

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.

(July 1, 1944, ch. 373, title XI, §1113, as added Pub. L. 110-204, §6, Apr. 24, 2008, 122 Stat. 710; amended Pub. L. 110-237, §1(a)(5), May 27, 2008, 122 Stat. 1557.)

AMENDMENTS

2008—Subsec. (b). Pub. L. 110-237 substituted “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.” for “2008, \$5,062,500 for fiscal year 2009, \$5,125,000 for fiscal year 2010, \$5,187,500 for fiscal year 2011, and \$5,250,000 for fiscal year 2012.”

§ 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 Health-

care 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.

(July 1, 1944, ch. 373, title XI, §1114, as added Pub. L. 110-204, §6, Apr. 24, 2008, 122 Stat. 710; amended Pub. L. 110-237, §1(a)(6), May 27, 2008, 122 Stat. 1557.)

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-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 consortia¹ 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.

(July 1, 1944, ch. 373, title XI, §1115, as added Pub. L. 110-204, §7, Apr. 24, 2008, 122 Stat. 711.)

¹ So in original. Probably should be “consortium”.

§ 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 2006.¹ 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.

(July 1, 1944, ch. 373, title XI, §1116, as added Pub. L. 110-204, §7, Apr. 24, 2008, 122 Stat. 711; amended Pub. L. 110-237, §1(a)(7), May 27, 2008, 122 Stat. 1557.)

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. 407.

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

2008—Subsec. (a)(1)(B). Pub. L. 110-237 substituted “, or” for “and or”.

PART B—SUDDEN INFANT DEATH SYNDROME

AMENDMENTS

1976—Pub. L. 94-278, title IV, §403(b)(2), Apr. 22, 1976, 90 Stat. 409, redesignated part C heading as part B.

§ 300c-11. Repealed. Pub. L. 97-35, title XXI, §2193(b)(1), Aug. 13, 1981, 95 Stat. 827

Section, act July 1, 1944, ch. 373, title XI, §1121, as added Apr. 22, 1974, Pub. L. 93-270, §3(a), 88 Stat. 91; amended Apr. 22, 1976, Pub. L. 94-278, title IV, §403(b)(1), 90 Stat. 409; S. Res. 4, Feb. 4, 1977; Aug. 1, 1977, Pub. L. 95-83, title III, §306(a), 91 Stat. 389; Dec. 19, 1977, Pub. L. 95-215, §8(a), 91 Stat. 1507; Nov. 8, 1978, Pub. L. 95-613, §2, 92 Stat. 3094; Dec. 12, 1979, Pub. L. 96-142, title II, §202, 93 Stat. 1070; H. Res. 549, Mar. 25, 1980; Aug. 13, 1981, Pub. L. 97-35, title XXI, §2193(a)(1)(C), 95 Stat. 827, related to sudden infant death syndrome counseling, information, educational, and statistical programs.

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-12. Sudden infant death syndrome research

From the sums appropriated to the Eunice Kennedy Shriver National Institute of Child

¹ See References in Text note below.