PART B—IMPROVING COORDINATION OF FEDERAL AND STATE PROGRAMS


EFFECTIVE DATE OF REPEAL

Section 955(b) of Pub. L. 97–35 provided that the repeal of this section is effective Oct. 1, 1981. For effective date, savings, and transitional provisions relating to the repeal of this section by section 2193(f) of Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

SUBCHAPTER IX—GENETIC DISEASES, HEMOPHILIA PROGRAMS, AND SUDDEN INFANT DEATH SYNDROME

AMENDMENTS


PART A—GENETIC DISEASES

AMENDMENTS


A prior section 300b, act July 1, 1944, ch. 373, title XI, § 1101, as added May 16, 1972, Pub. L. 92–294, § 3(c), 86 Stat. 137; amended Aug. 29, 1972, Pub. L. 92–414, § 4(2), 86 Stat. 652, authorized Secretary to make grants and enter contracts with public and private entities and in developing and disseminating informational and educational materials relating to sickle cell anemia screening and counseling programs and to develop and disseminate informational and educational materials relating to sickle cell anemia, prior to repeal by Pub. L. 94–278, title IV, § 403(a), Apr. 22, 1976, 90 Stat. 407.

EFFECTIVE DATE OF 1981 AMENDMENT AND REPEAL, SAVINGS, AND TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to the amendment and repeal of this section by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§ 300b–1. Research project grants and contracts

In carrying out section 241 of this title, the Secretary may make grants to public and non-profit 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, 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.


PRIOR PROVISIONS

A prior section 300b–1, act July 1, 1944, ch. 373, title XI, § 1102, as added May 16, 1972, Pub. L. 92–294, § 3(c), 86 Stat. 138, authorized Secretary to make grants and enter contracts with public and private entities and individuals for projects concerned with research, research training in diagnosis, treatment and control of sickle cell anemia, informational and educational programs with respect to sickle cell anemia and development of counseling and testing programs, prior to repeal by Pub. L. 94–278, title IV, § 403(a), Apr. 22, 1976, 90 Stat. 407.

EFFECTIVE DATE

Section 403(c) of Pub. L. 94–278 provided that: “The amendments made by subsections (a) and (b) [see section 401 of Pub. L. 94–278, set out as a Short Title of 1976 Amendment note under section 201 of this title] shall take effect July 1, 1976.”

SHORT TITLE OF 1976 AMENDMENT

For short title of title IV of Pub. L. 94–278, which enacted this part, omitted former part B of this subchapter, redesignated former parts C and D of this subchapter as parts B and C of this subchapter, respectively, as the “National Sickle Cell Anemia, Cooley’s Anemia, Tay–Sachs, and Genetic Diseases Act”, see section 401 of Pub. L. 94–278, set out as a note under section 201 of this title.

DEMONSTRATION PROGRAM FOR THE DEVELOPMENT AND ESTABLISHMENT OF SYSTEMIC MECHANISMS FOR THE PREVENTION AND TREATMENT OF SICKLE CELL DISEASE


“(A) IN GENERAL.—The Administrator, through the Bureau of Primary Health Care and the Maternal and Child Health Bureau, shall conduct a demonstration program by making grants to up to 40 eligible entities for each fiscal year in which the program is conducted under this section [probably means this subsection] for the purpose of developing and establishing systemic mechanisms to improve the prevention
and treatment of 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) GRANT AWARD REQUIREMENTS.—**

**(1) GEOGRAPHIC DIVERSITY.—**The Administrator shall, to the extent practicable, award grants under this section [probably means this subsection] to eligible entities located in different regions of the United States.

**(2) PRIORITY.—**In awarding grants under this subsection, the Administrator shall give priority to awarding grants to eligible entities that are—

"(i) Federally-qualified health centers that have a partnership or other arrangement with a comprehensive Sickle Cell Disease treatment center that does not receive funds from the National Institutes of Health; or

"(ii) Federally-qualified health centers that intend to develop a partnership or other arrangement with a comprehensive Sickle Cell Disease treatment center that does not receive funds from the National Institutes of Health.

**(3) NATIONAL COORDINATING CENTER.—**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 and shall—

**(A) ESTABLISHMENT.—**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 non-profit 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 non-profit 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 in section 1905(k)(2)(B) of the Social Security Act (42 U.S.C. 1396d(h)(2)(B))

**(D) AUTHORIZATION OF APPROPRIATIONS.—**There is authorized to be appropriated to carry out this subsection, $10,000,000 for each of fiscal years 2005 through 2009.

**CONGRESSIONAL DECLARATION OF PURPOSE**

Pub. L. 94–278, title IV, §462, Apr. 22, 1976, 90 Stat. 407, as amended by Pub. L. 95–626, title II, §205(a), Nov. 10, 1978, 92 Stat. 3583; Pub. L. 111–256, §2(1), Oct. 5, 2010, 124 Stat. 2644, provided that: "In order to preserve and protect the health and welfare of all citizens, it is the purpose of this title [see section 401 of Pub. L. 94–278, set out as a Short Title of 1976 Amendment note under section 201 of this title] to establish a national program to provide for basic and applied research, research training, testing, counseling, and information and education programs with respect to genetic diseases, and genetic conditions, such as Sickle Cell anemia, Cooley’s anemia, Tay–Sachs disease, cystic fibrosis, dysautonomia, hemophilia, retinitis pigmentosa, Huntington’s chorea, muscular dystrophy, and genetic conditions leading to intellectual disabilities or genetically caused mental disorders."

[For meaning of references to an intellectual disability and to individuals with intellectual disabilities in provisions amended by section 2 of Pub. L. 111–256, see section 2(k) of Pub. L. 111–256, set out as a note under section 1400 of Title 20, Education.]

**§300b–2. Voluntary participation by individuals**

The participation by any individual in any program or portion thereof 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, any other program.

(July 1, 1944, ch. 373, title XI, §1103, as added Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 408.)
§ 300b-3. Application; special consideration to prior sickle cell anemia grant recipients

(a) Manner of submission; contents

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 statewide 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) Considerations for grants and contracts under section 300b–1 of this title

In making grants and entering into contracts for any fiscal year under section 301 of this title the Secretary shall—

(A) 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.

(B) 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.


Effective date of 1981 amendment, savings, and transitional provisions

For effective date, savings, and transitional provisions relating to amendment by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§ 300b–4. Public Health Service facilities

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.


Prior provisions


Subsec. (a), (b), (d) which related to procedures applicable to grants, etc., under section 300b of this title.

Subsec. (c) which related to grants and contracts under section 300b of this title.

Amendments

1981—Subsec. (a)(4), (5). Pub. L. 97–35, § 2193(b)(2), redesignated par. (5) as (4). Former par. (4), which related to testing and counseling requirements, was struck out.

Subsec. (b). Pub. L. 97–35, § 2193(b)(3), struck out subsec. (b) which related to grants and contracts under section 300b of this title. Former subsec. (c) was redesignated (b) and, as so redesignated, struck out reference to section 300b of this title.

Subsec. (c). Pub. L. 97–35, § 2193(b)(3), redesignated subsec. (c) as (b).

Subsec. (d). Pub. L. 97–35, § 2193(b)(3), struck out subsec. (d) which related to procedures applicable to grants, etc., under section 300b of this title.

Subsec. (e). Pub. L. 95–626, § 205(c)(1), inserted requirement that application contain assurances for an evaluation whether performed by applicant or by Secretary and that grant or contract be made available on less than a statewide or regional basis.


Pub. L. 92–294, § 3(c), 86 Stat. 139, authorized Secretary to establish a program within the Public Health Service with respect to sickle cell anemia with such program to be made available through facilities of Public Health Service, prior to repeal by Pub. L. 94–278, title IV, § 403(a), Apr. 22, 1976, 90 Stat. 407.
§ 300b–6. Applied technology

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 702(a) of this title, make grants to or contracts with public or nonprofit private entities (including grants and contracts for demonstration projects).


AMENDMENTS

1981—Pub. L. 97–35 substituted provisions relating to allotments under section 702(a) of this title for provisions relating to appropriations under section 300b(b) of this title.

EFFECTIVE DATE OF 1981 AMENDMENT, SAVINGS, AND TRANSITIONAL PROVISIONS

For effective date, savings, and transitional provisions relating to amendment by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

§ 300b–7. Tourette Syndrome

(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) of this section 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.


§ 300b–8. Improved newborn and child screening for heritable disorders

(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.

(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 submitted under subsection (c)(2) of this section shall be made public by the Secretary to ensure the quality of programs conducted under this section.

(2) Comments
Comments received by the State after the publication described in paragraph (1) shall be addressed in the application submitted under subsection (c)(2) of this section.

(i) Technical assistance
The Secretary shall provide technical assistance under subsection (a) of this section such technical assistance as may be necessary to ensure the quality of programs conducted under this section.

(j) Authorization of appropriations
There are authorized to be appropriated:

1. To provide grants for the purpose of carrying out activities under subsection (a)(1), $15,000,000 for fiscal year 2008; 2. To provide grants for the purpose of carrying out activities under subsection (a)(1), $15,187,500 for fiscal year 2009; 3. To provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,375,000 for fiscal year 2010; 4. To provide grants for the purpose of carrying out activities under paragraphs (2), (3), and (4) of subsection (a), $15,562,500 for fiscal year 2011, and $15,750,000 for fiscal year 2012.

References in Text

2. See References in Text note below.

AMENDMENTS

2008—Subsecs. (a) to (c). Pub. L. 110–204, § 2(1), added subsecs. (a) to (c) and struck out former subsecs. (a) to (c) which provided for grants to promote screening, counseling, or health care services to newborns and children having or at risk for heritable disorders, enumerated permissible uses of grants, and set out grant applicants’ eligibility requirements.

Subsecs. (d) to (i). Pub. L. 110–204, § 2(2), (3), added subsec. (d) and redesignated former subsecs. (d) to (h) as (e) to (i), respectively. Former subsec. (i) redesignated (j).

Subsec. (j). Pub. L. 110–237 added subsec. (j) and struck out former subsec. (j). Prior to amendment, text read as follows: “There is authorized to be appropriated—

1. To provide grants for the purpose of carrying out 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 grants 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.”

Pub. L. 110–204, § 2(4), added subsec. (j) and struck out former subsec. (j). Prior to amendment, text read as follows: “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.”


§ 300b–9. Evaluating the effectiveness of newborn and child screening programs

(a) In general
The Secretary shall award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness of screening, 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, counseling, testing or specialty services for newborns and children at risk for heritable disorders in reducing the morbidity and mortality associated with such disorders;
§ 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 300b–8 of this title;

(2) provide technical information to the Secretary for the development of policies and priorities for the administration of grants under section 300b–8 of this title;

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

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

(5) consider ways to ensure that all States attain the capacity to screen for the conditions described in paragraph (3), and include in such consideration the results of grant funding under section 300b–8 of this title; and

(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

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)—
§ 300b–11  TITLE 42—THE PUBLIC HEALTH AND WELFARE  Page 912

(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) of this section.

(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 April 24, 2008, by not later than 180 days after April 24, 2008.

(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 justifications for the determination.

(e) Annual report
Not later than 3 years after April 24, 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 300b–13 of this title, 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 300b–11 of this title.

(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 April 24, 2008.

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

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 300b–10 of this title.

(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, nonprofit, 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 subchapter II, including information about supplemental screening that is available but not required, in the State where the infant is born;
(C) current research on both treatable and not-yet treatable conditions for which newborn screening tests are available;
(D) the availability of Federal funding for newborn and child screening for heritable disorders including grants authorized under the Newborn Screening Saves Lives Act of 2008; and
(E) other relevant information as determined appropriate by the Secretary.

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

(d) Authorization of appropriations
There are authorized to be appropriated $2,500,000 for fiscal year 2009, $2,531,250 for fiscal year 2010, $2,562,500 for fiscal year 2011, $2,593,750 for fiscal year 2012, and $2,625,000 for fiscal year 2013.

AMENDMENTS

§ 300b–12. 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 300b–10 of this title, shall provide for—
(1) quality assurance for laboratories involved in screening newborns and children for heritable disorders, including quality assurance for newborn-screening tests, performance evaluation services, and technical assistance and technology transfer to newborn screening laboratories to ensure analytic validity and utility of screening tests; and
(2) appropriate quality control and other performance test materials to evaluate the performance of new screening tools.

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

AMENDMENTS

§ 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 247b–4 of this title, 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 300b–10 of this title, including data on the incidence and prevalence of, as well as poor health outcomes resulting from, such disorders; and
(2) make recommendations for the establishment of regional centers for the conduct of applied epidemiological research on effective interventions to promote the prevention of poor health outcomes resulting from such disorders as well as providing information and education to the public on such effective interventions.

(b) Establishment

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

(c) Composition

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

(d) Activities

The Interagency Coordinating Committee shall—

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

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

(e) Authorization of appropriations

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

(AMENDMENTS)


§ 300b–14. National contingency plan for newborn screening

(a) In general

Not later than 180 days after April 24, 2008, 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.

(AMENDMENTS)

2008—Subsec. (e) Pub. L. 110–237 substituted “2009, $1,012,500 for fiscal year 2010, $1,025,000 for fiscal year 2011, $1,037,500 for fiscal year 2012, and $1,050,000 for fiscal year 2013.” for “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.”

§ 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; 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 300b–11 of this title.

(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.


REFERENCES IN TEXT

Section 403 of the National Institutes of Health Reform Act of 2006, referred to in subsec. (c), probably means section 403 of the Public Health Service Act, as added by section 104(a)(3) of the National Institutes of Health Reform Act of 2006, Pub. L. 109–482, which is classified to section 283 of this title.

PRIOR PROVISIONS

Prior sections 300c to 300c–4 were repealed by Pub. L. 94–278, title IV, §403(a), Apr. 22, 1976, 90 Stat. 409; §93 of this title.

Section 300c, act July 1, 1944, ch. 373, title XI, §1111, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 650, authorized Secretary to make grants and enter contracts with public and private entities for establishment of screening, treatment, and counseling programs with respect to Cooley’s Anemia.

Section 300c–1, act July 1, 1944, ch. 373, title XI, §1112, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 651, required that any participation by an individual in any Cooley’s Anemia programs should be on a purely voluntary basis.

Section 300c–2, act July 1, 1944, ch. 373, title XI, §1113, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 651, provided for making of grant upon application to Secretary and listed certain requirements to be met by applicant.

Section 300c–3, act July 1, 1944, ch. 373, title XI, §1114, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 652, authorized Secretary to establish a program with Public Health Service to provide for screening, counseling, and treatment with respect to Cooley’s Anemia.

Section 300c–4, act July 1, 1944, ch. 373, title XI, §1115, as added Aug. 29, 1972, Pub. L. 92–414, §3, 86 Stat. 652, provided for Secretary’s submission of a report to President for transmittal to Congress annually.

AMENDMENTS


AMENDMENTS


See References in Text note below.
for grants and contracts for research on sudden infant death syndrome and annual estimate of amounts requested for such research.


1965—Subsec. (a). Pub. L. 99–158 struck out “under section 2284 of this title” before “, the Secretary”.

**Effective Date of 2007 Amendment**

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of this title.

**Part C—Hemophilia Programs**

**Amendments**


**Effective Date of 1981 Amendment and Repeal, Savings, and Transitional Provisions**

For effective date, savings, and transitional provisions relating to the amendment and repeal of this section by Pub. L. 97–35, see section 2194 of Pub. L. 97–35, set out as a note under section 701 of this title.

**§ 300c–22. Blood-separation centers**

(a) Grants and contracts with public and nonprofit private entities for projects to develop and expand existing facilities; definitions

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 normal serum albumin, plasma, prothrombin complex, fibrinogen, AHP concentrate, immune serum globulin, and hyperimmune globulins.

(b) Grants for alleviation of insufficient supplies of blood fractions

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) Approval of application as prerequisite for grant or contract; form, manner of submission, and contents of application

No grant or contract may be made under subsection (a) or (b) of this section 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) Nonapplicability of statutory provisions to contracts

Contracts may be entered into under subsection (a) of this section without regard to section 3324(a) and (b) of title 31 and section 6101 of title 41.

(e) Authorization of appropriations

For the purpose of making payments under grants and contracts under subsections (a) and (b) of this section, 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, and $3,500,000 for the fiscal year ending September 30, 1981.


**Conformity**


**Amendments**


**Effective Date**

Section effective July 1, 1975, see section 608 of Pub. L. 94–63, set out as an Effective Date of 1975 Amendment note under section 247b of this title.

**RICKY RAY HEMOPHILIA RELIEF FUND**


“SECTION 1. SHORT TITLE: TABLE OF CONTENTS.

“(a) SHORT TITLE.—This Act may be cited as the ‘Ricky Ray Hemophilia Relief Fund Act of 1998’.

“(b) TABLE OF CONTENTS.—[Omitted.]
"SEC. 101. RICKY RAY HEMOPHILIA RELIEF FUND.

"(a) Establishment.—There is established in the Treasury of the United States a trust fund to be known as the "Ricky Ray Hemophilia Relief Fund", which shall be administered by the Secretary of the Treasury.

"(b) Investment of Amounts in Fund.—Amounts in the Fund shall be invested in accordance with section 9702 of title 31, United States Code, and any interest on and proceeds from any such investment shall be credited to and become part of the Fund.

"(c) Availability of Fund.—Amounts in the Fund shall be available only for disbursement by the Secretary of Health and Human Services under section 103.

"(d) Termination.—The Fund shall terminate upon the expiration of the 5-year period beginning on the date of the enactment of this Act [Nov. 12, 1998]. If all of the amounts in the Fund have not been expended by the end of the 5-year period, investments of amounts in the Fund shall be liquidated, the receipts of such liquidation shall be deposited in the Fund, and all funds remaining in the Fund shall be deposited in the miscellaneous receipts account in the Treasury of the United States.

"(e) Authorization of Appropriations.—There is authorized to be appropriated to the Fund to carry out this title $750,000,000. There is appropriated to the Fund $475,000,000 for fiscal year 2001, to remain available until expended.

"SEC. 102. COMPASSIONATE PAYMENT RELATING TO INDIVIDUALS WITH BLOOD-CLOTTING DISORDERS AND HIV.

"(a) In General.—If the conditions described in subsection (b) are met and if there are sufficient amounts in the Fund to make each payment, the Secretary shall make a single payment of $100,000 from the Fund to any individual who has an HIV infection and who is described in the following paragraph:

"(1) The individual has any form of blood-clotting disorder, such as hemophilia, and was treated with antihemophilic factor at any time during the period beginning on July 1, 1982, and ending on December 31, 1987.

"(2) The individual—

"(A) is the lawful spouse of an individual described in paragraph (1); or

"(B) is the former lawful spouse of an individual described in paragraph (1) and was the lawful spouse of the individual at any time after a date, within the period described in such subparagraph, on which the individual was treated as described in such paragraph and through medical documentation can assert reasonable certainty of transmission of HIV from individual described in paragraph (1).

"(3) The individual acquired the HIV infection through perinatal transmission from a parent who is an individual described in paragraph (1) or (2).

"(b) Conditions.—The conditions described in this subsection are, with respect to an individual, as follows:

"(1) Submission of Medical Documentation of HIV Infection.—The individual submits to the Secretary written medical documentation that the individual has an HIV infection.

"(2) Petition.—A petition for the payment is filed with the Secretary by or on behalf of the individual.

"(3) Determination.—The Secretary determines, in accordance with section 103(b), that the petition meets the requirements of this title.

"SEC. 103. DETERMINATION AND PAYMENT.

"(a) Establishment of Filing Procedures.—The Secretary of Health and Human Services shall establish procedures under which individuals may submit petitions for payment under this title. The procedures shall include a requirement that each petition filed under this Act include written medical documentation that the relevant individual described in section 102(a)(1) has (or had) a blood-clotting disorder, such as hemophilia, and was treated as described in such section.

"(b) Determination.—For each petition filed under this title, the Secretary shall determine whether the petition meets the requirements of this title.

"(c) Payment.—

"(1) In General.—To the extent there are sufficient amounts in the Fund to cover each payment, the Secretary shall pay, from the Fund, each petition that the Secretary determines meets the requirements of this title in the order received.

"(2) Payments in Case of Deceased Individuals.—

"(A) In General.—In the case of an individual referred to in section 102(a) who is deceased at the time that payment is made under this section on a petition filed by or on behalf of the individual, the payment shall be made as follows:

"(i) If the individual is survived by a spouse who is living at the time of payment, the payment shall be made to such surviving spouse.

"(ii) If the individual is not survived by a spouse described in clause (i), the payment shall be made in equal shares to all children of the individual who are living at the time of the payment.

"(iii) If the individual is not survived by a person described in clause (i) or (ii), the payment shall be made in equal shares to the parents of the individual who are living at the time of the payment.

"(iv) If the individual is not survived by a person described in clause (i), (ii), or (iii), the payment shall revert back to the Fund.

"(B) Filing of Petition by Survivor.—If an individual eligible for payment under section 102(a) dies before filing a petition under this title, a survivor of the individual may file a petition for payment under this title on behalf of the individual if the survivor may receive payment under subparagraph (A).

"(C) Definitions.—For purposes of this paragraph:

"(i) The term ‘spouse’ means an individual who was lawfully married to the relevant individual at the time of death.

"(ii) The term ‘child’ includes a recognized natural child, a stepchild who lived with the relevant individual in a regular parent-child relationship, and an adopted child.

"(iii) The term ‘parent’ includes fathers and mothers through adoption.

"(3) Timing of Payment.—The Secretary may not make a payment on a petition under this title before the expiration of the 120-day period beginning on the date of the enactment of this Act (Nov. 12, 1998) or after the expiration of the 5-year period beginning on the date of the enactment of this Act.

"(4) Action on Petitions.—The Secretary shall complete the determination required by subsection (b) regarding a petition not later than 120 days after the date the petition is filed under this title.

"(e) Humanitarian Nature of Payment.—This Act does not create or admit any claim of or on behalf of the individual against the United States or against any officer, employee, or agent thereof acting within the scope of employment or agency that relate to an HIV infection arising from treatment with antihemophilic factor, at any time during the period beginning on July 1, 1982, and ending on December 31, 1987. A payment under this Act shall, however, when accepted by or on behalf of the individual, be in full satisfaction of all such claims by or on behalf of that individual.

"(f) Administrative Costs Not Paid From Fund.—No costs incurred by the Secretary in carrying out this title may be paid from the Fund or set off against, or otherwise deducted from, any payment made under section (c)(1).

"(g) Termination of Duties of Secretary.—The duties of the Secretary under this section shall cease when the Fund terminates.
"(b) TREATMENT OF PAYMENTS UNDER OTHER LAWS.—
A payment under subsection (c)(1) to an individual—

(1) shall be treated for purposes of the Internal Revenue Code of 1986 as damages described in section 104(a)(2) of such Code;

(2) shall not be included as income or resources for purposes of determining the eligibility of the individual to receive benefits described in section 3803(c)(2)(C) of title 31, United States Code, or the amount of such benefits, and such benefits shall not be secondary to, conditioned upon reimbursement from, or subject to any reduction because of receipt of, any such payment; and

(3) shall not be treated as a third party payment or payment in relation to a legal liability with respect to such benefits and shall not be subject (whether by subrogation or otherwise) to recovery, recoupment, reimbursement, or collection with respect to such benefits (including the Federal or State governments or any entity that provides such benefits under a contract).

"(i) REGULATORY AUTHORITY.—The Secretary may issue regulations necessary to carry out this title.

"(j) TIME OF PAYMENT.—The Secretary may not make any payment with respect to more than one petition under this title unless the petition is filed within 3 years after the date of the enactment of this Act [Nov. 12, 1998].

"(k) DEFINITIONS.—

"(1) The term ‘AIDS’ means acquired immune deficiency syndrome.

"(2) The term ‘Fund’ means the Ricky Ray Hemophilia Relief Fund.

"(3) The term ‘HIV’ means human immunodeficiency virus.

"(4) Unless otherwise provided, the term ‘Secretary’ means Secretary of Health and Human Services.

"TITLE II—TREATMENT OF CERTAIN PAYMENTS IN HEMOPHILIA-CLOTTING-FACTOR SUIT UNDER THE SSI PROGRAM

"SECTION 201. TREATMENT OF CERTAIN PAYMENTS IN HEMOPHILIA-CLOTTING-FACTOR SUIT UNDER THE SSI PROGRAM

"(a) PRIVATE PAYMENTS.—

"(1) In general.—Notwithstanding any other provision of law, the payments described in paragraph (2) shall not be considered income or resources in determining eligibility for, or the amount of—

"(a) medical assistance under title XIX of the Social Security Act [section 1396 et seq. of this title]; or

"(b) supplemental security income benefits under title XVI of the Social Security Act [section 1381 et seq. of this title].

"(2) PRIVATE PAYMENTS DESCRIBED.—The payments described in this subsection are—

"(A) payments made from any fund established pursuant to a class settlement in the case of Susan Walker v. Bayer Corporation, et al., 96–C–5024 (N.D. Ill.); and

"(B) payments made pursuant to a release of all claims made from the Fund established pursuant to section 101 of this Act.

"(B) GOVERNMENT PAYMENTS.—

"(2) Government payments described.—The payments described in this subsection are payments made from the Fund established pursuant to section 201 of this Act.

SUBCHAPTER X—TRAUMA CARE

PART A—GENERAL AUTHORITY AND DUTIES OF SECRETARY

§ 300a. Establishment

(a) In general

The Secretary shall, with respect to trauma care—

(1) conduct and support research, training, evaluations, and demonstration projects;

(2) foster the development of appropriate, modern systems of such care through the sharing of information among agencies and individuals involved in the study and provision of such care;

(3) collect, compile, and disseminate information on the achievements of, and problems experienced by, State and local agencies and private entities in providing trauma care and emergency medical services and, in so doing, give special consideration to the unique needs of rural areas;

(4) provide to State and local agencies technical assistance to enhance each State’s capability to develop, implement, and sustain the trauma care component of each State’s plan...