

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.

(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; Pub. L. 113-240, §7, Dec. 18, 2014, 128 Stat. 2855.)

Editorial Notes

AMENDMENTS

2014—Subsec. (c). Pub. L. 113-240, §7(1), substituted “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,” for “the Administrator, the Director of the Agency for Healthcare Research and Quality.”

Subsec. (e). Pub. L. 113-240, §7(2), struck out subsec. (e). Text read as follows: “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.”

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 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.

(July 1, 1944, ch. 373, title XI, §1115, as added Pub. L. 110-204, §7, Apr. 24, 2008, 122 Stat. 711; amended Pub. L. 113-240, §8, Dec. 18, 2014, 128 Stat. 2855.)

Editorial Notes

AMENDMENTS

2014—Subsec. (a). Pub. L. 113-240 substituted “consortium” for “consortia” and inserted at end “The plan shall be updated as needed and at least every five years.”

§ 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 283 of this title. 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; Pub. L. 113-240, §9, Dec. 18, 2014, 128 Stat. 2855.)

Editorial Notes

AMENDMENTS

2014—Subsec. (a)(1)(C) to (E). Pub. L. 113-240, §9(1), added subpars. (C) and (D) and redesignated former subpar. (C) as (E).

Subsec. (c). Pub. L. 113-240, §9(2), substituted “section 283 of this title” for “section 403 of the National Institutes of Health Reform Act of 2006”.

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

§ 300b-16. Authorization of appropriations for newborn screening programs and activities

There are authorized to be appropriated—

(1) to carry out sections 300b-8, 300b-9, 300b-10, and 300b-11 of this title, \$11,900,000 for each of fiscal years 2015 through 2019; and

(2) to carry out section 300b-12 of this title, \$8,000,000 for each of fiscal years 2015 through 2019.

(July 1, 1944, ch. 373, title XI, §1117, as added Pub. L. 113-240, §10, Dec. 18, 2014, 128 Stat. 2856.)

§ 300b-17. Report by Secretary

(1) In general

The Secretary of Health and Human Services shall—

(A) not later than 1 year after December 18, 2014, submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on activities related to—

(i) newborn screening; and

(ii) screening children who have or are at risk for heritable disorders; and

(B) not less than every 2 years, submit to such committees an updated version of such report.

(2) Contents

The report submitted under this section shall contain a description of—

(A) the ongoing activities under sections 300b-8, 300b-9, and 300b-11 through 300b-14 of this title; and

(B) the amounts expended on such activities.

(Pub. L. 113-240, §11(b), Dec. 18, 2014, 128 Stat. 2856.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Newborn Screening Saves Lives Reauthorization Act of 2014, and not as part of the Public Health Service Act which comprises this chapter.

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.

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

Editorial Notes

CODIFICATION

Pub. L. 116-273, §2(1), Dec. 31, 2020, 134 Stat. 3352, substituted “Sudden Unexpected Infant Death, Sudden Infant Death Syndrome, and Sudden Unexpected Death in Childhood” for “Sudden Infant Death Syndrome” in part heading.

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

§ 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