

NEWBORN SCREENING SAVES LIVES ACT OF 2007

APRIL 8, 2008.—Ordered to be printed

Mr. KENNEDY, from the Committee on Health, Education, Labor and Pensions, submitted the following

R E P O R T

[To accompany S. 1858]

The Committee on Health, Education, Labor, and Pensions, to which was referred the bill (S. 1858) 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 in the nature of a substitute and recommends that the bill (as amended) do pass.

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I. PURPOSE AND NEED FOR LEGISLATION

The purpose of the “Newborn Screening Saves Lives Act of 2007” is to facilitate the creation of Federal guidelines on newborn screening, to assist State newborn screening programs in meeting Federal guidelines, to improve education, outreach, and coordinated follow-up care, and to improve the laboratory quality and surveillance for newborn screening.

Newborn screening is a public health activity, which provides early identification and follow-up for treatment of infants affected

by certain genetic, metabolic, hormonal and/or functional conditions. Since the early 1960s, when Robert Guthrie devised a screening test for phenylketonuria (PKU) using a newborn blood spot dried onto a filter paper card, more than 150 million infants have been screened for a number of genetic and congenital disorders. Screening detects disorders in newborns that, if left untreated, can cause disability, intellectual disabilities, serious illness and even death. Except for hearing, screening tests are done using a few drops of blood from the newborn's heel, usually taken in the hospital 24 to 48 hours after birth. With the advent of the tandem mass spectrometer, it is now possible to detect more than 40 conditions and for some conditions such as PKU, tandem mass spectrometry has been shown to reduce the false positive rate for this disorder.

Parents are often unaware that the number and quality of newborn screens varies from State to State and 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 United States Department of Health and Human Services which recommended that, at a minimum, 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. In fact, 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. If diagnosed early these conditions can be successfully managed.

The "Newborn Screening Saves Lives Act of 2007" will assist States in improving and expanding their newborn screening programs as well as provide for Federal guidelines on the conditions for which newborns in all States should be screened. The public health crisis that ensued after hurricanes such as Katrina and Rita demonstrated, among other things, that contingency planning for newborn screening is essential. Under this legislation the Secretary is required to develop a national contingency plan for newborn screening for use by States in the event of a public health emergency.

II. SUMMARY

This legislation authorizes \$58,500,000 in fiscal year 2008 to expand, improve, coordinate, and evaluate Federal research, educational, and programmatic activities related to newborn screening. Within this authorization is funding to enhance and expand the ability of State and local health agencies to provide screening, counseling, or health care services to newborns and children at risk for or diagnosed with heritable disorders as well as to educate and train health care professionals, State laboratory personnel, parents, families, and patient advocates about newborn screening, including new technologies, follow-up, and treatment.

The "Newborn Screening Saves Lives Act" would also allocate funding to analyze the effectiveness of these newborn screening

programs. It reauthorizes and expands the role of the Advisory Committee on Heritable Disorders in Newborns and Children, establishes an Interagency Coordinating Committee on Newborn and Child Screening, and creates an Internet-based information clearinghouse to provide information about newborn and child screening for heritable disorders. The bill requires the Secretary to ensure the quality of laboratories involved in newborn screening activities, and to develop a national contingency plan for newborn screening. Finally, it gives the National Institutes of Health the authority to carry out research in newborn screening, including identifying new screening technologies and researching disease management strategies for conditions that can be detected through screening, but for which no treatment is yet available.

III. HISTORY OF LEGISLATION AND VOTES IN COMMITTEE

The “Newborn Screening Saves Lives Act,” was first introduced in the second session of the 107th Congress, S. 2890, and was referred to the Senate Committee on Health, Education, Labor, and Pensions. A hearing on the bill took place on June 14, 2002 before the Committee on Health, Education, Labor, and Pensions Subcommittee on Children and Families. No further action on S. 2890 was taken during the 107th Congress. A companion bill was introduced in the House of Representatives during the second session of the 107th Congress, H.R. 5703. The bill was referred to the House Committee on Energy and Commerce Subcommittee on Health with no further action taken on it during the 107th Congress.

The “Newborn Screening Saves Lives Act” was reintroduced in the first session of the 108th Congress, S. 1068, the second session of the 109th Congress, S. 2663, and again in the first session of the 110th Congress, S. 634. The bills were referred to the Committee on Health, Education, Labor, and Pensions. Companion bills were reintroduced in the second session of the 108th Congress, H.R. 4493, the second session of the 109th Congress, H.R. 5397, and again in the first session of the 110th Congress, H.R. 1634. They were referred to the House Committee on Energy and Commerce Subcommittee on Health.

In the first session of the 110th Congress, the “Newborn Screening Saves Lives Act” was reintroduced as S. 1858 with additions from the Screening for Health of Infants and Newborns Act, S. 1712. On November 14, 2007, the Committee on Health, Education, Labor and Pensions ordered the bill to be reported favorably with an amendment in the nature of a substitute by voice vote. The amendment was co-sponsored by Senators Dodd, Hatch, Clinton, and Kennedy. A companion bill was introduced in the House, H.R. 3825, on October 15, 2007 and referred to the House Committee on Energy and Commerce Subcommittee on Health.

IV. EXPLANATION OF BILL AND COMMITTEE VIEWS

The bill has a variety of provisions, the explanation of and committee views on which follow below:

Newborn screening is an essential public health function provided to all newborns in the United States. Unfortunately, the number and quality of conditions screened for at birth varies from State to State. In addition, newborn screening programs should be

comprehensive, including not only screening and diagnosis, but also long-term follow-up care and treatment. The committee believes newborn screening programs should include high quality screening with state-of-the-art technology, proper educational materials for parents, trained personnel, and a system to assess and coordinate timely follow-up care and treatment of newborns screened and program evaluation.

The committee believes that reauthorization and expansion of section 1109 of the Public Health Service Act will help to address these issues. The bill amends the Public Health Service Act to require the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration (HRSA), and in consultation with the Advisory Committee on Heritable Disorders in Newborns and Children, to award grants to eligible entities for the enhancement, expansion or improvement of State newborn screening programs. The committee recognizes that there is a lack of uniformity in what conditions States screen for with some States screening as few as 9 conditions while others screen for more than 40 conditions. This puts the health of newborns in one State at greater risk for the conditions to go undetected and untreated than newborns in another State. The committee intends that the grants under section 1109 will be an incentive for States, at a minimum, to screen for all of the core conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children.

The bill expands section 1109 grants to eligible entities to assist in providing health care professionals and newborn screening laboratory personnel with education and training in newborn screening to include training in relevant and new technologies as well as congenital, genetic, and metabolic disorders. The committee believes that the education and training programs for health care professionals and laboratory personnel developed and delivered under these grants should include continuing medical education programs for health care professionals and newborn screening laboratory personnel; models to evaluate the prevalence of, and assess and communicate the risks of, congenital, genetic, and metabolic conditions based on family history; models to communicate effectively with parents and families about the process and benefits of newborn screening and the meaning of screening results, how to use information gathered from newborn screening, the right to refusal of newborn screening, if applicable; information and resources on systems of follow-up care and treatment after newborns are screened; and information on the disorders for which States require and offer newborn screening as well as information on additional newborn screening that may not be required by the State, but that may be available from other sources.

The bill expands section 1109 grants to eligible entities to develop and deliver educational programs about newborn screening to parents, families, and patient advocacy and support groups. The committee expects these programs to be provided at appropriate literacy levels and to be culturally competent. The committee believes that educational programs should include information on what newborn screening is and how it is performed; who performs newborn screening; where newborn screening is performed; the disorders for which the State requires newborns to be screened; op-

tions available to screen for additional disorders other than those mandated by the State; the meaning of various screening results, including the possibility of false positives and false negative findings; the prevalence and risk of newborn disorders, including the increased risk of disorders that may stem from family history; and systems of follow-up care and treatment after newborns are screened.

The bill further expands section 1109 grants to eligible entities to establish, maintain, and operate a system to assess and coordinate treatment relating to congenital, genetic, and metabolic disorders. The committee expects these grants to expand on existing procedures and systems, where appropriate and available, for the timely reporting of newborn screening results to individuals, families, primary care physicians, and appropriate subspecialists; coordinate ongoing follow-up care and treatment with individuals, families, primary care physicians, and appropriate subspecialists after a newborn receives an indication of the presence or increased risk of a disorder on a screening test; ensure the seamless integration of confirmatory testing, tertiary care medical services, comprehensive genetic services including genetic counseling, and information about Food and Drug Administration (FDA)-approved treatments or other safe and effective treatments as well as access to developing therapies by participating in approved clinical trials involving the primary health care of the infant; and analyze data, if appropriate and available, collected from newborn screening to identify populations at risk for disorders affecting newborns, examine and respond to health concerns, and recognize and address relevant environmental, behavioral, socioeconomic, demographic, and other relevant risk factors.

Eligible entities for section 1109 grants are a State or a political subdivision of a State, a consortium of 2 or more States or political subdivisions of States, a territory, a health facility or program operated by or pursuant to a contract with or a grant from the Indian Health Service, or any other entity with appropriate expertise in newborn screening, as determined by the Secretary. The committee intends that other entities with appropriate expertise include those that have the capacity to perform the core newborn screening tests recommended by the Advisory Committee, those with a demonstrated history of expertise with newborn screening activities, or those determined appropriate by the Secretary.

The bill reauthorizes Section 1110 of the Public Health Service Act to continue grants that evaluate the effectiveness of newborn and child screening programs. The committee believes HRSA's current activities aimed at assuring the best outcome for newborns should be continued. These activities include examining the impact of false positive screens, and the public's awareness, or lack thereof, and understanding about, newborn tests, tools, and technologies.

The bill reauthorizes and expands the role of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children. The committee strongly believes that Federal guidelines and recommendations on issues related to newborn screening are needed in order to address the disparities among State newborn screening programs. Therefore, the bill requires the Advisory Committee to make recommendations that include the heritable disorders for

which all newborns should be screened, to develop a model decision-matrix for newborn screening program expansion, and to consider ways to ensure that all States attain the capacity to screen for conditions recommended by the Advisory Committee, and include in such consideration the results of grant funding under section 1109. The bill includes several areas of particular concern where additional expertise from the Advisory Committee would be useful. The bill allows the Advisory Committee to make recommendations, advice or information dealing with follow-up care and treatment of newborns, implementation, monitoring, and evaluation of newborn screening activities, the availability and reporting of testing for conditions for which there is no existing treatment, the cost and effectiveness of newborn screening, coordination of surveillance activities, among other areas.

The committee is particularly concerned by the lack of response from the Secretary of Health and Human Services to previous recommendations made by the Advisory Committee. Although the bill requires the Secretary to accept or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment of the bill by not later than 180 days after the date of enactment, nothing in the bill prevents the Secretary from acting more expeditiously.

The bill authorizes the creation and maintenance of a central Internet clearinghouse of current educational and family support and services information, materials, resources, research and data on newborn screening. Such clearinghouse will also be used to maintain data on quality indicators to measure performance of newborn screening, as developed by the Advisory Committee. The committee believes this Internet clearinghouse will help parents and health care providers to be better informed about all aspects of newborn screening, which will lead to better outcomes for children.

Newborn screening has long been recognized as an essential, life-saving, and effective preventive public health service that has identified thousands of babies each year in the United States who are born with congenital, genetic and metabolic conditions that are not apparent at birth. The Center for Disease Control and Prevention (CDC)'s Environmental Health Laboratory houses the only comprehensive program in the world devoted to ensuring the accuracy of newborn screening tests. The Newborn Screening Quality Assurance Program (NSQAP) provides training, consultation, proficiency testing, guidelines, and reference materials to State public health laboratories and other laboratories responsible for newborn screening in the United States. Because of NSQAP, parents and doctors in the United States can trust the results of their newborn screening tests regardless of where their babies were born. To further facilitate this effort, the committee encourages CDC's Environmental Health Laboratory to continue its efforts in quality assurance and to harness the latest advances in science and technology so that additional disorders can be detected. Specifically, the committee intends for CDC's Environmental Health Laboratory to develop new screening methods for specific disorders; adapt innovative technologies, such as DNA testing and nanotechnology; transfer new screening technologies to State public health laboratories; and provide technical assistance to States in conducting pilot studies re-

lated to new screening tests for congenital, genetic and metabolic conditions not currently in the recommended core panel. Such conditions may include, but are not limited to, severe combined immune deficiency (SCID), metabolic storage disorders such as Pompe Disease and X-linked Adrenoleukodystrophy (XALD), and maternal or fetal infections such as lymphocytic choriomeningitis (LCM) virus.

The bill authorizes programs that build upon existing activities and infrastructures to collect, analyze and make available data on the heritable disorders recommended by the Advisory Committee; to identify regional centers to conduct epidemiological research; to provide information and education to the public on effective interventions for the prevention of poor health outcomes resulting from the disorders; and to conduct research on the health outcomes associated with these disorders. The committee believes these programs should build upon existing infrastructure and should be a collaborative effort administrated by an Interagency Group comprised of the Agency for Healthcare Research and Quality, CDC, HRSA and the National Institutes of Health. Surveillance forms the backbone of a vital, functional and responsive public health network and establishing a national program to track the incidence of heritable disorders will assist in efforts around the country to study these disorders. Also, additional research on these genetic, metabolic, hormonal and or functional conditions detected through newborn screening is sorely needed. Since many of these conditions are extremely rare it is necessary to conduct additional epidemiological studies to unveil the causes and potential treatments for these conditions. Epidemiological research into the causes of heritable disorders is a critical step in the development of cost-effective strategies to detect and treat these conditions.

Contingency planning for newborn screening is essential because of the short timeframe for detecting and treating congenital disorders. More than 11,000 babies are born each day in the United States, so it is important that every State have a contingency plan for newborn screening in place in the event of a public health emergency. A national plan is essential for integrating the components of the various State plans and assuring nationwide preparedness. The committee believes that a national contingency plan for newborn screening should address contingency measures for sample delivery, backup laboratory operations, and effective follow-up including care and treatment, medications and other safe and effective treatments, such as dietary interventions. Because of its primary role in national public health emergency planning and response, the committee believes that CDC is the appropriate Federal agency to oversee the development of a national contingency plan for newborn screening and to conduct practice drills that ensure its operational integrity.

The bill allows the Secretary, in conjunction with the Director of NIH and taking into consideration the recommendations of the Advisory Committee, to continue carrying out, coordinating, and expanding research on additional newborn conditions beyond those recommended by the Advisory Committee and adopted by the Secretary. Those conditions include, but are not limited to, Krabbe disease, Diabetes mellitus, insulin dependent, and Turner syndrome. The committee believes that engaging in such research is not only

essential to improving currently existing screening technology, but also to developing new treatments, interventions and possible cures for conditions that currently can be detected through newborn screening, but which have no existing treatment.

V. COST ESTIMATE

U.S. CONGRESS,
CONGRESSIONAL BUDGET OFFICE,
Washington, DC, April 1, 2008.

Hon. EDWARD M. KENNEDY,
*Chairman, Committee on Health, Education, Labor, and Pensions,
U.S. Senate, Washington, DC.*

DEAR MR. CHAIRMAN: The Congressional Budget Office has prepared the enclosed cost estimate for S. 1858, the Newborn Screening Saves Lives Act of 2007.

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

Sincerely,

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

Enclosure.

S. 1858—Newborn Screening Saves Lives Act of 2007

Summary: S. 1858 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 \$45 million for 2008 and \$229 million over the 2008–12 period. Assuming the appropriation of those amounts, CBO estimates that implementing the act would cost \$11 million in 2008 and \$218 million over the 2008–13 period. S. 1858 would not affect direct spending or revenues.

S. 1858 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 S. 1858 is shown in the following table. The costs of this legislation fall within budget function 550 (health).

	By fiscal year, in millions of dollars—					
	2008	2009	2010	2011	2012	2013
CHANGES IN SPENDING SUBJECT TO APPROPRIATION						
HRSA Activities:						
Authorization Level	39	39	39	40	40	0
Estimated Outlays	10	37	39	42	40	19
CDC Activities:						
Authorization Level	6	6	6	6	6	0
Estimated Outlays	1	5	6	6	6	5
Contingency Planning (CDC and HRSA):						
Estimated Authorization Level	0	2	0	0	0	0
Estimated Outlays	0	2	0	0	0	0
Total Changes:						
Estimated Authorization Level	45	47	45	46	46	0
Estimated Outlays	11	44	45	48	46	24

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

Basis of estimate: The activities authorized under S. 1858 would be carried out by the Health Resources and Services Administration (HRSA) and the Centers for Disease Control and Prevention (CDC). The estimate is based on historical spending patterns for similar activities, and assumes that the authorized amounts would be appropriated in the spring of 2008 and near the beginning of the fiscal year in subsequent years.

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 act would authorize the appropriation of \$39 million for 2008 and \$197 million over the 2008–12 period for those activities. CBO estimates that implementing those provisions would cost \$10 million in 2008 and \$187 million over the 2008–13 period.

S. 1858 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 act would authorize the appropriation of \$6 million for 2008 and \$30 million over the 2008–12 period. CBO estimates that implementing those provisions would cost \$1 million in 2008 and \$29 million over the 2008–13 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: S. 1858 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 for H.R. 3825, the Newborn Screening Saves Lives Act of 2008, as ordered reported by the House Committee on Energy and Commerce on March 13, 2008. The two bills are very similar, except that S. 1858 would authorize appropriations for the 2008–12 period (rather than the 2009–13 period specified in H.R. 3825). CBO's estimate for S. 1858 differs from that for H.R. 3825 because of the differences in the timing of the authorized appropriations.

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.

VI. APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

The committee has determined that there will be minimal increases in the regulatory burden imposed by this bill.

VII. REGULATORY IMPACT STATEMENT

The committee has determined that there is no legislative impact.

VIII. SECTION-BY-SECTION ANALYSIS

Section 1. Short title

“Newborn Screening Saves Lives Act of 2007.”

Section 2. Improved newborn and child screening for heritable disorders

This section amends Section 1109 of the Public Health Service Act to authorize grants for enhancing, improving, or expanding the ability of States and local public health agencies to provide screening, counseling or health care 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 on Heritable Disorders in Newborns and Children (Advisory Committee) that are adopted by the Secretary. The authorization of appropriations for this grant is \$15,000,000 for fiscal year 2008, \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012. Eligible entities for this grant 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.

This section authorizes grants for educating and training health care professionals and State laboratory personnel in newborn screening and relevant new technologies; developing and delivering educational programs to inform parents, families, and patient advocacy and support groups about newborn screening, testing, follow-up and treatment; and 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 2008, \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012. 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 3. Evaluating the effectiveness of newborn and child screening programs

This section amends Section 1110 of the Public Health Service Act to authorize \$5,000,000 for fiscal year 2008, \$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for fiscal year 2012 to evaluate the effectiveness of Newborn and Child Screening Programs.

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

This section amends Section 1111 of the Public Health Service Act to reauthorize 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.

This section 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 to the Advisory Committee. It requires the Secretary to adopt or reject any recommendation issued by the Advisory Committee that is pending on the date of enactment and requires the Secretary 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 2008, \$1,012,500 for fiscal year 2009, \$1,025,000 for fiscal year 2010, \$1,037,500 for fiscal year 2011, and \$1,050,000 for fiscal year 2012.

Section 5. Information clearinghouse

This section requires the Secretary of Health and Human Services to establish a central clearinghouse within the Health Resources and Services Administration, in consultation with the Centers for Disease Control and Prevention and the National Institutes of Health. 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 as well as 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 2008, \$2,531,250 for fiscal year 2009, \$2,562,500 for fiscal year 2010, \$2,593,750 for fiscal year 2011, and \$2,625,000 for fiscal year 2012.

Section 6. Laboratory quality and surveillance

This section requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with the Advisory Committee, to ensure the quality of laboratories involved in newborn screening 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 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 2008, \$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for fiscal year 2012.

This section also requires the Secretary, acting through an Interagency Group consisting of the Director of the Agency for Healthcare Research and Quality, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Resources and Services Administration, and the Director of the National Institutes of Health, to build upon existing programs to award grants to and enter into contracts with public and nonprofit private entities to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders. The Interagency Group is required to award grants to and enter into contracts with public and nonprofit private entities to carry out programs to identify regional centers for the conduct of applied epidemiological research on effective interventions for such disorders for the prevention of poor health outcomes and to provide information and education to the public on effective interventions for the prevention of poor health outcomes resulting from such disorders. The Interagency Group is also required to award grants to and enter into contracts with public and nonprofit private entities to carry out programs to conduct research on and to promote the prevention of poor health outcomes resulting from such disorders and secondary health conditions among individuals with such disorders. This section requires the Secretary to submit to Congress a report not later than 30 months after the date on which the first grant funds are awarded and again not later than 60 months after date on which the first grant funds are awarded containing information that is specific to various racial, ethnic, and socioeconomic groups, containing an assessment of the extent to which various approaches of preventing heritable disorders and secondary health conditions among individuals with such disorders have been effective, and containing information on the incidence and prevalence of individuals living with heritable disorders, information on their health status, information on any health disparities experienced by such

individuals, and recommendations for improving the health and wellness and quality of life of such individuals. The report must also contain a summary of recommendations from all heritable disorders research conferences sponsored by the Centers for Disease Control and Prevention or the National Institutes of Health. In carrying out this section, the Secretary shall coordinate, to the extent practicable, programs under this section with programs on birth defects and developmental disabilities under section 317C of the Public Health Service Act and give priority for grant funds to entities that demonstrate the ability to coordinate with existing birth defects surveillance activities. This section authorizes \$15,000,000 for fiscal year 2008, \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012.

Section 7. Contingency planning

This section requires the Secretary, acting through the Director of the Centers for Disease Control and Prevention, 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.

This section allows the Secretary, in conjunction with the Director of the National Institutes of Health 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 tests 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 that can be detected through newborn screening for which treatment is not yet available. In carrying out the research under this section, the Secretary and the Director shall ensure that entities receiving funding will focus their research on screening technology not currently performed in the State in which the entities are located and the conditions not on the uniform screening panel. 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 and, where applicable, the Internet clearinghouse established under section 5 of this bill.

IX. CHANGES IN EXISTING LAW

In compliance with rule XXVI paragraph 12 of the Standing Rules of the Senate, the following provides a print of the statute or the part or section thereof to be amended or replaced (existing law proposed to be omitted is enclosed in black brackets, new mat-

ter 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

RESEARCH PROJECT GRANTS AND CONTRACTS

SEC. 1102. * * *

* * * * *

SEC. 1109. [300b–8] 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 under-served populations;

[(B) a plan for the collection of outcome data or other methods of evaluating the degree to which amounts award-

ed 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.*—* * *

* * * * *

[(e)] (f) *VOLUNTARY PARTICIPATION.*—* * *

[(f)] (g) *SUPPLEMENT NOT SUPPLANT.*—* * *

[(g)] (h) *PUBLICATION.*—

(1) *IN GENERAL.*—* * *

* * * * *

[(h)] (i) *TECHNICAL ASSISTANCE.*—* * *

[(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 is authorized to be appropriated—

(1) to provide grants for the purpose of carrying activities under section (a)(1), \$15,000,000 for fiscal year 2008; \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012; and

(2) to provide grant for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), \$15,000,000 for fiscal year 2008, \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012.

* * * * *

SEC. 1110. [300b-9] EVALUATING THE EFFECTIVENESS OF NEWBORN AND CHILD SCREENING PROGRAMS.

(a) *IN GENERAL.*—* * *

* * * * *

(c) * * *

(d) *AUTHORIZATION OF APPROPRIATIONS.*—There are authorized to be appropriated to carry out this section \$5,000,000 for fiscal year 2008, \$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for fiscal year 2012.

* * * * *

SEC. 1111. [300b-10] ADVISORY COMMITTEE ON HERITABLE DISORDERS IN NEWBORNS AND CHILDREN.

(a) *ESTABLISH.*—* * *

(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 was 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) **IN GENERAL.**—* * *

(2) **REQUIRED MEMBERS.**—* * *

(A) * * *

* * * * *

(D) * * *

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

[(E)] (F) * * *

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

[(F)] (H) * * *

[(G)] (I) * * *

(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 2007 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 2007, 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, 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 2007.*

(g) **AUTHORIZATION OF APPROPRIATIONS.**—*There are authorized to be appropriated to carry out this section, \$1,000,000 for fiscal year 2008, \$1,012,500 for fiscal year 2009, \$1,025,000 for fiscal year 2010, \$1,037,500 for fiscal year 2011, and \$1,050,000 for fiscal year 2012.*

* * * * *

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 non-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 2007; 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 2008, \$2,531,250 for fiscal year 2009, \$2,562,500 for fiscal year

2010, \$2,593,750 for fiscal year 2011, and \$2,625,000 for fiscal year 2012.

* * * * *

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 2008, \$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for fiscal year 2012.

SEC. 1114. SURVEILLANCE PROGRAMS FOR HERITABLE DISORDERS SCREENING.

(a) *IN GENERAL.*—The Secretary, acting through an Interagency Group consisting of the Director of the Agency for Healthcare Research and Quality, the Director of the Centers for Disease Control and Prevention, the Administrator, and the Director of the National Institutes of Health, shall build upon existing activities and infrastructure to carry out programs—

(1) to collect, analyze, and make available data on the heritable disorders recommended by the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders;

(2) to identify regional centers for the conduct of applied epidemiological research on effective interventions for such disorders for the prevention of poor health outcomes;

(3) to provide information and education to the public on effective interventions for the prevention of poor health outcomes resulting from such disorders; and

(4) to conduct research on and to promote the prevention of poor health outcomes resulting from such disorders, and secondary health conditions among individuals with such disorders.

(b) *GRANTS AND CONTRACTS.*—

(1) *IN GENERAL.*—In carrying out subsection (a), the Secretary may make grants to and enter into contracts with public and nonprofit private entities.

(2) *SUPPLIES AND SERVICES IN LIEU OF AWARD FUNDS.*—

(A) *IN GENERAL.*—Upon the request of a recipient of an award of a grant or contract under paragraph (1), the Secretary may, subject to subparagraph (B), provide supplies, equipment, and services for the purpose of aiding the recipi-

ent in carrying out the purposes for which the award is made and, for such purposes, may detail to the recipient any officer or employee of the Department of Health and Human Services.

(B) *REDUCTION.*—With respect to a request described in subparagraph (A), the Secretary shall reduce the amount of payments under the award involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Secretary. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

(3) *APPLICATION FOR AWARD.*—The Secretary may make an award of a grant or contract under paragraph (1) only if an application for the award is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out the purposes for which the award is to be made.

(c) *REPORTS TO CONGRESS.*—

(1) *IN GENERAL.*—Subject to paragraph (2), the Secretary shall submit to the relevant committees of Congress reports—

(A) containing information under paragraph (1) that is specific to various racial, ethnic, and socioeconomic groups;

(B) containing an assessment of the extent to which various approaches of preventing heritable disorders and secondary health conditions among individuals with such disorders have been effective;

(C) describing the activities carried out under this section;

(D) containing information on the incidence and prevalence of individuals living with heritable disorders, information on the health status of individuals with such disorders including the extent to which such disorders have contributed to the incidence and prevalence of infant mortality, information on any health disparities experienced by such individuals, and recommendations for improving the health and wellness and quality of life of such individuals;

(E) containing a summary of recommendations from all heritable disorders research conferences sponsored by the Centers for Disease Control and Prevention or the National Institutes of Health; and

(F) containing any recommendations of the Secretary regarding this section.

(2) *TIMING OF REPORTS.*—The Secretary shall submit—

(A) an interim report that includes the information described in paragraph (1), not later than 30 months after the date on which the first grant funds are awarded under this section; and

(B) a subsequent report that includes the information described in paragraph (1), not later than 60 months after the date on which the first grant funds are awarded under this section.

(d) *COORDINATION.*—

(1) *IN GENERAL.*—In carrying out this section, the Secretary shall coordinate, to the extent practicable, programs under this section with programs on birth defects and developmental disabilities authorized under section 317C.

(2) *PRIORITY IN GRANTS AND CONTRACTS.*—In making grants and contracts under this section, the Secretary shall give priority to entities that demonstrate the ability to coordinate activities under a grant or contract made under this section with existing birth defects surveillance activities.

(e) *AUTHORIZATION OF APPROPRIATIONS.*—For the purpose of carrying out this section, there are authorized to be appropriated \$15,000,000 for fiscal year 2008, \$15,187,500 for fiscal year 2009, \$15,375,000 for fiscal year 2010, \$15,562,500 for fiscal year 2011, and \$15,750,000 for fiscal year 2012.

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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 and 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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