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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

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Newborn Screening Saves Lives Reauthorization Act of 2025''.

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

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

(1) in paragraph (1), by striking ''enhance, improve or'' and inserting ''facilitate, enhance, improve, or'';

(2) by amending paragraph (3) to read as follows:

''(3) to develop, and deliver to parents, families, and patient advocacy and support groups, educational programs that—

''(A) address newborn screening counseling, testing (including newborn screening pilot studies), follow-up, treatment, specialty services, and long-term care;

''(B) assess the target audience's current knowledge, incorporate health communications strategies, and measure impact; and

''(C) are at appropriate literacy levels;''; and

(3) in paragraph (4)—

(A) by striking ''followup'' and inserting ''follow-up''; and

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

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

(1) by striking ''or will use'' and inserting ''will use''; and

(2) by inserting '', or will use amounts received under such grant to enhance capacity and infrastructure to facilitate the adoption of,'' before ''the guidelines and recommendations''.

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

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

(1) in subsection (b)—

(A) in paragraph (5), by inserting ''and adopt process improvements'' after ''take appropriate steps'';

(B) in paragraph (7) by striking ''and'' at the end;

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

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

''(8) develop, maintain, and publish on a publicly accessible website consumer-friendly materials detailing—

''(A) the uniform screening panel nomination process, including data requirements, standards, and the use of international data in nomination submissions; and

''(B) the process for obtaining technical assistance for submitting nominations to the uniform screening panel and detailing the instances in which the provision of technical assistance would introduce a conflict of interest for members of the Advisory Committee; and''; and

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

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

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

''(K) the appropriate and recommended use of safe and effective genetic testing by health care professionals in newborns and children 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)—

(i) by striking ''performance test materials'' and inserting ''test performance materials''; and

(ii) by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(3) performance evaluation services to enhance disease detection, including the development of tools, resources, and infrastructure to improve data analysis, test result interpretation, data harmonization, and dissemination of laboratory best practices.''; and

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

''(b) SURVEILLANCE ACTIVITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, shall provide for the coordination of national surveillance activities, including—

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

''(2) by promoting data sharing linkages between State newborn screening programs and State-based birth defects and developmental disabilities surveillance programs to help families connect with services to assist in evaluating long-term outcomes.''.

SEC. 6. HUNTER KELLY RESEARCH PROGRAM.

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

(1) in subsection (a)(1)—

(A) by striking ''may'' and inserting ''shall''; and

(B) in subparagraph (D)—

(i) by inserting '', or with a high probability of being recommended by,'' after ''recommended by''; and

(ii) by striking ''that screenings are ready for nationwide implementation'' and inserting ''that reliable newborn screening technologies are piloted and ready for use''; and

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

''(b) FUNDING.—In carrying out the research program under this section, the Secretary and the Director shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such

entities will work in consultation with State departments of health, as appropriate.''.

SEC. 7. AUTHORIZATION OF APPROPRIATIONS FOR NEWBORN SCREENING PROGRAMS AND ACTIVITIES.

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

(1) in paragraph (1)—

(A) by striking ''$11,900,000'' and inserting ''$20,883,000'';

(B) by striking ''2015'' and inserting ''2026''; and

(C) by striking ''2019'' and inserting ''2030''; and

(2) in paragraph (2)—

(A) by striking ''$8,000,000'' and inserting ''$22,250,000'';

(B) by striking ''2015'' and inserting ''2026''; and

(C) by striking ''2019'' and inserting ''2030''.

SEC. 8. INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM.

Section 12 of the Newborn Screening Saves Lives Reauthorization Act of 2014 (42 U.S.C. 289 note) is amended to read as follows:

"SEC. 12. INSTITUTIONAL REVIEW BOARDS; ETHICS GUIDANCE PROGRAM.

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

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