

119TH CONGRESS
1ST SESSION

H. R. 4709

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

JULY 23, 2025

Ms. MORRISON (for herself, Mr. SIMPSON, Ms. SCHRIER, and Mr. LANGWORTHY) 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 2025”.

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

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

1 (1) in paragraph (1), by striking “enhance, im-
2 prove or” and inserting “facilitate, enhance, im-
3 prove, or”;

4 (2) by amending paragraph (3) to read as fol-
5 lows:

6 “(3) to develop, and deliver to parents, families,
7 and patient advocacy and support groups, edu-
8 cational programs that—

9 “(A) address newborn screening coun-
10 seling, testing (including newborn screening
11 pilot studies), follow-up, treatment, specialty
12 services, and long-term care;

13 “(B) assess the target audience’s current
14 knowledge, incorporate health communications
15 strategies, and measure impact; and

16 “(C) are at appropriate literacy levels;”;
17 and

18 (3) in paragraph (4)—

19 (A) by striking “followup” and inserting
20 “follow-up”; and

21 (B) by inserting before the semicolon at
22 the end the following: “, including re-engaging
23 patients who have not received recommended
24 follow-up services and supports”.

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

4 (1) by striking “or will use” and inserting “will
5 use”; and

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

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

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

14 (1) in subsection (b)—

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

18 (B) in paragraph (7) by striking “and” at
19 the end;

20 (C) by redesignating paragraph (8) as
21 paragraph (9);

22 (D) by inserting after paragraph (7) the
23 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 and

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

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

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

21 “(K) the appropriate and recommended
22 use of safe and effective genetic testing by
23 health care professionals in newborns and chil-
24 dren with an initial diagnosis of a disease or

condition characterized by a variety of genetic causes and manifestations;” and

(2) in subsection (g)—

(A) in paragraph (1) by striking “2019” and inserting “2030”; and

(B) in paragraph (2) by striking “2019” and inserting “2030”.

SEC. 4. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

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

SEC. 5. LABORATORY QUALITY AND SURVEILLANCE.

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

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking “performance evaluation services,” and inserting “development of new screening tests,”; and

(ii) by striking “and” at the end;

(B) in paragraph (2)—

1 (i) by striking “performance test ma-
2 terials” and inserting “test performance
3 materials”; and

4 (ii) by striking the period at the end
5 and inserting “; and”; and

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

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

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

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

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

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

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

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

9 (1) in subsection (a)(1)—

10 (A) by striking “may” and inserting
11 “shall”; and

12 (B) in subparagraph (D)—

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

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

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

22 “(b) FUNDING.—In carrying out the research pro-
23 gram under this section, the Secretary and the Director
24 shall ensure that entities receiving funding through the
25 program will provide assurances, as practicable, that such

1 entities will work in consultation with State departments
2 of health, as appropriate.”.

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

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

8 (1) in paragraph (1)—

9 (A) by striking “\$11,900,000” and insert-
10 ing “\$20,883,000”;

11 (B) by striking “2015” and inserting
12 “2026”; and

13 (C) by striking “2019” and inserting
14 “2030”; and

15 (2) in paragraph (2)—

16 (A) by striking “\$8,000,000” and inserting
17 “\$22,250,000”;

18 (B) by striking “2015” and inserting
19 “2026”; and

20 (C) by striking “2019” and inserting
21 “2030”.

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.).”.

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