To amend the Public Health Service Act to reauthorize programs under part A of title XI of such Act.

IN THE HOUSE OF REPRESENTATIVES

MARCH 20, 2013

Ms. ROYBAL-ALLARD (for herself and Mr. SIMPSON) 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 programs under part A of title XI of such Act.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the “Newborn Screening Saves Lives Reauthorization Act of 2013”.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.
Sec. 2. Improved newborn and child screening for heritable disorders.
Sec. 3. Evaluating the effectiveness of newborn and child screening and followup programs.
Sec. 4. Advisory committee on heritable disorders in newborns and children.
Sec. 5. Clearinghouse of Newborn Screening Information.
Sec. 6. Laboratory quality.
Sec. 7. Interagency Coordinating Committee on Newborn and Child Screening.
Sec. 8. National contingency plan for newborn screening.
Sec. 9. Hunter Kelly Research Program.
Sec. 10. Newborn screening surveillance, followup, and applied research.
Sec. 11. Authorization of appropriations.

SEC. 2. IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

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

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking “and in consultation with the Advisory Committee” and inserting “and taking into consideration the recommendations of the Advisory Committee”; 

(B) in paragraph (2), by striking “screening and training” and inserting “screening, counseling, and training”; and

(C) in paragraph (4), by striking “treatment” and inserting “followup and treatment”; 

(2) in subsection (b)—

(A) in paragraph (4), by striking “or” at the end; 

(B) by redesignating paragraph (5) as paragraph (7); and 

(C) by inserting after paragraph (4) the following:
“(5) a health professional organization;
“(6) an early childhood health system; or”; and
(3) by striking subsection (j) (relating to au-
thorization of appropriations).

SEC. 3. EVALUATING THE EFFECTIVENESS OF NEWBORN
AND CHILD SCREENING AND FOLLOWUP

PROGRAMS.

Section 1110 of the Public Health Service Act (42
U.S.C. 300b–9) is amended—

(1) in the section heading, by inserting “AND
FOLLOWUP” after “CHILD SCREENING”;

(2) in subsection (a), by inserting “followup,”
after “the effectiveness of screening,”;

(3) in subsection (b)—

(A) in paragraph (1), by inserting “ascer-
tainment, treatment,” after “the effectiveness
of screening, counseling,”;

(B) in paragraph (2)—

(i) by inserting “ascertainment, treat-
ment,” after “the effectiveness of screen-
ing, counseling,”; and

(ii) by striking “or” at the end;

(C) in paragraph (3), by striking the pe-
riod at the end and inserting “; or”; and

(D) by adding at the end the following:
“(4) the availability and effectiveness of treatment and followup care for newborns and their families after screening and diagnosis.”; and

(4) by striking subsection (d) (relating to authorization of appropriations).

SEC. 4. 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 (4), by striking “public health impact” and inserting “public health impact and cost”; and

(B) in paragraph (6)—

(i) in subparagraph (A), by striking “achieve rapid diagnosis” and inserting “achieve best practices in rapid diagnosis and appropriate treatment”; and

(ii) in subparagraph (D), by inserting before the semicolon “, including information on cost and incidence”;

(2) by redesignating subsections (f) and (g) as subsections (g) and (h), respectively;

(3) by inserting after subsection (e) the following new subsection:
“(f) MEETINGS.—The Advisory Committee shall meet in person at least twice each year.”;

(4) by amending subsection (g), as redesignated by paragraph (2), to read as follows:

“(g) CONTINUATION OF OPERATION OF COMMITTEE.—

“(1) IN GENERAL.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate for the period beginning on the date of enactment of the Newborn Screening Saves Lives Reauthorization Act of 2013 and concluding at the end of the fifth fiscal year which begins after such date.

“(2) CONTINUATION IF NOT REAUTHORIZED.—If at the end of the fifth fiscal year described in paragraph (1) the duration of the Advisory Committee has not been extended by statute—

“(A) the Advisory Committee may be considered, for the purposes of the Federal Advisory Committee Act, to be an advisory committee established by the President or an officer of the Federal Government under section 9(a) of such Act; and
“(B) the Secretary may renew the Advisory Committee under section 14(a)(1)(A) of such Act.”; and

(5) by striking subsection (h) (relating to authorization of appropriations), as redesignated by paragraph (2).

SEC. 5. CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

Section 1112 of the Public Health Service Act (42 U.S.C. 300b–11) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking “; and” and inserting a semicolon;

(B) in paragraph (3), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following new paragraphs:

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

“(5) establish or disseminate guidelines for services and personnel necessary for followup, diagnosis, counseling, and treatment with respect to conditions detected by newborn screening.”;}
(2) in subsection (b)(4)(D), by striking “Newborn Screening Saves Lives Act of 2008” and inserting “Newborn Screening Saves Lives Reauthorization Act of 2013”; and

(3) by striking subsection (d) (relating to authorization of appropriations).

SEC. 6. LABORATORY QUALITY.

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

(1) in subsection (a)—

(A) by striking the subsection enumerator and heading; and

(B) by striking “and in consultation with the Advisory Committee” and inserting “and taking into consideration the recommendations of the Advisory Committee”; and

(2) by striking subsection (b) (relating to authorization of appropriations).

SEC. 7. INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

Section 1114 of the Public Health Service Act (42 U.S.C. 300b–13) is amended—

(1) in subsection (e), by striking “the Administrator, the Director of the Agency for Healthcare Research and Quality” and inserting “the Administrator, the Director of the Agency for Healthcare Research and Quality” and inserting “the Adminis-
trator of the Health Resources and Services Admin-
istration, the Director of the Agency for Healthcare
Research and Quality, the Commissioner of Food
and Drugs,”; and

(2) by striking subsection (e) (relating to au-
thorization of appropriations) and inserting the fol-
lowing:

“(e) REPORT TO CONGRESS.—

“(1) IN GENERAL.—The Secretary shall—

“(A) not later than 1 year after the date
of enactment of the Newborn Screening Saves
Lives Reauthorization Act of 2013, submit to
the Health, Education, Labor, and Pensions
Committee of the Senate and the Energy and
Commerce Committee of the House of Rep-
resentatives a report on activities related to—

“(i) newborn screening; and

“(ii) screening children who have or
are at risk for heritable disorders; and

“(B) not less than every 2 years, shall sub-
mit to such committees an updated version of
such report.

“(2) CONTENTS.—The report submitted under
subsection (a) shall contain a description of—
“(A) the implementation of sections 1111 through 1116B, including this section; and
“(B) the amounts expended on such implementa-
tion.”.

**SEC. 8. NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.**

Section 1115(a) of the Public Health Service Act (42 U.S.C. 300b–14(a)) is amended by adding at the end the following: “The plan shall be updated as needed and at least every five years.”.

**SEC. 9. HUNTER KELLY RESEARCH PROGRAM.**

Section 1116(a)(1) of the Public Health Service Act (42 U.S.C. 300b–15(a)(1)) is amended—

(1) in subparagraph (B), by striking “; and” and inserting a semicolon;

(2) by redesignating subparagraph (C) as sub-
paragraph (E); and

(3) by inserting after subparagraph (B) the fol-
lowing:

“(C) providing research and data for new-
born 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 the Advisory Committee on Heritable Disorders in Newborns and Children to ensure that screenings are ready for nationwide implementation; and’’.

SEC. 10. NEWBORN SCREENING SURVEILLANCE, FOLLOWUP, AND APPLIED RESEARCH.

The Public Health Service Act is amended by inserting after section 1116 of such Act (42 U.S.C. 300b–15) the following:

“SEC. 1116A. NEWBORN SCREENING SURVEILLANCE, FOLLOWUP, AND APPLIED RESEARCH.

“(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to, or enter into cooperative agreements with, eligible entities to develop longitudinal followup and tracking programs for newborn screening.

“(b) PROGRAM.—Longitudinal followup and tracking programs developed through a grant under subsection (a) shall incorporate standardized procedures for data management and program effectiveness and costs, such as—

“(1) studying the costs and effectiveness of newborn screening, evaluation and intervention programs, and surveillance systems conducted by State-
based programs in order to answer issues of importance to State and national policymakers;

“(2) studying the effectiveness of newborn screening followup and intervention programs by assessing the health and development of children at school age and as young adults;

“(3) promoting the sharing of data regarding newborn screening with State-based birth defects and developmental disabilities monitoring programs;

“(4) ensuring coordination of surveillance activities, including—

“(A) standardized data collection and reporting; and

“(B) use of electronic health records;

“(5) facilitating quality improvement in treatment and disease management based on gaps in services or care identified by longitudinal tracking systems; and

“(6) utilizing data from longitudinal tracking systems to support the development and evaluation of evidence-based guidelines for diagnosis, treatment, and disease management.

“(c) 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 subdivisions described in paragraph (1);

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

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

SEC. 11. AUTHORIZATION OF APPROPRIATIONS.

The Public Health Service Act is amended by inserting after section 1116A of such Act, as added by section 10 of this Act, the following:

“SEC. 1116B. 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, $13,334,000 for each of fiscal years 2014 through 2018;

“(2) to carry out section 1113, $7,500,000 for each of fiscal years 2014 through 2018; and
“(3) to carry out section 1116A, $5,000,000 for each of fiscal years 2014 through 2018.”.