

NEWBORN SCREENING SAVES LIVES REAUTHORIZATION
ACT OF 2019

JULY 23, 2019.—Committed to the Committee of the Whole House on the State of
the Union and ordered to be printed

Mr. PALLONE, from the Committee on Energy and Commerce,
submitted the following

R E P O R T

[To accompany H.R. 2507]

The Committee on Energy and Commerce, to whom was referred the bill (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, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the “Newborn Screening Saves Lives Reauthorization Act of 2019”.

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;”;

(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;”;

(2) in subsection (g)—

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

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

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;”;

(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 evaluated 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—
 - “(1) shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such entities will work in consultation with the appropriate State departments of health; and
 - “(2) may accept, use, and dispose of donations and bequests from private for-profit and non-profit entities, in accordance with Federal law.”.

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 “2020”; and
 - (C) by striking “2019” and inserting “2024”; and
 - (2) in paragraph (2)—
 - (A) by striking “\$8,000,000” and inserting “\$29,650,000”;
 - (B) by striking “2015” and inserting “2020”; and
 - (C) by striking “2019” and inserting “2024”.

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 part 4 of section 46.104 of title 45, Code of Federal 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 2020 and 2021 to carry out this section.

I. PURPOSE AND SUMMARY

H.R. 2507, the “Newborn Screening Saves Lives Reauthorization Act of 2019”, was introduced on May 2, 2019, by Reps. Roybal-Allard (D-CA), Simpson (R-ID), Clark (D-MA), and Herrera Beutler (R-WA) and referred to the Committee on Energy and Commerce. H.R. 2507 would reauthorize newborn screening programs at the U.S. Department of Health and Human Services for five years. The bill includes reforms to ensure that the activities of the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) at the Health Resources and Services Administration (HRSA) are transparent, including requiring the creation of a publicly accessible website that details the uniform screening panel nomination process. The bill also requires the Centers for Disease Control and Prevention (CDC) to standardize data collection and reporting to track and monitor newborn screening in real time. Additionally, the bill orders a study on the modernization of

newborn screening. The bill authorizes appropriations of \$60.65 million per fiscal year from 2020 through 2024.

II. BACKGROUND AND NEED FOR LEGISLATION

Every year, more than 12,000 newborns are born with conditions that require early detection and treatment.¹ Newborn screening provides for early identification of certain genetic, metabolic, hormonal, and functional conditions that may be treatable, but not apparent at birth. With proper screening, parents can receive education and children can receive appropriate follow-up treatment. As medical and scientific knowledge have advanced since the first newborn screening test was developed in the early 1960s, dozens more tests and treatments became available. However, a patchwork of state requirements for screening led to some newborns being screened for many disorders, and others very few.² In 2004, the American College of Medical Genetics recommended that every baby born in the United States be screened for a core set of 29 treatable disorders.³ At that time, only 21 states screened for at least nine of the recommended conditions.⁴ By 2008, significant improvements were made, but still, only 15 states and the District of Columbia required that infants be screened for all 29 recommended disorders.⁵

While newborn screening remains a state public health activity, Congress passed the Newborn Screening Saves Lives Act in 2008, to better standardize and improve state universal newborn screening programs.⁶ The law codified the Recommended Universal Screening Panel (RUSP), which the ACHDNC at HRSA uses to make recommendations for conditions for which all newborns should be screened. To be considered as a core condition recommended for the RUSP, the condition must: (1) be able to be identified at a stage prior to when it would otherwise be apparent clinically (i.e., the screening must be necessary to identify the condition); (2) have a test with appropriate sensitivity and specificity available; and (3) have demonstrated benefits of early detection, timely intervention, and efficacious treatment of the condition.⁷ The law also authorized HRSA to develop a model decision-matrix for newborn screening expansion, and consider ways to ensure that all states attain the capacity to screen for the recommended conditions. The law also authorized research at the National Institutes of Health (NIH) to carry out research on newborn screening. Congress last reauthorized the law in 2014.

Today, the RUSP includes 35 core conditions.⁸ While all states have caught up to testing for the original 29 recommended condi-

¹Government Accountability Office, GAO-17-196, *Newborn Screening Timeliness* (Dec. 15, 2016).

²Examining Public Health Legislation to Help Local Communities: Hearing on H.R. 1281 Before the Subcommittee on Health, Committee on Energy & Commerce, 113th Cong. (Nov. 20, 2013) (statement of Edward R.B. McCabe, Chief Medical Officer, March of Dimes Foundation).

³*Id.*

⁴S. Rept. No. 110-280, at 2.

⁵*Id.*

⁶Pub. L. No. 110-204.

⁷National Conference of State Legislatures, *State Newborn Health Screening Policies*, 25 LegisBrief 14 (Apr. 2017).

⁸Health Resources and Services Administration, *Recommended Uniform Screening Panel* (Feb. 2019) (www.hrsa.gov/advisory-committees/heritable-disorders/rusp/index.html).

tions,⁹ and some have exceeded the current 35 recommended core conditions, others have lagged behind as more tests have been added.¹⁰ The funding authorized in this legislation is intended to help break down those barriers preventing some states from adopting all 35 conditions, ensuring that children across the country are screened for all core conditions included on the RUSP.

III. COMMITTEE HEARINGS

For the purposes of section 103(i) of H. Res. 6 of the 116th Congress the following hearing was used to develop or consider H.R. 2507:

The Subcommittee on Health held a legislative hearing on June 25, 2019 on H.R. 2507, “Newborn Screening Saves Lives Reauthorization Act of 2019” and three other bills. The hearing was entitled “Reauthorizing Vital Health Programs for American Families.” The Subcommittee received testimony from:

- Amy Hewitt, Ph.D., Director, Institute on Community Integration, University of Minnesota;
- Joseph Bocchini, M.D., Professor, Department of Pediatrics Louisiana State University Health, Shreveport;
- Patricia Kunz Howard, Ph.D., RN, President, Emergency Nurses Association, Director, Emergency Services, University of Kentucky Healthcare; and
- Jill Kagan, Director, ARCH National Respite Network and Resource Center.

IV. COMMITTEE CONSIDERATION

H.R. 2507, the “Newborn Screening Saves Lives Reauthorization Act of 2019” was introduced in the House on May 2, 2019, by Reps. Roybal-Allard, Simpson, Clark, and Herrera Beutler, and referred to the Committee on Energy and Commerce. Subsequently, the bill was referred to the Subcommittee on Health on May 3, 2019. Following a legislative hearing, the Subcommittee met in open markup session, pursuant to notice, on July 11, 2019, for consideration of the bill H.R. 2507. During consideration of the bill, an amendment offered by Ms. Kelly (D–IL) was agreed to by a voice vote. Subsequently, the Subcommittee on Health agreed to a motion by Ms. Eshoo, Chairwoman of the Subcommittee, that H.R. 2507 be forwarded favorably to the full Committee on Energy and Commerce, amended, by a voice vote.

On July 17, 2019, the full Committee met in open markup session, pursuant to notice, to consider the bill H.R. 2507, as amended by the Subcommittee. At the conclusion of consideration of the bill, the full Committee on Energy and Commerce agreed to a motion by Mr. Pallone, Chairman of the Committee, that H.R. 2507 be ordered reported favorably to the House, as amended, by a voice vote, a quorum being present.

V. COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list each record vote on the motion

⁹Scott M. Shone, *Newborn Screening Policy Decisions*, 80 N.C. Med. J. 1, 43 (Jan. 2019).

¹⁰See note 7.

to report legislation and amendments thereto. The Committee advises that there were no record votes taken on H.R. 2507.

VI. OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Committee's oversight findings and recommendations are reflected in the descriptive portion of the report.

VII. NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Pursuant to 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee adopts as its own the estimate of new budget authority, entitlement authority, or tax expenditures or revenues contained in the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

The Committee has requested but not received from the Director of the Congressional Budget Office a statement as to whether this bill contains any new budget authority, spending authority, credit authority, or an increase or decrease in revenues or tax expenditures.

VIII. FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

IX. STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

Pursuant to clause 3(c)(4) of rule XIII, the general performance goal or objective of this legislation is to reauthorize funding for the programs of the Newborn Screen Saves Lives Act, provide for transparency at ACHDNC, and authorize reforms to modernize and standardize newborn screening programs.

X. DUPLICATION OF FEDERAL PROGRAMS

Pursuant to clause 3(c)(5) of rule XIII, no provision of H.R. 2507 is known to be duplicative of another Federal program, including any program that was included in a report to Congress pursuant to section 21 of Public Law 111-139 or the most recent Catalog of Federal Domestic Assistance.

XI. COMMITTEE COST ESTIMATE

Pursuant to clause 3(d)(1) of rule XIII, the Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

XII. EARMARKS, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

Pursuant to clause 9(e), 9(f), and 9(g) of rule XXI, the Committee finds that H.R. 2507 contains no earmarks, limited tax benefits, or limited tariff benefits.

XIII. ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

XIV. APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

XV. SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 designates that the short title may be cited as the “Newborn Screening Saves Lives Reauthorization Act of 2019”.

Section 2. Improved newborn and child screening and follow-up for heritable disorders

Section 2 amends the authorization terms for the grant program established under section 1109 of the Public Health Service Act to ensure that educational programs address newborn screening pilot studies and assess the target audience’s current knowledge, incorporate health communication strategies, and measure the impact of these programs. This Section also authorizes grantees to establish, maintain, and operate a system to address and coordinate follow-up, “including re-engaging patients who have not received recommended follow-up services and supports.”

Section 3. Advisory Committee on Heritable Disorders in Newborns and Children

Section 3 amends the duties of ACHDNC to include the adoption of process improvements and requires the creation of a publicly accessible website which details the uniform screening panel nomination process, the process for obtaining technical assistance for submitting nominations for the uniform screening panel, and the instances in which the provision of technical assistance would introduce a conflict of interest for members of the Advisory Committee. The Committee does not intend for this section to necessarily preclude the NIH from providing agency expertise to the ACHDNC.

Section 4. Clearing house of newborn screening information

Section 4 clarifies that the Secretary ensure that newborn screening activities under this program complement other Federal newborn screening information sharing activities.

Section 5. Laboratory quality and surveillance

Section 5 amends laboratory quality and surveillance authorization language to instruct the Secretary, acting through the Director

of the CDC and taking into consideration the expertise of ACHDNC to provide for quality assurance for laboratories involved in screening newborns and children for heritable disorders, including developing new screening tests. This section also instructs the Secretary to provide for 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.” The Secretary, acting through CDC, is also instructed to provide for the coordination of national surveillance activities, including standardizing data collection and reporting through the use of electronic and other health records to monitor the newborn screening system in real time, and by promoting data sharing between state newborn screening programs and developmental disabilities surveillance programs.

Section 6. Hunter Kelly research program

Section 6 amends the authorizing language for the Hunter Kelly Newborn Screening Program at NIH by authorizing the Secretary, in conjunction with the NIH Director, to conduct pilot studies on conditions recommended by, or with a high probability of being recommended by the ACHDNC to ensure that reliable newborn screening technologies are evaluated and ready for use. This section also directs the Secretary and NIH Director to ensure that entities receiving funding through the program will provide reassurances that entities will work in consultation with State departments of health, as appropriate, and clarifies that the Secretary and Director may accept, use, and dispose of donations and bequest from private for-profit and non-profit entities, in accordance with Federal law.

Section 7. Authorization of appropriations for newborn screening programs and activities

Section 7 extends authorization of appropriations for newborn screening programs and activities.

Paragraph (1) authorizes \$31,000,000 to carry out sections 1109, 1110, 1111, and 1112 for fiscal years 2020 through 2024.

Paragraph (2) authorizes \$29,650,000 to carry out section 1113 for fiscal years 2020 through 2024.

Section 8. Institutional review boards; ethics guidance program

Section 8 clarifies that research on nonidentified newborn dried blood spots be considered “secondary research” as defined by part 4 of subsection d of section 46.104 of title 45 of the Code of Federal Regulations, also known as the Common Rule, which governs human research and privacy.

Section 9. NAM report on the modernization of newborn screening

Section 9 directs the Secretary to enter into an agreement with the National Academy of Medicine to conduct a study on certain newborn screening activities and issue a report to Congress with recommendations to modernize the newborn screening processes. This section authorizes \$2,000,000 in fiscal years 2020 and 2021 for the report.

XVI. CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

* * * * *

TITLE XI—GENETIC DISEASES, HEMOPHILIA PROGRAMS,
AND SUDDEN INFANT DEATH SYNDROME

PART A—GENETIC DISEASES

* * * * *

SEC. 1109. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

(a) AUTHORIZATION OF GRANT PROGRAM.—From amounts appropriated under section 1117, the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the “Administrator”) and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children (referred to in this section as the “Advisory Committee”), shall award grants to eligible entities to enable such entities—

(1) to **enhance, improve or** *facilitate, enhance, improve, or* expand the ability of State and local public health agencies to provide screening, counseling, or health care services to newborns and children having or at risk for heritable disorders;

(2) to assist in providing health care professionals and newborn screening laboratory personnel with education in newborn screening, counseling, and training in—

(A) relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

(B) the importance of the timeliness of collection, delivery, receipt, and screening of specimens; and

(C) sharing of medical and diagnostic information with providers and families;

[(3) to develop and deliver educational programs (at appropriate literacy levels) about newborn screening counseling, testing, follow-up, treatment, and specialty services to parents, families, and patient advocacy and support groups;]

(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;

(4) to establish, maintain, and operate a system to assess and coordinate **【followup】** *follow-up* and treatment relating to congenital, genetic, and metabolic disorders, *including re-engaging patients who have not received recommended follow-up services and supports*; and

(5) to improve the timeliness of—

(A) the collection, delivery, receipt, and screening of specimens; and

(B) the diagnosis of heritable disorders in newborns.

(b) **ELIGIBLE ENTITY.**—In this section, the term “eligible entity” means—

(1) a State or a political subdivision of a State;

(2) a consortium of 2 or more States or political subdivisions of States;

(3) a territory;

(4) a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Service; or

(5) any other entity with appropriate expertise in newborn screening, as determined by the Secretary.

(c) **APPROVAL FACTORS.**—An application for a grant under this section shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, **【or will use】** *will use* amounts received under such grant to adopt and implement, *or will use amounts received under such grant to enhance capacity and infrastructure to facilitate the adoption of*, the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary and in effect at the time the grant is awarded or renewed under this section, which shall include the screening of each newborn for the heritable disorders recommended by the Advisory Committee and adopted by the Secretary.

(d) **COORDINATION.**—The Secretary shall take all necessary steps to coordinate programs funded with grants received under this section and to coordinate with existing newborn screening activities.

(e) **LIMITATION.**—An eligible entity may not use amounts received under this section to—

(1) provide cash payments to or on behalf of affected individuals;

(2) provide inpatient services;

(3) purchase land or make capital improvements to property;

or

(4) provide for proprietary research or training.

(f) **VOLUNTARY PARTICIPATION.**—The participation by any individual in any program or portion thereof established or operated with funds received under this section shall be wholly voluntary and shall not be a prerequisite to eligibility for or receipt of any other service or assistance from, or to participation in, another Federal or State program.

(g) **SUPPLEMENT NOT SUPPLANT.**—Funds appropriated under this section shall be used to supplement and not supplant other Federal, State, and local public funds provided for activities of the type described in this section.

(h) **PUBLICATION.**—

(1) **IN GENERAL.**—An application for a grant under this section shall be made public by the State in such a manner as to

facilitate comment from any person, including through hearings and other methods used to facilitate comments from the public.

(2) COMMENTS.—Comments received by the State after the publication described in paragraph (1) shall be addressed in the application for a grant under this section.

(i) TECHNICAL ASSISTANCE.—The Secretary shall provide to entities receiving grants under subsection (a) such technical assistance as may be necessary to ensure the quality of programs conducted under this section.

* * * * *

SEC. 1111. ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

(a) ESTABLISHMENT.—The Secretary shall establish an advisory committee to be known as the “Advisory Committee on Heritable Disorders in Newborns and Children” (referred to in this section as the “Advisory Committee”).

(b) DUTIES.—The Advisory Committee shall—

(1) provide advice and recommendations to the Secretary concerning grants and projects awarded or funded under section 1109;

(2) provide technical information to the Secretary for the development of policies and priorities for the administration of grants under section 1109;

(3) make systematic evidence-based and peer-reviewed recommendations that include the heritable disorders that have the potential to significantly impact public health for which all newborns should be screened, including secondary conditions that may be identified as a result of the laboratory methods used for screening;

(4) provide technical assistance, as appropriate, to individuals and organizations regarding the submission of nominations to the uniform screening panel, including prior to the submission of such nominations;

(5) take appropriate steps *and adopt process improvements*, at its discretion, to prepare for the review of nominations prior to their submission, including for conditions for which a screening method has been validated but other nomination criteria are not yet met, in order to facilitate timely action by the Advisory Committee once such submission has been received by the Committee;

(6) develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact, including the cost of such expansion, and periodically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

(7) consider ways to ensure that all States attain the capacity to screen for the conditions described in paragraph (3), and include in such consideration the results of grant funding under section 1109; **[and]**

(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*

[(8)] (9) provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity from heritable disorders, which may include recommendations, advice, or information dealing with—

(A) follow-up activities, including those necessary to achieve best practices in rapid diagnosis and appropriate treatment in the short-term, and those that ascertain long-term case management outcomes and appropriate access to related services;

(B) implementation, monitoring, and evaluation of newborn screening activities, including diagnosis, screening, follow-up, and treatment activities;

(C) diagnostic and other technology used in screening;

(D) the availability and reporting of testing for conditions for which there is no existing treatment, including information on cost and incidence;

(E) conditions not included in the recommended uniform screening panel that are treatable with Food and Drug Administration-approved products or other safe and effective treatments, as determined by scientific evidence and peer review;

(F) minimum standards and related policies and procedures used by State newborn screening programs, such as language and terminology used by State newborn screening programs to include standardization of case definitions and names of disorders for which newborn screening tests are performed;

(G) quality assurance, oversight, and evaluation of State newborn screening programs, including ensuring that tests and technologies used by each State meet established standards for detecting and reporting positive screening results;

(H) public and provider awareness and education;

(I) the cost and effectiveness of newborn screening and medical evaluation systems and intervention programs conducted by State-based programs;

(J) identification of the causes of, public health impacts of, and risk factors for heritable disorders;

(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;*

[(K)] (L) coordination of surveillance activities, including standardized data collection and reporting, harmonization of laboratory definitions for heritable disorders and

testing results, and confirmatory testing and verification of positive results, in order to assess and enhance monitoring of newborn diseases; and

[(L)] (M) the timeliness of collection, delivery, receipt, and screening of specimens to be tested for heritable disorders in newborns in order to ensure rapid diagnosis and followup.

(c) MEMBERSHIP.—

(1) IN GENERAL.—The Secretary shall appoint not to exceed 15 members to the Advisory Committee. In appointing such members, the Secretary shall ensure that the total membership of the Advisory Committee is an odd number.

(2) REQUIRED MEMBERS.—The Secretary shall appoint to the Advisory Committee under paragraph (1)—

(A) the Administrator of the Health Resources and Services Administration;

(B) the Director of the Centers for Disease Control and Prevention;

(C) the Director of the National Institutes of Health;

(D) the Director of the Agency for Healthcare Research and Quality;

(E) the Commissioner of the Food and Drug Administration;

(F) medical, technical, or scientific professionals with special expertise in heritable disorders, or in providing screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(G) individuals with expertise in ethics and infectious diseases who have worked and published material in the area of newborn screening;

(H) members of the public having special expertise about or concern with heritable disorders; and

(I) representatives from such Federal agencies, public health constituencies, and medical professional societies as determined to be necessary by the Secretary, to fulfill the duties of the Advisory Committee, as established under subsection (b).

(d) DECISION ON RECOMMENDATIONS.—

(1) IN GENERAL.—Not later than 120 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation. If the Secretary is unable to make a determination to adopt or reject such recommendation within such 120-day period, the Secretary shall notify the Advisory Committee and the appropriate committees of Congress of such determination together with an explanation for why the Secretary was unable to comply within such 120-day period, as well as a plan of action for consideration of such pending recommendation.

(2) DETERMINATIONS TO BE MADE PUBLIC.—The Secretary shall publicize any determination on adopting or rejecting a recommendation of the Advisory Committee pursuant to this subsection, including the justification for the determination.

(3) DEADLINE FOR REVIEW.—For each condition nominated to be added to the recommended uniform screening panel in accordance with the requirements of this section, the Advisory

Committee shall review and vote on the nominated condition within 9 months of the date on which the Advisory Committee referred the nominated condition to the condition review workgroup.

(e) ANNUAL REPORT.—Not later than 3 years after the date of enactment of the Newborn Screening Saves Lives Act of 2008, and each fiscal year thereafter, the Advisory Committee shall—

(1) publish a report on peer-reviewed newborn screening guidelines, including follow-up and treatment, in the United States;

(2) submit such report to the appropriate committees of Congress, the Secretary, the Interagency Coordinating Committee established under Section 1114, and the State departments of health; and

(3) disseminate such report on as wide a basis as practicable, including through posting on the internet clearinghouse established under section 1112.

(f) MEETINGS.—The Advisory Committee shall meet at least 4 times each calendar year, or at the discretion of the Designated Federal Officer in consultation with the Chair.

(g) CONTINUATION OF OPERATION OF COMMITTEE.—

(1) IN GENERAL.—Notwithstanding section 14 of the Federal Advisory Committee Act, the Advisory Committee shall continue to operate through the end of fiscal year **[2019] 2024**.

(2) CONTINUATION IF NOT REAUTHORIZED.—If at the end of fiscal year **[2019] 2024** the duration of the Advisory Committee has not been extended by statute, the Advisory Committee may be deemed, for purposes of the Federal Advisory Committee Act, an advisory committee established by the President or an officer of the Federal Government under section 9(a) of such Act.

SEC. 1112. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

(a) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this part as the “Administrator”), in consultation with the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish and maintain a central clearinghouse of current educational and family support and services information, materials, resources, research, and data on newborn screening to—

(1) enable parents and family members of newborns, health professionals, industry representatives, and other members of the public to increase their awareness, knowledge, and understanding of newborn screening;

(2) increase awareness, knowledge, and understanding of newborn diseases and screening services for expectant individuals and families;

(3) maintain current information on quality indicators to measure performance of newborn screening, such as false-positive rates and other quality indicators as determined by the Advisory Committee under section 1111;

(4) maintain current information on the number of conditions for which screening is conducted in each State; and

(5) disseminate available evidence-based guidelines related to diagnosis, counseling, and treatment with respect to conditions detected by newborn screening.

(b) INTERNET AVAILABILITY.—The Secretary, acting through the Administrator, shall ensure that the clearinghouse described under subsection (a)—

- (1) is available on the Internet;
 - (2) includes an interactive forum;
 - (3) is updated on a regular basis, but not less than quarterly;
- and
- (4) provides—

(A) links to Government-sponsored, non-profit, and other Internet websites of laboratories that have demonstrated expertise in newborn screening that supply research-based information on newborn screening tests currently available throughout the United States;

(B) information about newborn conditions and screening services available in each State from laboratories certified under subpart 2 of part F of title III, including information about supplemental screening that is available but not required, in the State where the infant is born;

(C) current research on both treatable and not-yet treatable conditions for which newborn screening tests are available;

(D) the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized under the Newborn Screening Saves Lives Reauthorization Act of 2014; and

(E) other relevant information as determined appropriate by the Secretary.

(c) NONDUPLICATION.—In carrying out activities under this section, the Secretary shall ensure that such activities minimize duplication [and supplement, not supplant, existing information sharing efforts] *and complement other Federal newborn screening information sharing activities.*

SEC. 1113. LABORATORY QUALITY AND SURVEILLANCE.

(a) IN GENERAL.—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—

(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, timeliness for processing such tests, [performance evaluation services,] *development of new screening tests*, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; [and]

(2) appropriate quality control and other [performance test materials] *test performance materials* to evaluate the performance of new screening tools[.]; *and*

(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.

[(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, may provide, as appropriate, for the coordination of surveillance activities, including—

[(1) through standardized data collection and reporting, as well as the use of electronic health records; and

[(2) by promoting data sharing regarding newborn screening with State-based birth defects and developmental disabilities monitoring programs.]

(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.*

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SEC. 1116. HUNTER KELLY RESEARCH PROGRAM.

(a) **NEWBORN SCREENING ACTIVITIES.**—

(1) **IN GENERAL.**—The Secretary, in conjunction with the Director of the National Institutes of Health and taking into consideration the recommendations of the Advisory Committee, [may] *shall* continue carrying out, coordinating, and expanding research in newborn screening (to be known as “Hunter Kelly Newborn Screening Research Program”) including—

(A) identifying, developing, and testing the most promising new screening technologies, in order to improve already existing screening tests, increase the specificity of newborn screening, and expand the number of conditions for which screening tests are available;

(B) experimental treatments and disease management strategies for additional newborn conditions, and other genetic, metabolic, hormonal, or functional conditions that can be detected through newborn screening for which treatment is not yet available;

(C) providing research findings and data for newborn conditions under review by the Advisory Committee on Heritable Disorders in Newborns and Children to be added to the recommended uniform screening panel;

(D) conducting pilot studies on conditions recommended by, *or with a high probability of being recommended by,*

the Advisory Committee on Heritable Disorders in Newborns and Children to ensure [that screenings are ready for nationwide implementation] *that reliable newborn screening technologies are evaluated and ready for use*; and

(E) other activities that would improve newborn screening, as identified by the Director.

(2) ADDITIONAL NEWBORN CONDITION.—For purposes of this subsection, the term “additional newborn condition” means any condition that is not one of the core conditions recommended by the Advisory Committee and adopted by the Secretary.

[(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 the appropriate State departments of health, and, as practicable, focus their research on screening technology not currently performed in the States in which the entities are located, and the conditions on the uniform screening panel (or the standard test existing on the uniform screening panel).]

(b) FUNDING.—In carrying out the research program under this section, the Secretary and the Director—

(1) shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such entities will work in consultation with the appropriate State departments of health; and

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

(c) REPORTS.—The Director is encouraged to include information about the activities carried out under this section in the biennial report required under section 403. If such information is included, the Director shall make such information available to be included on the Internet Clearinghouse established under section 1112.

(d) NONDUPLICATION.—In carrying out programs under this section, the Secretary shall minimize duplication and supplement, not supplant, existing efforts of the type carried out under this section.

(e) PEER REVIEW.—Nothing in this section shall be construed to interfere with the scientific peer-review process at the National Institutes of Health.

SEC. 1117. AUTHORIZATION OF APPROPRIATIONS FOR NEWBORN SCREENING PROGRAMS AND ACTIVITIES.

There are authorized to be appropriated—

(1) to carry out sections 1109, 1110, 1111, and 1112, ~~[\$11,900,000]~~ *\$31,000,000* for each of fiscal years ~~[2015]~~ *2020* through ~~[2019]~~ *2024*; and

(2) to carry out section 1113, ~~[\$8,000,000]~~ *\$29,650,000* for each of fiscal years ~~[2015]~~ *2020* through ~~[2019]~~ *2024*.

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**NEWBORN SCREENING SAVES LIVES
REAUTHORIZATION ACT OF 2014**

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[SEC. 12. INFORMED CONSENT FOR NEWBORN SCREENING RESEARCH.

[(a) IN GENERAL.—Research on newborn dried blood spots shall be considered research carried out on human subjects meeting the definition of section 46.102(f)(2) of title 45, Code of Federal Regulations, for purposes of Federally funded research conducted pursuant to the Public Health Service Act until such time as updates to the Federal Policy for the Protection of Human Subjects (the Common Rule) are promulgated pursuant to subsection (c). For purposes of this subsection, sections 46.116(c) and 46.116(d) of title 45, Code of Federal Regulations, shall not apply.

[(b) EFFECTIVE DATE.—Subsection (a) shall apply only to newborn dried blood spots used for purposes of Federally funded research that were collected not earlier than 90 days after the date of enactment of this Act.

[(c) REGULATIONS.—Not later than 6 months after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate proposed regulations related to the updating of the Federal Policy for the Protection of Human Subjects (the Common Rule), particularly with respect to informed consent. Not later than 2 years after such date of enactment, the Secretary shall promulgate final regulations based on such proposed regulations.]

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 part 4 of section 46.104 of title 45, Code of Federal 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.).