PUBLIC HEALTH SERVICE ACT

[As Amended Through P.L. 117–286, Enacted December 27, 2022]

[Currency: This publication is a compilation of the text of title XI of Chapter 373 of the 78th Congress. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

[References in brackets [] are to title 42, United States Code]

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

PART A—GENETIC DISEASES

RESEARCH PROJECT GRANTS AND CONTRACTS

SEC. 1102. [300b–1] In carrying out section 301, the Secretary, may make grants to public and nonprofit private entities, and may enter into contracts with public and private entities and individuals, for projects for (1) basic or applied research leading to the understanding, diagnosis, treatment, and control of genetic diseases, (2) planning, establishing, demonstrating, and developing special programs for the training of genetic counselors, social and behavioral scientists, and other health professionals, (3) the development of programs to educate practicing physicians, other health professionals and the public regarding the nature of genetic processes, the inheritance patterns of genetic diseases, and the means, methods, and facilities available to diagnose, control, counsel, and treat genetic diseases, and (4) the development of counseling and testing programs and other programs for the diagnosis, control, and treatment of genetic diseases. In making grants and entering into contracts for projects described in clause (1) of the preceding sentence, the Secretary shall give priority to applications for such grants or contracts which are submitted for research on sickle cell anemia and for research on Cooley's anemia.

VOLUNTARY PARTICIPATION

SEC. 1103. [300b–2] The participation by any individual in any program or portion thereof under this part 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, any other program.

APPLICATION; ADMINISTRATION OF GRANTS AND CONTRACT PROGRAMS

SEC. 1104. [300b–3] (a) A grant or contract under this part may be made upon application submitted to the Secretary at such time, in such manner, and containing and accompanied by such information, as the Secretary may require including assurances for an evaluation whether performed by the applicant or by the Secretary. Such grant or contract may be made available on less than a state-wide or regional basis. Each applicant shall—

(1) provide that the programs and activities for which assistance under this part is sought will be administered by or under the supervision of the applicant;

(2) provide for strict confidentiality of all test results, medical records, and other information regarding testing, diagnosis, counseling, or treatment of any person treated, except for (A) such information as the patient (or his guardian) gives informed consent to be released, or (B) statistical data compiled without reference to the identity of any such patient;

(3) provide for community representation where appropriate in the development and operation of voluntary genetic testing or counseling programs funded by a grant or contract under this part; and

(4) establish fiscal control and fund accounting procedures as may be necessary to assure proper disbursement of and accounting of Federal funds paid to the applicant under this part.

(b) In making grants and entering into contracts for any fiscal year under section 301 for projects described in section 1102 the Secretary shall give special consideration to applications from entities that received grants from, or entered into contracts with, the Secretary for the preceding fiscal year for the conduct of comprehensive sickle cell centers or sickle cell screening and education clinics.

PUBLIC HEALTH SERVICE FACILITIES

SEC. 1105. [300b–4] The Secretary shall establish a program within the Service to provide voluntary testing, diagnosis, counseling, and treatment of individuals respecting genetic diseases. Services under such program shall be made available through facilities of the Service to persons requesting such services, and the program shall provide appropriate publicity of the availability and voluntary nature of such services.

SEC. 1106. [300b–5] SICKLE CELL DISEASE AND OTHER HERITABLE BLOOD DISORDERS RESEARCH, SURVEILLANCE, PREVENTION, AND TREATMENT.

(a) GRANTS.—

(1) IN GENERAL.—The Secretary may award grants related to heritable blood disorders, including sickle cell disease, for one or more of the following purposes:

(A) To collect and maintain data on such diseases and conditions, including subtypes as applicable, and their associated health outcomes and complications, including for the purpose of—

(i) improving national incidence and prevalence data;

(ii) identifying health disparities, including the geographic distribution, related to such diseases and conditions;

(iii) assessing the utilization of therapies and strategies to prevent complications; and

(iv) evaluating the effects of genetic, environmental, behavioral, and other risk factors that may affect such individuals.

(B) To conduct public health activities with respect to such conditions, which may include—

(i) developing strategies to improve health outcomes and access to quality health care for the screening for, and treatment and management of, such diseases and conditions, including through public-private partnerships;

(ii) providing support to community-based organizations and State and local health departments in conducting education and training activities for patients, communities, and health care providers concerning such diseases and conditions;

(iii) supporting State health departments and regional laboratories, including through training, in testing to identify such diseases and conditions, including specific forms of sickle cell disease, in individuals of all ages; and

(iv) the identification and evaluation of best practices for treatment of such diseases and conditions, and prevention and management of their related complications.

(2) POPULATION INCLUDED.—The Secretary shall, to the extent practicable, award grants under this subsection to eligible entities across the United States to improve data on the incidence and prevalence of heritable blood disorders, including sickle cell disease, and the geographic distribution of such diseases and conditions.

(3) APPLICATION.—To seek a grant under this subsection, an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(4) PRIORITY.—In awarding grants under this subsection, the Secretary may give priority, as appropriate, to eligible entities that have a relationship with a community-based organization that has experience in, or is capable of, providing services to individuals with heritable blood disorders, including sickle cell disease.

(5) ELIGIBLE ENTITY.—In this subsection, the term "eligible entity" includes the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, the Federated States of Micronesia, the Republic of Marshall Islands, the Republic of Palau, Indian tribes, a State or local health department, an institution of higher education, or a nonprofit entity with appropriate experience to conduct the activities under this subsection.

(b) DEMONSTRATION PROGRAM FOR THE DEVELOPMENT AND ESTABLISHMENT OF SYSTEMIC MECHANISMS FOR THE PREVENTION AND TREATMENT OF SICKLE CELL DISEASE.—

(1) AUTHORITY TO CONDUCT DEMONSTRATION PROGRAM.—

(A) IN GENERAL.—The Administrator, through the Bureau of Primary Health Care and the Maternal and Child Health Bureau, shall continue efforts, including by awarding grants, to develop or establish mechanisms to improve the treatment of sickle cell disease, and to improve the prevention and treatment of complications of sickle cell disease, in populations with a high proportion of individuals with sickle cell disease, including through—

(i) the coordination of service delivery for individuals with sickle cell disease;

(ii) genetic counseling and testing;

(iii) bundling of technical services related to the prevention and treatment of sickle cell disease;

(iv) training of health professionals; and

(v) identifying and establishing other efforts related to the expansion and coordination of education, treatment, and continuity of care programs for individuals with sickle cell disease.

(B) GEOGRAPHIC DIVERSITY.—The Administrator shall, to the extent practicable, award grants under this section to eligible entities located in different regions of the United States.

(2) ADDITIONAL REQUIREMENTS.—An eligible entity awarded a grant under this subsection shall use funds made available under the grant to carry out, in addition to the activities described in paragraph (1)(A), the following activities:

(A) To facilitate and coordinate the delivery of education, treatment, and continuity of care for individuals with sickle cell disease under—

(i) the entity's collaborative agreement with a community-based sickle cell disease organization or a nonprofit entity that works with individuals who have sickle cell disease;

(ii) the sickle cell disease newborn screening program for the State in which the entity is located; and

(iii) the maternal and child health program under title V of the Social Security Act (42 U.S.C. 701 et seq.) for the State in which the entity is located.

(B) To train nursing and other health staff who provide care for individuals with sickle cell disease.

(C) To enter into a partnership with adult or pediatric hematologists in the region and other regional experts in sickle cell disease at tertiary and academic health centers and State and county health offices.

(D) To identify and secure resources for ensuring reimbursement under the medicaid program, State children's health insurance program, and other health programs for the prevention and treatment of sickle cell disease.

(E) To provide or coordinate services for adolescents with sickle cell disease making the transition to adult health care.

(3) NATIONAL COORDINATING CENTER.—

(A) ESTABLISHMENT.—The Administrator shall enter into a contract with an entity to serve as the National Coordinating Center for the demonstration program conducted under this subsection.

(B) ACTIVITIES DESCRIBED.—The National Coordinating Center shall—

(i) collect, coordinate, monitor, and distribute data, best practices, and findings regarding the activities funded under grants made to eligible entities under the demonstration program;

(ii) develop a model protocol for eligible entities with respect to the prevention and treatment of sickle cell disease;

(iii) develop educational materials regarding the prevention and treatment of sickle cell disease; and

(iv) prepare and submit to Congress a final report that includes recommendations regarding the effectiveness of the demonstration program conducted under this subsection and such direct outcome measures as—

(I) the number and type of health care resources utilized (such as emergency room visits, hospital visits, length of stay, and physician visits for individuals with sickle cell disease); and

(II) the number of individuals that were tested and subsequently received genetic counseling for the sickle cell trait.

(4) APPLICATION.—An eligible entity desiring a grant under this subsection shall submit an application to the Administrator at such time, in such manner, and containing such information as the Administrator may require.

(5) DEFINITIONS.—In this subsection:

(A) ADMINISTRATOR.—The term "Administrator" means the Administrator of the Health Resources and Services Administration.

(B) ELIGIBLE ENTITY.—The term "eligible entity" means a Federally-qualified health center, a nonprofit hospital or clinic, or a university health center that provides primary health care, that—

(i) has a collaborative agreement with a community-based sickle cell disease organization or a nonprofit entity with experience in working with individuals who have sickle cell disease; and

(ii) demonstrates to the Administrator that either the Federally-qualified health center, the nonprofit hospital or clinic, the university health center, the organization or entity described in clause (i), or the experts described in paragraph (2)(C), has at least 5 years of experience in working with individuals who have sickle cell disease.

(C) FEDERALLY-QUALIFIED HEALTH CENTER.—The term "Federally-qualified health center" has the meaning given that term in section 1905(l)(2)(B) of the Social Security Act (42 U.S.C. 1396d(l)(2)(B)).

(6) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, $4,455,000 for each of fiscal years 2019 through 2023.

APPLIED TECHNOLOGY

SEC. 1107. [300b–6] The Secretary, acting through an identifiable administrative unit, shall—

(1) conduct epidemiological assessments and surveillance of genetic diseases to define the scope and extent of such diseases and the need for programs for the diagnosis, treatment, and control of such diseases, screening for such diseases, and the counseling of persons with such diseases;

(2) on the basis of the assessments and surveillance described in paragraph (1), develop for use by the States programs which combine in an effective manner diagnosis, treatment, and control of such diseases, screening for such diseases, and counseling of persons with such diseases; and

(3) on the basis of the assessments and surveillance described in paragraph (1), provide technical assistance to States to implement the programs developed under paragraph (2) and train appropriate personnel for such programs.

In carrying out this section, the Secretary may, from funds allotted for use under section 502(a) of the Social Security Act, make grants to or contracts with public or nonprofit private entities (including grants and contracts for demonstration projects).

TOURETTE SYNDROME

SEC. 1108. [300b–7] (a) IN GENERAL.—The Secretary shall develop and implement outreach programs to educate the public, health care providers, educators and community based organizations about the etiology, symptoms, diagnosis and treatment of Tourette Syndrome, with a particular emphasis on children with Tourette Syndrome. Such programs may be carried out by the Secretary directly and through awards of grants or contracts to public or nonprofit private entities.

(b) CERTAIN ACTIVITIES.—Activities under subsection (a) shall include—

(1) the production and translation of educational materials, including public service announcements;

(2) the development of training material for health care providers, educators and community based organizations; and

(3) outreach efforts directed at the misdiagnosis and underdiagnosis of Tourette Syndrome in children and in minority groups.

(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2001 through 2005.

SEC. 1109. [300b–8] IMPROVED NEWBORN AND CHILD SCREENING FOR HERITABLE DISORDERS.

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

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

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

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

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

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

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

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

(5) to improve the timeliness of—

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

(B) the diagnosis of heritable disorders in newborns.

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

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

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

(3) a territory;

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

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

(c) APPROVAL FACTORS.—An application for a grant under this section shall not be approved by the Secretary unless the application contains assurances that the eligible entity has adopted and implemented, is in the process of adopting and implementing, or will use 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 rec-

ommended by the Advisory Committee and adopted by the Secretary.

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

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

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

(2) provide inpatient services;

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

(4) provide for proprietary research or training.

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

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

(h) PUBLICATION.—

(1) IN GENERAL.—An application for a grant under this section shall be made public by the State in such a manner as to facilitate comment from any person, including through hearings and other methods used to facilitate comments from the public.

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

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

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

(a) IN GENERAL.—The Secretary shall award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness, including with respect to timeliness, of screening, followup, counseling or health care services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

(b) DEMONSTRATION PROGRAMS.—A demonstration program conducted under a grant under this section shall be designed to evaluate and assess, within the jurisdiction of the entity receiving such grant—

(1) the effectiveness of screening, treatment, counseling, testing, followup, or specialty services for newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders, including, as ap-

propriate, through the assessment of health and development outcomes for such children through adolescence;

(2) the effectiveness of screening, treatment, counseling, testing, followup, or specialty services in accurately and reliably diagnosing heritable disorders in newborns and children in a timely manner;

(3) the availability of screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders;

(4) methods that may be identified to improve quality in the diagnosis, treatment, and disease management of heritable disorders based on gaps in services or care; or

(5) methods or best practices by which the eligible entities described in section 1109 can achieve in a timely manner—

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

(B) diagnosis of heritable disorders in newborns.

(c) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a) an entity shall be a State or political subdivision of a State, or a consortium of two or more States or political subdivisions of States.

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

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

(b) DUTIES.—The Advisory Committee shall—

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

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

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

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

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

(6) develop a model decision-matrix for newborn screening expansion, including an evaluation of the potential public health impact, including the cost of such expansion, and peri-

odically update the recommended uniform screening panel, as appropriate, based on such decision-matrix;

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

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

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

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

(C) diagnostic and other technology used in screening;

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

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

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

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

(H) public and provider awareness and education;

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

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

(K) coordination of surveillance activities, including standardized data collection and reporting, harmonization of laboratory definitions for heritable disorders and testing results, and confirmatory testing and verification of positive results, in order to assess and enhance monitoring of newborn diseases; and

(L) the timeliness of collection, delivery, receipt, and screening of specimens to be tested for heritable disorders

in newborns in order to ensure rapid diagnosis and followup.

(c) MEMBERSHIP.—

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

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

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

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

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

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

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

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

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

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

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

(d) DECISION ON RECOMMENDATIONS.—

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

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

(3) DEADLINE FOR REVIEW.—For each condition nominated to be added to the recommended uniform screening panel in accordance with the requirements of this section, the Advisory Committee shall review and vote on the nominated condition within 9 months of the date on which the Advisory Committee referred the nominated condition to the condition review workgroup.

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

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

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

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

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

(g) CONTINUATION OF OPERATION OF COMMITTEE.—

(1) IN GENERAL.—Notwithstanding section 1013 of title 5, United States Code, the Advisory Committee shall continue to operate through the end of fiscal year 2019.

(2) CONTINUATION IF NOT REAUTHORIZED.—If at the end of fiscal year 2019 the duration of the Advisory Committee has not been extended by statute, the Advisory Committee may be deemed, for purposes of chapter 10 of title 5, United States Code, an advisory committed established by the President or an officer of the Federal Government under section 1008(a) of title 5, United States Code.

SEC. 1112. [300b–11] CLEARINGHOUSE OF NEWBORN SCREENING INFORMATION.

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

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

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

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

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

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

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

(1) is available on the Internet;

(2) includes an interactive forum;

(3) is updated on a regular basis, but not less than quarterly; and

(4) provides—

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

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

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

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

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

(c) NONDUPLICATION.—In carrying out activities under this section, the Secretary shall ensure that such activities minimize duplication and supplement, not supplant, existing information sharing efforts.

SEC. 1113. [300b–12] LABORATORY QUALITY AND SURVEILLANCE.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, shall provide for—

(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, timeliness for processing such tests, performance evaluation services, 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) SURVEILLANCE ACTIVITIES.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and taking into consideration the expertise of the Advisory Committee on Heritable Disorders in Newborns and Children established under section 1111, may provide, as appropriate, for the coordination of surveillance activities, including—

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

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

SEC. 1114. [300b–13] 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 of the Health Resources and Services Administration, the Director of the Agency for Healthcare Research and Quality, the Commissioner of Food and Drugs, 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.

SEC. 1115. [300b–14] 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 consortium of States in the event of a public health emergency. The plan shall be updated as needed and at least every five years.

(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. [300b–15] 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;

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

(D) conducting pilot studies on conditions recommended by the Advisory Committee on Heritable Disorders in Newborns and Children to ensure that screenings are ready for nationwide implementation; and

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

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

(b) FUNDING.—In carrying out the research program under this section, the Secretary and the Director shall ensure that entities receiving funding through the program will provide assurances, as practicable, that such entities will work in consultation with the appropriate State departments of health, and, as practicable, focus their research on screening technology not currently performed in the States in which the entities are located, and the conditions on the uniform screening panel (or the standard test existing on the uniform screening panel).

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

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

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

SEC. 1117. [300b–16] AUTHORIZATION OF APPROPRIATIONS FOR NEWBORN SCREENING PROGRAMS AND ACTIVITIES.

There are authorized to be appropriated—

(1) to carry out sections 1109, 1110, 1111, and 1112, $11,900,000 for each of fiscal years 2015 through 2019; and

(2) to carry out section 1113, $8,000,000 for each of fiscal years 2015 through 2019.

PART B—SUDDEN UNEXPECTED INFANT DEATH, SUDDEN INFANT DEATH SYNDROME, AND SUDDEN UNEXPECTED DEATH IN CHILDHOOD [3]

SEC. 1121. [300c-11] ADDRESSING SUDDEN UNEXPECTED INFANT DEATH AND SUDDEN UNEXPECTED DEATH IN CHILDHOOD.

(a) IN GENERAL.—The Secretary may develop, support, or maintain programs or activities to address sudden unexpected infant death and sudden unexpected death in childhood, including by—

(1) continuing to support the Sudden Unexpected Infant Death and Sudden Death in the Young Case Registry of the Centers for Disease Control and Prevention and other fatality case reporting systems that include data pertaining to sudden unexpected infant death and sudden unexpected death in childhood, as appropriate, including such systems supported by the Health Resources and Services Administration, in order to—

(A) increase the number of States and jurisdictions participating in such registries or systems; and

(B) improve the utility of such registries or systems, which may include—

(i) making summary data available to the public in a timely manner on the internet website of the Department of Health and Human Services, in a manner that, at a minimum, protects personal privacy to the extent required by applicable Federal and State law; and

(ii) making the data submitted to such registries or systems available to researchers, in a manner that,

[3] Section 2(1) of Public Law 116–273 amends the heading for part B which has been carried out above. The formatting and casing provided for in both the stricken and inserted matter does not conform with the existing style of the heading of such part B; however, it was executed to reflect the probable intent of Congress.

at a minimum, protects personal privacy to the extent required by applicable Federal and State law; and

(2) awarding grants or cooperative agreements to States, Indian Tribes, and Tribal organizations for purposes of—

(A) supporting fetal and infant mortality and child death review programs for sudden unexpected infant death and sudden unexpected death in childhood, including by establishing such programs at the local level;

(B) improving data collection related to sudden unexpected infant death and sudden unexpected death in childhood, including by—

(i) improving the completion of death scene investigations and comprehensive autopsies that include a review of clinical history and circumstances of death with appropriate ancillary testing; and

(ii) training medical examiners, coroners, death scene investigators, law enforcement personnel, emergency medical technicians, paramedics, emergency department personnel, and others who perform death scene investigations with respect to the deaths of infants and children, as appropriate;

(C) identifying, developing, and implementing best practices to reduce or prevent sudden unexpected infant death and sudden unexpected death in childhood, including practices to reduce sleep-related infant deaths;

(D) increasing the voluntary inclusion, in registries established for the purpose of conducting research on sudden unexpected infant death and sudden unexpected death in childhood, of samples of tissues or genetic materials from autopsies that have been collected pursuant to Federal or State law and for which the parent or guardian has provided informed consent for inclusion in such registries;

(E) disseminating information and materials to health care professionals and the public on risk factors that contribute to sudden unexpected infant death and sudden unexpected death in childhood, which may include information on risk factors that contribute to sleep-related sudden unexpected infant death or sudden unexpected death in childhood; or

(F) providing information, referrals, or peer or follow-up support services to families who have experienced sudden unexpected infant death or sudden unexpected death in childhood.

(b) APPLICATION.—To be eligible to receive a grant or cooperative agreement under subsection (a)(2), a State, Indian Tribe, or Tribal organization shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, including information on how such State will ensure activities conducted under this section are coordinated with other federally-funded programs to reduce infant and child mortality, as appropriate.

(c) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States, Tribes, and Tribal organizations receiving a grant or cooperative agreement under subsection (a)(2) for

purposes of carrying out the program in accordance with this section.

(d) REPORTING FORMS.—

(1) IN GENERAL.—The Secretary shall, as appropriate, encourage the use of sudden unexpected infant death and sudden unexpected death in childhood reporting forms developed in collaboration with the Centers for Disease Control and Prevention to improve the quality of data submitted to the Sudden Unexpected Infant Death and Sudden Death in the Young Case Registry, and other fatality case reporting systems that include data pertaining to sudden unexpected infant death and sudden unexpected death in childhood.

(2) UPDATE OF FORMS.—The Secretary shall assess whether updates are needed to the sudden unexpected infant death investigation reporting form used by the Centers for Disease Control and Prevention in order to improve the use of such form with other fatality case reporting systems supported by the Department of Health and Human Services, and shall make such updates as appropriate.

(e) DEFINITIONS.—In this section:

(1) SUDDEN INFANT DEATH SYNDROME.—The term "sudden infant death syndrome" means a sudden unexpected infant death that remains unexplained after a thorough case investigation.

(2) SUDDEN UNEXPECTED INFANT DEATH.—The term "sudden unexpected infant death" means the sudden death of an infant under 1 year of age that when first discovered did not have an obvious cause. Such term includes such deaths that are explained, as well as deaths that remain unexplained (which are known as sudden infant death syndrome).

(3) SUDDEN UNEXPECTED DEATH IN CHILDHOOD.—The term "sudden unexpected death in childhood" means the sudden death of a child who is at least 1 year of age but not more than 17 years of age that, when first discovered, did not have an obvious cause. Such term includes such deaths that are explained, as well as deaths that remain unexplained (which are known as sudden unexplained death in childhood).

(4) SUDDEN UNEXPLAINED DEATH IN CHILDHOOD.—The term "sudden unexplained death in childhood" means a sudden unexpected death in childhood that remains unexplained after a thorough case investigation.

(f) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $12,000,000 for each of fiscal years 2022 through 2026.

SUDDEN INFANT DEATH SYNDROME RESEARCH AND RESEARCH REPORTS

SEC. 1122. [300c–12] From the sums appropriated to the Eunice Kennedy Shriver National Institute of Child Health and Human Development, the Secretary shall assure that there are applied to research of the type described in subparagraphs (A) and (B) of subsection (b)(1) of this section such amounts each year as will be adequate, given the leads and findings then available from

such research, in order to make maximum feasible progress toward identification of infants at risk of sudden infant death syndrome and prevention of sudden infant death syndrome.

PART C—HEMOPHILIA PROGRAMS

BLOOD SEPARATION CENTERS

SEC. 1132. [300c–22] (a) The Secretary may make grants to and enter into contracts with public and nonprofit private entities for projects to develop and expand, within existing facilities, blood-separation centers to separate and make available for distribution blood components to providers of blood services and manufacturers of blood fractions. For purposes of this section—

(1) the term "blood components" means those constituents of whole blood which are used for therapy and which are obtained by physical separation processes which result in licensed products such as red blood cells, platelets, white blood cells, AHF-rich plasma, fresh-frozen plasma, cryoprecipitate, and single unit plasma for infusion; and

(2) the term "blood fractions" means those constituents of plasma which are used for therapy and which are obtained by licensed fractionation processes presently used in manufacturing which result in licensed products such as normal serum albumin, plasma, protein fraction, prothrombin complex, fibrinogen, AHF concentrate, immune serum globulin, and hyperimmune globulins.

(b) In the event the Secretary finds that there is an insufficient supply of blood fractions available to meet the needs for treatment of persons suffering from hemophilia, and that public and other nonprofit private centers already engaged in the production of blood fractions could alleviate such insufficiency with assistance under this subsection, he may make grants not to exceed $500,000 to such centers for the purposes of alleviating the insufficiency.

(c) No grant or contract may be made under subsection (a) or (b) unless an application therefor has been submitted to and approved by the Secretary. Such an application shall be in such form, submitted in such manner, and contain such information as the Secretary shall by regulation prescribe.

(d) Contracts may be entered into under subsection (a) without regard to section 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

(e) For the purpose of making payments under grants and contracts under subsections (a) and (b), there are authorized to be appropriated $4,000,000 for fiscal year 1976, $5,000,000 for the fiscal year ending September 30, 1977, $3,450,000 for the fiscal year ending September 30, 1978, $2,500,000 for the fiscal year ending September 30, 1979, $3,000,000 for the fiscal year ending September 30, 1980, $3,500,000 for the fiscal year ending September 30, 1981.