

117TH CONGRESS
1ST SESSION

H. R. 482

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

JANUARY 25, 2021

Ms. ROYBAL-ALLARD (for herself, Mr. SIMPSON, Ms. CLARK of Massachusetts, Ms. HERRERA BEUTLER, Ms. CLARKE of New York, Mr. DANNY K. DAVIS of Illinois, Mr. FITZPATRICK, Mr. SIRES, Mr. RASKIN, Ms. DEGETTE, Mr. HIGGINS of New York, Mr. STEWART, Mr. CALVERT, Mrs. AXNE, Mr. STIVERS, Ms. WILLIAMS of Georgia, Mr. BUTTERFIELD, Mr. SMITH of Washington, Mr. CASTEN, Mr. COHEN, Ms. CASTOR of Florida, Mr. HASTINGS, Mr. GALLEG0, Mr. KHANNA, and Mr. NEGUSE) 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 2021”.

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

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

5 (1) in paragraph (1), by striking “enhance, im-
6 prove or” and inserting “facilitate, enhance, im-
7 prove, or”;

8 (2) by amending paragraph (3) to read as fol-
9 lows:

10 “(3) to develop, and deliver to parents, families,
11 and patient advocacy and support groups, edu-
12 cational programs that—

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

17 “(B) assess the target audience’s current
18 knowledge, incorporate health communications
19 strategies, and measure impact; and

20 “(C) are at appropriate literacy levels;”;
21 and

22 (3) in paragraph (4)—

23 (A) by striking “followup” and inserting
24 “follow-up”; and

25 (B) by inserting before the semicolon at
26 the end the following: “, including re-engaging

1 patients who have not received recommended
2 follow-up services and supports”.

3 (b) APPROVAL FACTORS.—Section 1109(c) of the
4 Public Health Service Act (42 U.S.C. 300b–8(c)) is
5 amended—

6 (1) by striking “or will use” and inserting “will
7 use”; and

8 (2) by inserting “, or will use amounts received
9 under such grant to enhance capacity and infra-
10 structure to facilitate the adoption of,” before “the
11 guidelines and recommendations”.

12 **SEC. 3. ADVISORY COMMITTEE ON HERITABLE DISORDERS**
13 **IN NEWBORNS AND CHILDREN.**

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

16 (1) in subsection (b)—

17 (A) in paragraph (5), by inserting “and
18 adopt process improvements” after “take ap-
19 propriate steps”;

20 (B) in paragraph (7) by striking “and” at
21 the end;

22 (C) by redesignating paragraph (8) as
23 paragraph (9);

24 (D) by inserting after paragraph (7) the
25 following:

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

4 “(A) the uniform screening panel nomina-
5 tion process, including data requirements,
6 standards, and the use of international data in
7 nomination submissions; and

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

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

15 (i) by redesignating subparagraphs
16 (K) and (L) as subparagraphs (L) and
17 (M), respectively; and

18 (ii) by inserting after subparagraph
19 (J) the following:

20 “(K) the appropriate and recommended
21 use of safe and effective genetic testing by
22 health care professionals in newborns and chil-
23 dren with an initial diagnosis of a disease or
24 condition characterized by a variety of genetic
25 causes and manifestations;” and

1 (2) in subsection (g)—

2 (A) in paragraph (1) by striking “2019”

3 and inserting “2026”; and

4 (B) in paragraph (2) by striking “2019”

5 and inserting “2026”.

6 **SEC. 4. CLEARINGHOUSE OF NEWBORN SCREENING INFOR-**
7 **MATION.**

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

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

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

16 (1) in subsection (a)—

17 (A) in paragraph (1)—

18 (i) by striking “performance evalua-
19 tion services,” and inserting “development
20 of new screening tests,”; and

21 (ii) by striking “and” at the end;

22 (B) in paragraph (2)—

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

1 (ii) by striking the period at the end
2 and inserting “; and”; and

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

4 “(3) performance evaluation services to enhance
5 disease detection, including the development of tools,
6 resources, and infrastructure to improve data anal-
7 ysis, test result interpretation, data harmonization,
8 and dissemination of laboratory best practices.”; and

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

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

17 “(1) standardizing data collection and reporting
18 through the use of electronic and other forms of
19 health records to achieve real-time data for tracking
20 and monitoring the newborn screening system, from
21 the initial positive screen through diagnosis and
22 long-term care management; and

23 “(2) by promoting data sharing linkages be-
24 tween State newborn screening programs and State-
25 based birth defects and developmental disabilities

1 surveillance programs to help families connect with
2 services to assist in evaluating long-term outcomes.”.

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

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

6 (1) in subsection (a)(1)—

7 (A) by striking “may” and inserting
8 “shall”; and

9 (B) in subparagraph (D)—

10 (i) by inserting “, or with a high prob-
11 ability of being recommended by,” after
12 “recommended by”; and

13 (ii) by striking “that screenings are
14 ready for nationwide implementation” and
15 inserting “that reliable newborn screening
16 technologies are piloted and ready for
17 use”; and

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

19 “(b) **FUNDING.**—In carrying out the research pro-
20 gram under this section, the Secretary and the Director
21 shall ensure that entities receiving funding through the
22 program will provide assurances, as practicable, that such
23 entities will work in consultation with State departments
24 of health, as appropriate.”.

1 **SEC. 7. AUTHORIZATION OF APPROPRIATIONS FOR NEW-**
2 **BORN SCREENING PROGRAMS AND ACTIVI-**
3 **TIES.**

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

6 (1) in paragraph (1)—

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

9 (B) by striking “2015” and inserting
10 “2022”; and

11 (C) by striking “2019” and inserting
12 “2026”; and

13 (2) in paragraph (2)—

14 (A) by striking “\$8,000,000” and inserting
15 “\$29,650,000”;

16 (B) by striking “2015” and inserting
17 “2022”; and

18 (C) by striking “2019” and inserting
19 “2026”.

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

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

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

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

10 **SEC. 9. NAM REPORT ON THE MODERNIZATION OF NEW-**
11 **BORN SCREENING.**

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

20 (1) The uniform screening panel review and
21 recommendation processes to identify factors that
22 impact decisions to add new conditions to the uni-
23 form screening panel, to describe challenges posed
24 by newly nominated conditions, including low-inci-
25 dence diseases, late onset variants, and new treat-
26 ments without long-term efficacy data.

1 (2) The barriers that preclude States from add-
2 ing new uniform screening panel conditions to their
3 State screening panels with recommendations on re-
4 sources needed to help States implement uniform
5 screening panel recommendations.

6 (3) The current state of federally and privately
7 funded newborn screening research with rec-
8 ommendations for optimizing the capacity of this re-
9 search, including piloting multiple prospective condi-
10 tions at once and addressing rare disease questions.

11 (4) New and emerging technologies that would
12 permit screening for new categories of disorders, or
13 would make current screening more effective, more
14 efficient, or less expensive.

15 (5) Technological and other infrastructure
16 needs to improve timeliness of diagnosis and short-
17 and long-term follow-up for infants identified
18 through newborn screening and improve public
19 health surveillance.

20 (6) Current and future communication and edu-
21 cational needs for priority stakeholders and the pub-
22 lic to promote understanding and knowledge of a
23 modernized newborn screening system with an em-
24 phasis on evolving communication channels and mes-
25 saging.

1 (7) The extent to which newborn screening
2 yields better data on the disease prevalence for
3 screened conditions and improves long-term out-
4 comes for those identified through newborn screen-
5 ing, including existing systems supporting such data
6 collection and recommendations for systems that
7 would allow for improved data collection.

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

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

16 (c) REPORT.—Not later than 18 months after the ef-
17 fective date of the agreement under subsection (a), such
18 agreement shall require NAM, or such other appropriate
19 entity, to submit to the Secretary of Health and Human
20 Services and the appropriate committees of jurisdiction of
21 Congress a report containing—

22 (1) the results of the study conducted under
23 subsection (a);

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

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

4 (d) AUTHORIZATION OF APPROPRIATIONS.—There is
5 authorized to be appropriated \$2,000,000 for the period
6 of fiscal years 2022 and 2023 to carry out this section.

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