required under subparagraphs (B) and (C) of paragraph (2). The Director may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(iii) Matching funds

As a condition for receiving an award under this subsection, an eligible entity shall contribute to the project non-Federal funds in the amount of $1 for every $3 awarded under clauses (i) and (ii), except that the Director of the Center may waive or modify such matching requirement in any case where the Director determines that the goals and objectives of this section cannot adequately be carried out unless such requirement is waived.

(B) The cures acceleration grant awards

(i) Initial award amount

Each award under this subparagraph shall be not more than $15,000,000 per project for the first fiscal year for which the project is funded, which shall be payable in one payment.

(ii) Funding in subsequent fiscal years

An eligible entity receiving an award under clause (i) may apply for additional funding for such project by submitting to the Board the information required under subparagraphs (B) and (C) of paragraph (2). The Director of the Center may fund a project of such eligible entity in an amount not to exceed $15,000,000 for a fiscal year subsequent to the initial award under clause (i).

(C) The cures acceleration flexible research awards

If the Director of the Center determines that the goals and objectives of this section cannot adequately be carried out through a contract, grant, or cooperative agreement, the Director of the Center shall have flexible research authority to use other transactions to fund projects in accordance with the terms and conditions of this section. Awards made under such flexible research authority for a fiscal year shall not exceed 20 percent of the total funds appropriated under subsection (g)(1) for such fiscal year.

(4) Suspension of awards for defaults, noncompliance with provisions and plans, and diversion of funds; repayment of funds

The Director of the Center may suspend the award to any entity upon noncompliance by such entity with provisions and plans under this section or diversion of funds.

(5) Audits

The Director of the Center may enter into agreements with other entities to conduct periodic audits of the projects funded by grants or contracts awarded under this subsection.

(6) Closeout procedures

At the end of a grant or contract period, a recipient shall follow the closeout procedures under section 74.71 of title 45, Code of Federal Regulations (or any successor regulation).

(7) Review

A determination by the Director of the Center as to whether a drug, device, or biological product is a high need cure (for purposes of subsection (a)(3)) shall not be subject to judicial review.

(f) Competitive basis of awards

Any grant, cooperative agreement, or contract awarded under this section shall be awarded on a competitive basis.

(g) Authorization of appropriations

(1) In general

For purposes of carrying out this section, there are authorized to be appropriated $500,000,000 for fiscal year 2010, and such sums as may be necessary for subsequent fiscal years. Funds appropriated under this section shall be available until expended.

(2) Limitation on use of funds otherwise appropriated

No funds appropriated under this chapter, other than funds appropriated under paragraph (1), may be allocated to the Cures Acceleration Network.

(July 1, 1944, ch. 373, title IV, § 480, formerly § 402C, as added Pub. L. 111–148, title X, § 10409(d), Mar. 23, 2010, 124 Stat. 978; renumbered § 480 and amended Pub. L. 112–74, div. F, title II, § 221(c)(1), Dec. 23, 2011, 125 Stat. 1089.)

REFERENCES IN TEXT

Section 262(i) of this title, referred to in subsec. (a)(3), was in the original ''section 262(i)'', and was translated as meaning section 351(i) of act July 1, 1944, ch. 373, to reflect the probable intent of Congress.

CODIFICATION

Section was formerly classified to section 282d of this title.

PRIOR PROVISIONS

A prior section 287a, July 1, 1944, ch. 373, title IV, § 480, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 101–381, title I, § 102(3), Aug. 18, 1990, 104 Stat. 586; Pub. L. 102–405, title III, § 302(e)(1), Oct. 9, 1992, 106 Stat. 1985; Pub. L. 103–43, title XV, § 1501(2)(C), (D), title XX, §§ 2008(b)(12), 2010(b)(4), June 10, 1993, 107 Stat. 172, 173, 211, 214, related to the advisory council for the National Center for Research Resources, prior to repeal by Pub. L. 112–74, div. F, title II, § 221(a)(1)(B), Dec. 23, 2011, 125 Stat. 1086.

AMENDMENTS

2011—Pub. L. 112–74, § 221(c)(1)(C), substituted ''Director of the Center'' for ''Director of NIH'' wherever appearing.

Subsec. (b). Pub. L. 112–74, § 221(c)(1)(B), substituted ''within the Center'' for ''within the Office of the Director of NIH'' in introductory provisions.

Subsec. (d)(4). Pub. L. 112–74, § 221(c)(1)(D), substituted ''Director of the Center'' for ''Director of NIH'' in heading.

Subsec. (d)(4)(B). Pub. L. 112–74, § 221(c)(1)(D), substituted ''Director of the Center'' for ''Director of NIH'' in heading.

§ 287a–1. Office of Rare Diseases

(a) Establishment

There is established within the Center an office to be known as the Office of Rare Diseases

(in this section referred to as the ''Office''), which shall be headed by a Director (in this section referred to as the ''Director''), appointed by the Director of the Center.

(b) Duties

(1) In general

The Director of the Office shall carry out the following:

(A) The Director shall recommend an agenda for conducting and supporting research on rare diseases through the national research institutes and centers. The agenda shall provide for a broad range of research and education activities, including scientific workshops and symposia to identify research opportunities for rare diseases.

(B) The Director shall, with respect to rare diseases, promote coordination and cooperation among the national research institutes and centers and entities whose research is supported by such institutes.

(C) The Director, in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants for regional centers of excellence on rare diseases in accordance with section 287a–2 of this title.

(D) The Director shall promote the sufficient allocation of the resources of the National Institutes of Health for conducting and supporting research on rare diseases.

(E) The Director shall promote and encourage the establishment of a centralized clearinghouse for rare and genetic disease information that will provide understandable information about these diseases to the public, medical professionals, patients and families.

(2) Principal advisor regarding orphan diseases

With respect to rare diseases, the Director shall serve as the principal advisor to the Director of NIH and shall provide advice to other relevant agencies. The Director shall provide liaison with national and international patient, health and scientific organizations concerned with rare diseases.

(c) Definition

For purposes of this section, the term ''rare disease'' means any disease or condition that affects less than 200,000 persons in the United States.

(July 1, 1944, ch. 373, title IV, § 481, formerly § 404F, as added Pub. L. 107–280, § 3, Nov. 6, 2002, 116 Stat. 1989; amended Pub. L. 109–482, title I, §§ 103(b)(5), 104(b)(1)(B), Jan. 15, 2007, 120 Stat. 3687, 3693; renumbered § 481 and amended Pub. L. 112–74, div. F, title II, § 221(c)(2)(A), Dec. 23, 2011, 125 Stat. 1089.)

CODIFICATION

Section was formerly classified to section 283h of this title.

PRIOR PROVISIONS

A prior section 287a–1, act July 1, 1944, ch. 373, title IV, § 481, as added Pub. L. 99–158, § 2, Nov. 20, 1985, 99 Stat. 866; amended Pub. L. 103–43, title XV, § 1501(2)(C), (D), June 10, 1993, 107 Stat. 172, 173, required biennial reports regarding the activities and policies of the National Center for Research Resources, prior to repeal by Pub. L. 112–74, div. F, title II, § 221(a)(1)(B), Dec. 23, 2011, 125 Stat. 1086.

AMENDMENTS

2011—Subsec. (a). Pub. L. 112–74, § 221(c)(2)(A)(ii), substituted ''within the Center'' for ''within the Office of the Director of NIH'' and ''Director of the Center'' for ''Director of NIH''.

Subsec. (b)(1)(C). Pub. L. 112–74, § 221(c)(2)(A)(iii), substituted ''287a–2'' for ''283i''.

2007—Subsec. (b)(1)(F), (G). Pub. L. 109–482, § 104(b)(1)(B), struck out subpars. (F) and (G) which read as follows:

''(F) The Director shall biennially prepare a report that describes the research and education activities on rare diseases being conducted or supported through the national research institutes and centers, and that identifies particular projects or types of projects that should in the future be conducted or supported by the national research institutes and centers or other entities in the field of research on rare diseases.

''(G) The Director shall prepare the NIH Director's annual report to Congress on rare disease research conducted by or supported through the national research institutes and centers.''

Subsec. (d). Pub. L. 109–482, § 103(b)(5), struck out heading and text of subsec. (d). Text read as follows: ''For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $4,000,000 for each of the fiscal years 2003 through 2006.''

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.

FINDINGS AND PURPOSES

Pub. L. 107–280, § 2, Nov. 6, 2002, 116 Stat. 1988, provided that:

''(a) FINDINGS.—Congress makes the following findings:

''(1) Rare diseases and disorders are those which affect small patient populations, typically populations smaller than 200,000 individuals in the United States. Such diseases and conditions include Huntington's disease, amyotrophic lateral sclerosis (Lou Gehrig's disease), Tourette syndrome, Crohn's disease, cystic fibrosis, cystinosis, and Duchenne muscular dystrophy.

''(2) For many years, the 25,000,000 Americans suffering from the over 6,000 rare diseases and disorders were denied access to effective medicines because prescription drug manufacturers could rarely make a profit from marketing drugs for such small groups of patients. The prescription drug industry did not adequately fund research into such treatments. Despite the urgent health need for these medicines, they came to be known as 'orphan drugs' because no companies would commercialize them.

''(3) During the 1970s, an organization called the National Organization for Rare Disorders (NORD) was founded to provide services and to lobby on behalf of patients with rare diseases and disorders. NORD was instrumental in pressing Congress for legislation to encourage the development of orphan drugs.

''(4) The Orphan Drug Act [Pub. L. 97–414, see Short Title of 1983 Amendments note set out under section 301 of Title 21, Food and Drugs] created financial incentives for the research and production of such orphan drugs. New Federal programs at the National Institutes of Health and the Food and Drug Administration encouraged clinical research and commercial product development for products that target rare diseases. An Orphan Products Board was established

to promote the development of drugs and devices for rare diseases or disorders.

''(5) Before 1983, some 38 orphan drugs had been developed. Since the enactment of the Orphan Drug Act [Jan. 4, 1983], more than 220 new orphan drugs have been approved and marketed in the United States and more than 800 additional drugs are in the research pipeline.

''(6) Despite the tremendous success of the Orphan Drug Act, rare diseases and disorders deserve greater emphasis in the national biomedical research enterprise. The Office of Rare Diseases at the National Institutes of Health was created in 1993, but lacks a statutory authorization.

''(7) The National Institutes of Health has received a substantial increase in research funding from Congress for the purpose of expanding the national investment of the United States in behavioral and biomedical research.

''(8) Notwithstanding such increases, funding for rare diseases and disorders at the National Institutes of Health has not increased appreciably.

''(9) To redress this oversight, the Department of Health and Human Services has proposed the establishment of a network of regional centers of excellence for research on rare diseases.

''(b) PURPOSES.—The purposes of this Act [see Short Title of 2002 Amendments note set out under section 201 of this title] are to—

''(1) amend the Public Health Service Act [42 U.S.C. 201 et seq.] to establish an Office of Rare Diseases at the National Institutes of Health; and

''(2) increase the national investment in the development of diagnostics and treatments for patients with rare diseases and disorders.''

§ 287a–2. Rare disease regional centers of excellence

(a) Cooperative agreements and grants

(1) In general

The Director of the Office of Rare Diseases (in this section referred to as the ''Director''), in collaboration with the directors of the other relevant institutes and centers of the National Institutes of Health, may enter into cooperative agreements with and make grants to public or private nonprofit entities to pay all or part of the cost of planning, establishing, or strengthening, and providing basic operating support for regional centers of excellence for clinical research into, training in, and demonstration of diagnostic, prevention, control, and treatment methods for rare diseases.

(2) Policies

A cooperative agreement or grant under paragraph (1) shall be entered into in accordance with policies established by the Director of NIH.

(b) Coordination with other institutes

The Director shall coordinate the activities under this section with similar activities conducted by other national research institutes, centers and agencies of the National Institutes of Health and by the Food and Drug Administration to the extent that such institutes, centers and agencies have responsibilities that are related to rare diseases.

(c) Uses for Federal payments under cooperative agreements or grants

Federal payments made under a cooperative agreement or grant under subsection (a) may be used for—

(1) staffing, administrative, and other basic operating costs, including such patient care costs as are required for research;

(2) clinical training, including training for allied health professionals, continuing education for health professionals and allied health professions personnel, and information programs for the public with respect to rare diseases; and

(3) clinical research and demonstration programs.

(d) Period of support; additional periods

Support of a center under subsection (a) may be for a period of not to exceed 5 years. Such period may be extended by the Director for additional periods of not more than 5 years if the operations of such center have been reviewed by an appropriate technical and scientific peer review group established by the Director and if such group has recommended to the Director that such period should be extended.

(July 1, 1944, ch. 373, title IV, § 481A, formerly § 404G, as added Pub. L. 107–280, § 4, Nov. 6, 2002, 116 Stat. 1990; amended Pub. L. 109–482, title I, § 103(b)(6), Jan. 15, 2007, 120 Stat. 3687; renumbered § 481A, Pub. L. 112–74, div. F, title II, § 221(c)(3), Dec. 23, 2011, 125 Stat. 1089.)

CODIFICATION

Section was formerly classified to section 283i of this title.

PRIOR PROVISIONS

A prior section 481A of act July 1, 1944, was renumbered section 404I, and is classified to section 283k of this title.

AMENDMENTS

2007—Subsec. (e). Pub. L. 109–482 struck out heading and text of subsec. (e). Text read as follows: ''For the purpose of carrying out this section, there are authorized to be appropriated such sums as already have been appropriated for fiscal year 2002, and $20,000,000 for each of the fiscal years 2003 through 2006.''

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.

§§ 287a–3, 287a–3a. Transferred

CODIFICATION

Section 287a–3, act July 1, 1944, ch. 373, title IV, § 481B, as added Pub. L. 103–43, title XV, § 1503, June 10, 1993, 107 Stat. 178; amended Pub. L. 105–392, title IV, § 411, Nov. 13, 1998, 112 Stat. 3590; Pub. L. 106–505, title III, § 304, Nov. 13, 2000, 114 Stat. 2335; Pub. L. 109–482, title I, § 103(b)(41), Jan. 15, 2007, 120 Stat. 3688, which related to construction of regional centers for research on primates, was renumbered section 404J of act July 1, 1944, by Pub. L. 112–74, div. F, title II, § 221(b)(2)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283*l* of this title.

Section 287a–3a, July 1, 1944, ch. 373, title IV, § 481C, as added Pub. L. 106–551, § 2, Dec. 20, 2000, 114 Stat. 2752; amended Pub. L. 110–170, § 2(a), Dec. 26, 2007, 121 Stat. 2465, which related to sanctuary system for surplus chimpanzees, was renumbered section 404K of act July 1, 1944, by Pub. L. 112–74, div. F, title II, § 221(b)(3)(A), Dec. 23, 2011, 125 Stat. 1088, and transferred to section 283m of this title.

A prior section 481C of act July 1, 1944, was renumbered section 481B of act July 1, 1944, and is classified to section 287a–4 of this title.