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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. GALLEGO, Mr. KHANNA, and Mr. NEGUSE) 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 2021''.

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'';

(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 ''2026''; and

(B) in paragraph (2) by striking ''2019'' and inserting ''2026''.

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 ''$31,000,000'';

(B) by striking ''2015'' and inserting ''2022''; and

(C) by striking ''2019'' and inserting ''2026''; and

(2) in paragraph (2)—

(A) by striking ''$8,000,000'' and inserting ''$29,650,000'';

(B) by striking ''2015'' and inserting ''2022''; and

(C) by striking ''2019'' and inserting ''2026''.

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.).''.

SEC. 9. NAM REPORT ON THE MODERNIZATION OF NEWBORN SCREENING.

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

(1) The uniform screening panel review and recommendation processes to identify factors that impact decisions to add new conditions to the uniform screening panel, to describe challenges posed by newly nominated conditions, including low-incidence diseases, late onset variants, and new treatments without long-term efficacy data.

(2) The barriers that preclude States from adding new uniform screening panel conditions to their State screening panels with recommendations on resources needed to help States implement uniform screening panel recommendations.

(3) The current state of federally and privately funded newborn screening research with recommendations for optimizing the capacity of this research, including piloting multiple prospective conditions at once and addressing rare disease questions.

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

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

(6) Current and future communication and educational needs for priority stakeholders and the public to promote understanding and knowledge of a modernized newborn screening system with an emphasis on evolving communication channels and messaging.

(7) The extent to which newborn screening yields better data on the disease prevalence for screened conditions and improves long-term outcomes for those identified through newborn screening, including existing systems supporting such data collection and recommendations for systems that would allow for improved data collection.

(8) The impact on newborn morbidity and mortality in States that adopt newborn screening tests included on the uniform panel.

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

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

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

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

(3) recommendations for such legislative and administrative action as NAM, or such other appropriate entity, determines appropriate.

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

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