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REPORT
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NEWBORN SCREENING SAVES LIVES ACT OF 2008

APRIL 8, 2008.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 3825]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3825) to amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated followup care once newborn screening has been conducted, to reauthorize programs under part A of title XI of such Act, and for other purposes, having considered the same, reports favorably thereon with an amendment and recommends that the bill as amended do pass.

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AMENDMENT

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 Act of 2008".

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

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

(1) by striking subsections (a), (b), and (c) and inserting the following:

"(a) AUTHORIZATION OF GRANT PROGRAM.—From amounts appropriated under subsection (j), the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the 'Administrator') and in consultation with 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 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 and training in relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

"(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; and

"(4) to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.

"(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 submitted for a grant under subsection (a)(1) 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 amounts received under such grant to adopt and implement 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.";

(2) by redesignating subsections (d) through (i) as subsections (e) through (j), respectively;

(3) by inserting after subsection (c), the following:

"(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."; and

(4) by striking subsection (j) (as so redesignated) and inserting the following:

"(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

"(1) to provide grants for the purpose of carrying out activities under subsection (a)(1), $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013; and

"(2) to provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013.".

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

Section 1110 of the Public Health Service Act (42 U.S.C. 300b–9) is amended by adding at the end the following:

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.".

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) by redesignating paragraph (3) as paragraph (6);

(B) in paragraph (2), by striking "and" after the semicolon;

(C) by inserting after paragraph (2) the following:

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

"(5) 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";

(D) in paragraph (6) (as so redesignated by subparagraph (A)), by striking the period at the end and inserting ", which may include recommendations, advice, or information dealing with—

"(A) follow-up activities, including those necessary to achieve rapid diagnosis 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;

"(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; and

"(K) 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

(2) in subsection (c)(2)—

(A) by redesignating subparagraphs (E), (F), and (G) as subparagraphs (F), (H), and (I), respectively;

(B) by inserting after subparagraph (D) the following:

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

(C) by inserting after subparagraph (F), as so redesignated, the following:

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

(3) by adding at the end the following:

"(d) DECISION ON RECOMMENDATIONS.—

"(1) IN GENERAL.—Not later than 180 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation.

"(2) PENDING RECOMMENDATIONS.—The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment of the Newborn Screening Saves Lives Act of 2008 by not later than 180 days after the date of enactment of such Act.

"(3) 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.

"(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) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on the date of enactment of the Newborn Screening Saves Lives Act of 2008.

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.".

SEC. 5. INFORMATION CLEARINGHOUSE.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.) is amended by adding at the end the following:

"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; and

"(3) maintain current data 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.

"(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 Act of 2008; and

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

"(c) NONDUPLICATION.—In developing the clearinghouse under this section, the Secretary shall ensure that such clearinghouse minimizes duplication and supplements, not supplants, existing information sharing efforts.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $2,500,000 for fiscal year 2009, $2,531,250 for fiscal

year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.".

SEC. 6. LABORATORY QUALITY AND SURVEILLANCE.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.), as amended by section 5, is further amended by adding at the end the following:

"SEC. 1113. LABORATORY QUALITY.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with 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, performance evaluation services, 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 to evaluate the performance of new screening tools.

"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.

"SEC. 1114. INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

"(a) PURPOSE.—It is the purpose of this section to—

"(1) assess existing activities and infrastructure, including activities on birth defects and developmental disabilities authorized under section 317C, in order to make recommendations for programs to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children under section 1111, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders; and

"(2) make recommendations for the establishment of regional centers for the conduct of applied epidemiological research on effective interventions to promote the prevention of poor health outcomes resulting from such disorders as well as providing information and education to the public on such effective interventions.

"(b) ESTABLISHMENT.—The Secretary shall establish an Interagency Coordinating Committee on Newborn and Child Screening (referred to in this section as the 'Interagency Coordinating Committee') to carry out the purpose of this section.

"(c) COMPOSITION.—The Interagency Coordinating Committee shall be composed of the Director of the Centers for Disease Control and Prevention, the Administrator, the Director of the Agency for Healthcare Research and Quality, and the Director of the National Institutes of Health, or their designees.

"(d) ACTIVITIES.—The Interagency Coordinating Committee shall—

"(1) report to the Secretary and the appropriate committees of Congress on its recommendations related to the purpose described in subsection (a); and

"(2) carry out other activities determined appropriate by the Secretary.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.".

SEC. 7. CONTINGENCY PLANNING.

Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.), as amended by section 6, is further amended by adding at the end the following:

"SEC. 1115. NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.

"(a) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator and State departments of health (or related agencies), shall develop a national contingency plan for newborn screening for use by a State, region, or consortia of States in the event of a public health emergency.

"(b) CONTENTS.—The contingency plan developed under subsection (a) shall include a plan for—

"(1) the collection and transport of specimens;

"(2) the shipment of specimens to State newborn screening laboratories;

"(3) the processing of specimens;

"(4) the reporting of screening results to physicians and families;
"(5) the diagnostic confirmation of positive screening results;
"(6) ensuring the availability of treatment and management resources;
"(7) educating families about newborn screening; and
"(8) carrying out other activities determined appropriate by the Secretary.

"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 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; and
"(C) 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).
"(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 of the National Institutes of Health Reform Act of 2006. 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.".

PURPOSE AND SUMMARY

The purpose of H.R. 3825, the "Newborn Screening Saves Lives Act of 2008", is to amend the Public Health Service Act to establish grant programs to provide for education and outreach on newborn screening and coordinated follow-up care once newborn screening has been conducted, to reauthorize programs under Part A of title XI of such Act, and for other purposes.

BACKGROUND AND NEED FOR LEGISLATION

Newborn screening is a public health activity that provides early identification and follow-up for treatment of infants affected by certain genetic, metabolic, hormonal, and functional conditions for which there may be an effective treatment or intervention. If left untreated, these disorders can cause death, disability, mental retardation, and other serious conditions. Since the early 1960s, more than 150 million infants have been screened for a number of genetic and congenital disorders. Every year, more than 4 million infants are born and screened to detect conditions that could threat-

en their lives and long-term health, and an estimated 3,000 babies are identified and treated for such conditions.

Parents are often unaware that the number and quality of newborn screens varies from State to State. While newborns are regularly screened and treated for debilitating conditions in some States, in others screening may not be required and conditions may go undiagnosed and untreated. In 2004, the American College of Medical Genetics completed a report commissioned by the U.S. Department of Health and Human Services (HHS) recommending, at a minimum, that every baby born in the U.S. be screened for a core set of 29 treatable disorders regardless of the State in which he or she is born. At present, only 15 States and the District of Columbia require infants to be screened for all 29 of the recommended disorders. Some States currently mandate screening newborns for as few as 9 conditions while others mandate more than 40 conditions. An estimated 1,000 of the 5,000 babies born every year in the United States with one of the 29 core conditions potentially go unscreened through newborn screening.

H.R. 3825 will educate parents and healthcare providers about newborn screening, improve follow-up care for infants with an illness detected through newborn screening, and help States expand and improve their newborn screening programs, as well as provide for Federal guidelines on the conditions for which newborns in all States should be screened.

HEARINGS

There were no hearings held in connection to the bill reported by the Committee.

COMMITTEE CONSIDERATION

Tuesday, March 11, 2008, the Subcommittee on Health met in open markup session and favorably forwarded H.R. 3825, amended, to the full Committee for consideration, by a voice vote. On Thursday, March 13, 2008, the full Committee met in open markup session and ordered H.R. 3825 favorably reported to the House, as amended by the Subcommittee on Health, by a voice vote. No amendments were offered during full Committee consideration.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments thereto. There were no record votes taken on amendments or in connection with ordering H.R. 3825 reported to the House. A motion by Mr. Dingell to order H.R. 3825 favorably reported to the House, as amended, was agreed to by a voice vote.

COMMITTEE OVERSIGHT FINDINGS

Regarding clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the oversight findings of the Committee regarding H.R. 3825 are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 3825 is to amend the Public Health Service Act to require the Secretary of HHS, acting through the Administrator of the Health Resources and Services Administration (HRSA), to award grants to eligible entities to provide education and training in newborn screening and congenital, genetic, and metabolic disorders to healthcare professionals and newborn screening laboratory personnel. H.R. 3825 requires the Advisory Committee on Heritable Disorders in Newborns and Children (Advisory Committee) to make recommendations that include the heritable disorders for which all newborns should be screened and develop a model decision-matrix for newborn screening program expansion. H.R. 3825 requires the Secretary of HHS, acting through the Administrator of HRSA, to establish a central clearinghouse for information on newborn screening and award grants for newborn screening educational programs and for a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders. The legislation further requires the Secretary of HHS, acting through the Director of the Centers for Disease Control and Prevention (CDC), to provide (1) quality assurance for screening laboratories; (2) population-based pilot testing for evaluating new screening tools; and (3) a national contingency plan for newborn screening in the event of a public health emergency.

H.R. 3825 requires the Secretary of HHS, acting through an Interagency Group, to (1) collect, analyze, and make available data on certain heritable disorders; (2) operate regional centers to conduct applied epidemiological research on interventions to prevent poor health outcomes from such disorders; and (3) research and promote the prevention of poor health outcomes. Lastly, the legislation allows the Secretary of HHS, in conjunction with the Director of the National Institutes of Health (NIH), to continue carrying out, coordinating, and expanding research in newborn screening (to be known as the "Hunter Kelly Newborn Screening Research Program").

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

Regarding compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 3825 would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARKS AND TAX AND TARIFF BENEFITS

Regarding compliance with clause 9 of rule XXI of the Rules of the House of Representatives, H.R. 3825 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9(d), 9(e), or 9(f) of rule XXI.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate on H.R. 3825 prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

Pursuant to clause 3(c)(3) of Rule XIII of the Rules of the House of Representatives, the following is the cost estimate on H.R. 3825 provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974:

APRIL 1, 2008.

Hon. JOHN D. DINGELL,
Chairman, Committee on Energy and Commerce,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for H.R. 3825, the Newborn Screening Saves Lives Act of 2008.

If you wish further details on this estimate, we will be pleased to provide them. The CBO staff contacts are Sarah Evans, Tim Gronniger, Lara Robillard, and Andrea Noda.

Sincerely,

ROBERT A. SUNSHINE
(For Peter R. Orszag.)

Enclosure.

H.R. 3825—Newborn Screening Saves Lives Act of 2008

Summary: H.R. 3825 would amend the Public Health Service Act to authorize grant programs and other initiatives to promote expanded screening of newborns and children for heritable diseases.

CBO estimates that the act would authorize the appropriation of $47 million for 2009 and $229 million over the 2009–2013 period. Assuming the appropriation of those amounts, CBO estimates that implementing the act would cost $24 million in 2009 and $199 million over the 2009–2013 period. H.R. 3825 would not affect direct spending or revenues.

H.R. 3825 contains no intergovernmental or private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA).

Estimated cost to the Federal Government: The estimated budgetary impact of H.R. 3825 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—				
	2009	2010	2011	2012	2013
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
HRSA Activities:					
Authorization Level	39	39	39	40	40
Estimated Outlays	20	35	37	40	40
CDC Activities:					
Authorization Level	6	6	6	6	6
Estimated Outlays	2	5	6	6	6
Contingency Planning (CDC and HRSA):					
Estimated Authorization Level	2	0	0	0	0
Estimated Outlays	2	0	0	0	0
Total Changes Under:					
Estimated Authorization Level	47	45	45	46	46
Estimated Outlays	24	40	43	46	46

Note: HRSA = Health Resources and Services Administration; CDC = Centers for Disease Control and Prevention.

Basis of estimate: The activities authorized under H.R. 3825 would be carried out by the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Preven-

tion (CDC). The estimate is based on historical spending patterns for similar activities, and assumes that the authorized amounts would be appropriated near the beginning of each fiscal year.

The act would direct HRSA to establish grant programs to promote expanded screening of newborns and children for heritable diseases, and to establish a clearinghouse on heritable diseases. The bill would authorize the appropriation of $39 million for 2009 and $197 million over the 2009–2013 period for those activities. CBO estimates that implementing those provisions would cost $20 million in 2009 and $172 million over the 2009–2013 period.

H.R. 3825 also would authorize CDC to implement programs to promote quality in clinical laboratories that test for heritable diseases and to create a surveillance program for heritable disorders. The bill would authorize the appropriation of $6 million for 2009 and $30 million over the 2009–2013 period. CBO estimates that implementing those provisions would cost $2 million in 2009 and $25 million over the 2009–2013 period.

In addition, the act would direct CDC and HRSA to collaborate to create a national contingency plan for newborn screening in the event of a public health disaster. CBO estimates that it would cost $2 million in 2009 to develop that plan, assuming the availability of appropriated funds.

Intergovernmental and private-sector impact: H.R. 3825 contains no intergovernmental or private-sector mandates as defined in UMRA. State and local governments that participate in newborn and child screening programs would benefit from funds authorized by the bill.

Previous CBO estimate: On April 1, 2008, CBO transmitted a cost estimate of S. 1858, the Newborn Screening Saves Lives Act of 2007, as passed by the Senate on December 13, 2007. The two bills are very similar, except that S. 1858 would authorize appropriations for the 2008–2012 period (rather than the 2009–2013 period specified in H.R. 3825). CBO's estimate for S. 1858 differs from that for H.R. 3825 because the amounts specified for appropriation in each year are different.

Estimate prepared by: Federal Costs: Sarah Evans, Tim Gronniger, Andrea Noda, and Lara Robillard; Impact on State, Local, and Tribal Governments: Lisa Ramirez-Branum; Impact on the Private Sector: Patrick Bernhardt.

Estimate approved by: Keith J. Fontenot, Deputy Assistant Director for Health and Human Resources, Budget Analysis Division.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates regarding H.R. 3825 prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act would be created by H.R. 3825.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the Constitutional authority for H.R. 3825 is provided in the provisions of Article I, section 8, clause 1, that relate to expending funds to provide for the general welfare of the United States.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that H.R. 3825 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 of 1995.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Section 1. Short title

Section 1 establishes the short title of the Act as the "Newborn Screening Saves Lives Act of 2008".

Section 2. Improved newborn and child screening for heritable disorder

Section 2 amends Section 1109 of the Public Health Service Act (42 U.S.C. 300b–8). Section 2 authorizes grants for enhancing, improving, or expanding the ability of States and local public health agencies to provide screening, counseling, or healthcare services to newborns and children having or at risk for heritable disorders. In order to receive a grant, an eligible entity must commit to adopting and implementing or be in the process of adopting and implementing the guidelines and recommendations of the Advisory Committee that are adopted by the Secretary of HHS. The authorization of appropriations for this program is $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013. Eligible entities for these grants are a State, a consortium of 2 or more States, a territory, a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Services, or any other entity with appropriate expertise in newborn screening, as determined by the Secretary.

Section 2 authorizes grants for (1) educating and training healthcare professionals and State laboratory personnel in newborn screening and relevant new technologies; (2) developing and delivering educational programs to inform parents, families, and patient advocacy and support groups about newborn screening, testing, follow-up, and treatment; and (3) establishing, operating, and maintaining a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders. The authorization of appropriations for these grants is $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013. Eligible entities for these grants are a State, a consortium of 2 or more States, a territory, a health facility or program operated by or pursuant to a contract with or grant from the Indian Health Services, or any other entity with appropriate expertise in newborn screening, as determined by the Secretary of HHS.

Section 3. Evaluating the effectiveness of newborn and child screening programs

Section 3 amends Section 1110 of the Public Health Service Act (42 U.S.C. 300b–9), to authorize $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013 to evaluate the effectiveness of Newborn and Child Screening Programs.

Section 4. Advisory Committee on Heritable Disorders in Newborns and Children

Section 4 amends Section 1111 of the Public Health Service Act (42 U.S.C. 300b–10).

Section 4 reauthorizes the Advisory Committee for the 5-year period beginning on the date of enactment of the bill. It expands the role of the Advisory Committee to require that the Advisory Committee make systematic evidence-based and peer-reviewed recommendations that include heritable disorders, including secondary conditions that may be identified. It requires the Advisory Committee to develop a model decision-matrix for newborn screening expansion and periodic updating of the recommended uniform screening panel as well as to consider ways to ensure that all States attain the capacity to screen for the recommended panel of disorders. The Advisory Committee is also required to provide recommendations, advice, or information to the Secretary of HHS to reduce the mortality or morbidity from heritable disorders, which may include:

- Follow-up activities including those necessary to achieve rapid diagnosis in the short term and those that ascertain long-term case management outcomes;
- Implementation, monitoring, and evaluation of newborn screening activities, including diagnosis, screening, follow-up, and treatment activities;
- Quality assurance, oversight, and evaluation of State newborn screening programs;
- The availability and reporting of testing for conditions for which there is no existing treatment;
- Standardized data collection and reporting for assessment of newborn screening programs;
- The cost and effectiveness of newborn screening and medical evaluation systems and intervention programs conducted by State-based programs; and
- Coordination of surveillance activities in order to enhance monitoring of newborn diseases.

Section 4 adds individuals with expertise in ethics and infectious diseases who have worked and published material in newborn screening and the Commissioner of the Food and Drug Administration (FDA) to the Advisory Committee. It requires the Secretary of HHS to adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment and requires the Secretary of HHS to adopt or reject future recommendations of the Advisory Committee after not more than 180 days and make public such determination. It also requires the Advisory Committee to report to Congress and the public not later than 3 years after the date of enactment, and each year thereafter, on newborn

screening guidelines, including follow-up and treatment, in the United States.

This section authorizes $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.

Section 5. Information clearinghouse

Section 5 amends Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.). Section 5 requires the Secretary of HHS to establish a central clearinghouse within HRSA, in consultation with CDC and NIH. This clearinghouse is to be made available via the Internet to provide current educational and family support information, resources, and data on newborn screening for parents and family members of newborns; information about newborn screening services available in each State; current research on both treatable and not-yet treatable conditions for which newborn screening tests are available; and the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized by the bill.

This section authorizes $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.

Section 6. Laboratory quality and surveillance

Section 6 amends Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.). Section 6 requires the Secretary of HHS, acting through the Director of the CDC and in consultation with the Advisory Committee, to ensure the quality of laboratories involved in newborn screening including quality assurance for newborn screening tests, and performance evaluation services. Quality assurance activities shall also include technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests as well as to provide for appropriate quality control and other performance test materials to evaluate the performance of new screening tools. This section authorizes $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.

Section 6 also requires the Secretary of HHS to establish an Interagency Coordinating Committee consisting of the Director of the Agency for Healthcare Research and Quality (AHRQ), the Director of the CDC, the Administrator of the HRSA, and the Director of NIH. The Interagency Coordinating Committee shall assess existing activities and infrastructure, including activities on birth defects and developmental disabilities authorized under Section 317C, in order to make recommendations for programs to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee. The Interagency Coordinating Committee shall also make recommendations for the establishment of regional centers for the conduct of applied epidemiological research on effective interventions to promote the prevention of poor health outcomes resulting from disorders and to provide information and education to the public on such effective interventions. The Interagency Coordinating Committee shall report to the

Secretary of HHS and the appropriate Committees of Congress on its recommendations.

For the purposes of this section, there are authorized to be appropriated $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.

Section 7. Contingency planning

Section 7 amends Part A of title XI of the Public Health Service Act (42 U.S.C. 300b–1 et seq.). Section 7 requires the Secretary of HHS, acting through the Director of the CDC, to develop a national contingency plan for newborn screening for use by a State, region, or consortia of States in the event of a public health emergency. The national contingency plan shall be developed not later than 180 days after enactment of the bill and shall include a plan for the collection and transport of specimens, the shipment and processing of specimens, the reporting of screening results to physicians and families, the diagnostic confirmation of positive screening results, the availability of treatment and management resources, and the education of families about newborn screening.

Section 7 allows the Secretary of HHS, in conjunction with the Director of the NIH, and taking into consideration the recommendations of the Advisory Committee, to continue carrying out, coordinating, and expanding research in newborn screening (to be known as the "Hunter Kelly Newborn Screening Research Program") including identifying, developing, and testing the most promising new screening technologies in order to improve already existing screening tests and expand the number of conditions for which screening test are available and experimental treatments and disease management strategies for additional newborn conditions beyond those recommended by the Advisory Committee and adopted by the Secretary of HHS that can be detected through newborn screening for which treatment is not yet available. In carrying out the research under this section, the Secretary of HHS and the Director of NIH shall ensure that entities receiving funding focus their research on screening technology not currently performed in the State in which the entities are located and on the conditions not on the uniform screening panel. The Director of NIH is encouraged to include information about the activities carried out under this section in the biennial report required under section 403 of the National Institutes of Health Reform Act of 2006 and, where applicable, the Internet clearinghouse established under section 5 of this bill.

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, 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) IN GENERAL.—The Secretary shall award grants to eligible entities to 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.

[(b) USE OF FUNDS.—Amounts provided under a grant awarded under subsection (a) shall be used to—

[(1) establish, expand, or improve systems or programs to provide screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

[(2) establish, expand, or improve programs or services to reduce mortality or morbidity from heritable disorders;

[(3) establish, expand, or improve systems or programs to provide information and counseling on available therapies for newborns and children with heritable disorders;

[(4) improve the access of medically underserved populations to screening, counseling, testing and specialty services for newborns and children having or at risk for heritable disorders; or

[(5) conduct such other activities as may be necessary to enable newborns and children having or at risk for heritable disorders to receive screening, counseling, testing or specialty services, regardless of income, race, color, religion, sex, national origin, age, or disability.

[(c) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall—

[(1) be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States; and

[(2) prepare and submit to the Secretary an application that includes—

[(A) a plan to use amounts awarded under the grant to meet specific health status goals and objectives relative to heritable disorders, including attention to needs of medically underserved populations;

[(B) a plan for the collection of outcome data or other methods of evaluating the degree to which amounts awarded under this grant will be used to achieve the goals and objectives identified under subparagraph (A);

[(C) a plan for monitoring and ensuring the quality of services provided under the grant;

[(D) an assurance that amounts awarded under the grant will be used only to implement the approved plan for the State;

[(E) an assurance that the provision of services under the plan is coordinated with services provided under programs implemented in the State under title V, XVIII, XIX, XX, or XXI of the Social Security Act (subject to Federal

regulations applicable to such programs) so that the coverage of services under such titles is not substantially diminished by the use of granted funds; and

[(F) such other information determined by the Secretary to be necessary.]

(a) AUTHORIZATION OF GRANT PROGRAM.—From amounts appropriated under subsection (j), the Secretary, acting through the Administrator of the Health Resources and Services Administration (referred to in this section as the "Administrator") and in consultation with 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 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 and training in relevant and new technologies in newborn screening and congenital, genetic, and metabolic disorders;

(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; and

(4) to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders.

(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 submitted for a grant under subsection (a)(1) 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 amounts received under such grant to adopt and implement 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.

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

(1) * * *

* * * * * * *

[(e)] *(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.

[(f)] *(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.

[(g)] *(h)* PUBLICATION.—

(1) * * *

* * * * * * *

[(h)] *(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.

[(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of the fiscal years 2001 through 2005.]

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

(1) to provide grants for the purpose of carrying out activities under subsection (a)(1), $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013; and

(2) to provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,000,000 for fiscal year 2009, $15,187,500 for fiscal year 2010, $15,375,000 for fiscal year 2011, $15,562,500 for fiscal year 2012, and $15,750,000 for fiscal year 2013.

SEC. 1110. EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING PROGRAMS.

(a) * * *

* * * * * * *

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.

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

(a) * * *

(b) DUTIES.—The Advisory Committee shall—

(1) * * *

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

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

(5) 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

[(3)**]** *(6)* 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 rapid diagnosis 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;

(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; and

(K) 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.

(c) MEMBERSHIP.—

(1) * * *

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

(A) * * *

* * * * * * *

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

[(E)] *(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;

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

[(G)] *(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 180 days after the Advisory Committee issues a recommendation pursuant to this section, the Secretary shall adopt or reject such recommendation.

(2) PENDING RECOMMENDATIONS.—The Secretary shall adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment of the Newborn Screening Saves Lives Act of 2008 by not later than 180 days after the date of enactment of such Act.

(3) 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.

(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) CONTINUATION OF OPERATION OF COMMITTEE.—Notwithstanding section 14 of the Federal Advisory Committee Act (5 U.S.C. App.), the Advisory Committee shall continue to operate during the 5-year period beginning on the date of enactment of the Newborn Screening Saves Lives Act of 2008.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.

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; and

(3) maintain current data 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.

(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 Act of 2008; and

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

(c) NONDUPLICATION.—In developing the clearinghouse under this section, the Secretary shall ensure that such clearinghouse mini-

mizes duplication and supplements, not supplants, existing information sharing efforts.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.

SEC. 1113. LABORATORY QUALITY.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with 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, performance evaluation services, 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 to evaluate the performance of new screening tools.

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2009, $5,062,500 for fiscal year 2010, $5,125,000 for fiscal year 2011, $5,187,500 for fiscal year 2012, and $5,250,000 for fiscal year 2013.

SEC. 1114. INTERAGENCY COORDINATING COMMITTEE ON NEWBORN AND CHILD SCREENING.

(a) PURPOSE.—It is the purpose of this section to—

(1) assess existing activities and infrastructure, including activities on birth defects and developmental disabilities authorized under section 317C, in order to make recommendations for programs to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children under section 1111, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders; and

(2) make recommendations for the establishment of regional centers for the conduct of applied epidemiological research on effective interventions to promote the prevention of poor health outcomes resulting from such disorders as well as providing information and education to the public on such effective interventions.

(b) ESTABLISHMENT.—The Secretary shall establish an Interagency Coordinating Committee on Newborn and Child Screening (referred to in this section as the "Interagency Coordinating Committee") to carry out the purpose of this section.

(c) COMPOSITION.—The Interagency Coordinating Committee shall be composed of the Director of the Centers for Disease Control and Prevention, the Administrator, the Director of the Agency for Healthcare Research and Quality, and the Director of the National Institutes of Health, or their designees.

(d) ACTIVITIES.—The Interagency Coordinating Committee shall—

(1) report to the Secretary and the appropriate committees of Congress on its recommendations related to the purpose described in subsection (a); and

(2) carry out other activities determined appropriate by the Secretary.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $1,000,000 for fiscal year 2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.

SEC. 1115. NATIONAL CONTINGENCY PLAN FOR NEWBORN SCREENING.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this section, the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Administrator and State departments of health (or related agencies), shall develop a national contingency plan for newborn screening for use by a State, region, or consortia of States in the event of a public health emergency.

(b) CONTENTS.—The contingency plan developed under subsection (a) shall include a plan for—

(1) the collection and transport of specimens;

(2) the shipment of specimens to State newborn screening laboratories;

(3) the processing of specimens;

(4) the reporting of screening results to physicians and families;

(5) the diagnostic confirmation of positive screening results;

(6) ensuring the availability of treatment and management resources;

(7) educating families about newborn screening; and

(8) carrying out other activities determined appropriate by the Secretary.

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 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; and

(C) 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).

(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 of the National Institutes of Health Reform Act of 2006. 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.

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