such other appropriate
24 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

7 (3) recommendations for such legislative and
8 administrative action as NAM, or such other appro-
9 priate entity, determines appropriate.

10 (c) 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.

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