§ 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.

[1] See References in Text note below.

(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

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)[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.

(July 1, 1944, ch. 373, title XI, § 1122, as added Pub. L. 96–142, title II, § 202, Dec. 12, 1979, 93 Stat. 1072; amended Pub. L. 99–158, § 3(a)(6), Nov. 20, 1985, 99 Stat. 879; Pub. L. 103–437, § 15(a)(1), Nov. 2, 1994, 108 Stat. 4591; Pub. L. 109–482, title I, § 104(b)(2)(B), Jan. 15, 2007, 120 Stat. 3693; Pub. L. 110–154, § 1(b)(10), Dec. 21, 2007, 121 Stat. 1827.)

REFERENCES IN TEXT

Subsection (b), referred to in text, was repealed by Pub. L. 109–482, title I, § 104(b)(2)(B)(ii), Jan. 15, 2007, 120 Stat. 3693. Prior to repeal, subparagraphs (A) and (B) of subsection (b)(1) read as follows:

''(A) the (i) number of applications approved by the Secretary in the fiscal year reported on for grants and contracts under this chapter for research which relates specifically to sudden infant death syndrome, (ii) total amount requested under such applications, (iii) number of such applications for which funds were provided in such fiscal year, and (iv) total amount of such funds; and

''(B) the (i) number of applications approved by the Secretary in such fiscal year for grants and contracts under this chapter for research which relates generally to sudden infant death syndrome, including high-risk pregnancy and high-risk infancy research which directly relates to sudden infant death syndrome, (ii) relationship of the high-risk pregnancy and high-risk infancy research to sudden infant death syndrome, (iii) total amount requested under such applications, (iv) number of such applications for which funds were provided in such fiscal year, and (v) total amount of such funds.''

AMENDMENTS

2007—Pub. L. 110–154 substituted ''Eunice Kennedy Shriver National Institute of Child Health and Human Development'' for ''National Institute of Child Health and Human Development''.

Pub. L. 109–482 struck out subsec. (a) designation before ''From the sums'' and subsecs. (b) and (c) which related to annual report on data relating to applications for grants and contracts for research on sudden infant death syndrome and annual estimate of amounts requested for such research.

1994—Subsecs. (b)(1), (c). Pub. L. 103–437 substituted ''Energy and Commerce'' for ''Interstate and Foreign Commerce''.

1985—Subsec. (a). Pub. L. 99–158 struck out ''under section 289d 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

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

[1] See References in Text note below.

§ 300c–21. 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, § 1131, as added July 29, 1975, Pub. L. 94–63, title VI, § 606, 89 Stat. 350; amended Aug. 1, 1977, Pub. L. 95–83, title III, § 306(b), 91 Stat. 389; Nov. 10, 1978, Pub. L. 95–626, title II, § 206(a), 92 Stat. 3584; Aug. 13, 1981, Pub. L. 97–35, title XXI, § 2193(a)(1)(D), 95 Stat. 827, related to comprehensive hemophilia diagnostic and treatment centers.

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 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) 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.