

(5) known research activity of other entities that is or will expand upon research activity of the Center;

(6) the methods and tools, if any, that have been developed since the last biennial report was prepared; and

(7) the methods and tools, if any, that have been developed and are being utilized by the Food and Drug Administration to support medical product reviews.

(d) Inclusion of list

The first biennial report submitted under this section after December 13, 2016, shall include a complete list of all of the methods and tools, if any, which have been developed by research supported by the Center.

(e) Rule of construction

Nothing in this section shall be construed as authorizing the Secretary to disclose any information that is a trade secret, or other privileged or confidential information subject to section 552(b)(4) of title 5 or section 1905 of title 18.

(July 1, 1944, ch. 373, title IV, § 479, as added Pub. L. 99-158, § 2, Nov. 20, 1985, 99 Stat. 864; amended Pub. L. 103-43, title XV, § 1501(2)(B), June 10, 1993, 107 Stat. 172; Pub. L. 112-74, div. F, title II, § 221(a)(1)(C), Dec. 23, 2011, 125 Stat. 1086; Pub. L. 114-255, div. A, title II, §§ 2037, 2042(e), Dec. 13, 2016, 130 Stat. 1063, 1073.)

AMENDMENTS

2016—Subsec. (b)(1). Pub. L. 114-255, § 2037(a)(1), substituted “phase IIB” for “phase IIA”.

Subsec. (b)(2). Pub. L. 114-255, § 2037(a)(2)(A), substituted “phase III” for “phase IIB” in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 114-255, § 2037(a)(2)(B), substituted “phase III” for “phase IIB”.

Subsec. (b)(2)(B). Pub. L. 114-255, § 2037(a)(2)(C), substituted “phase IIB” for “phase IIA”.

Subsec. (b)(2)(C). Pub. L. 114-255, § 2037(a)(2)(D), substituted “phase III” for “phase IIB”.

Subsec. (c). Pub. L. 114-255, § 2042(e), substituted “Biennial” for “Annual” in heading and “a report on a biennial basis” for “an annual report” in introductory provisions.

Subsec. (c)(6), (7). Pub. L. 114-255, § 2037(b)(1), added pars. (6) and (7).

Subsecs. (d), (e). Pub. L. 114-255, § 2037(b)(2), added subsecs. (d) and (e).

2011—Pub. L. 112-74 amended section generally. Prior to amendment, text read as follows: “The general purpose of the National Center for Research Resources (in this subpart referred to as the ‘Center’) is to strengthen and enhance the research environments of entities engaged in health-related research by developing and supporting essential research resources.”

1993—Pub. L. 103-43 substituted “the National Center for Research Resources (in this subpart referred to as the ‘Center’)” for “the Division of Research Resources”.

SHARED INSTRUMENTATION GRANT PROGRAM

Pub. L. 106-505, title III, § 305, Nov. 13, 2000, 114 Stat. 2335, which was formerly set out as a note under this section, was renumbered section 404L of act July 1, 1944, ch. 373, the Public Health Service Act, by Pub. L. 112-74, div. F, title II, § 221(b)(4)(A), Dec. 23, 2011, 125 Stat. 1088, and is classified to section 283n of this title.

§ 287a. Cures Acceleration Network

(a) Definitions

In this section:

(1) Biological product

The term “biological product” has the meaning given such term in section 262 of this title.

(2) Drug; device

The terms “drug” and “device” have the meanings given such terms in section 321 of title 21.

(3) High need cure

The term “high need cure” means a drug (as that term is defined by section 321(g)(1) of title 21,¹ biological product (as that term is defined by section 262(i)² of this title), or device (as that term is defined by section 321(h) of title 21) that, in the determination of the Director of the Center—

(A) is a priority to diagnose, mitigate, prevent, or treat harm from any disease or condition; and

(B) for which the incentives of the commercial market are unlikely to result in its adequate or timely development.

(4) Medical product

The term “medical product” means a drug, device, biological product, or product that is a combination of drugs, devices, and biological products.

(b) Establishment of the Cures Acceleration Network

Subject to the appropriation of funds as described in subsection (g), there is established within the Center a program to be known as the Cures Acceleration Network (referred to in this section as “CAN”), which shall—

(1) be under the direction of the Director of the Center, taking into account the recommendations of a CAN Review Board (referred to in this section as the “Board”), described in subsection (d); and

(2) award grants and contracts to eligible entities, as described in subsection (e), to accelerate the development of high need cures, including through the development of medical products and behavioral therapies.

(c) Functions

The functions of the CAN are to—

(1) conduct and support revolutionary advances in basic research, translating scientific discoveries from bench to bedside;

(2) award grants and contracts to eligible entities to accelerate the development of high need cures;

(3) provide the resources necessary for government agencies, independent investigators, research organizations, biotechnology companies, academic research institutions, and other entities to develop high need cures;

(4) reduce the barriers between laboratory discoveries and clinical trials for new therapies; and

(5) facilitate review in the Food and Drug Administration for the high need cures funded by the CAN, through activities that may include—

¹ So in original. A closing parenthesis probably should precede the comma.

² See References in Text note below.

(A) the facilitation of regular and ongoing communication with the Food and Drug Administration regarding the status of activities conducted under this section;

(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of countermeasures and products; and

(C) connecting interested persons with additional technical assistance made available under section 360bbb-4 of title 21.

(d) CAN Board

(1) Establishment

There is established a Cures Acceleration Network Review Board (referred to in this section as the “Board”), which shall advise the Director of the Center on the conduct of the activities of the Cures Acceleration Network.

(2) Membership

(A) In general

(i) Appointment

The Board shall be comprised of 24 members who are appointed by the Secretary and who serve at the pleasure of the Secretary.

(ii) Chairperson and Vice Chairperson

The Secretary shall designate, from among the 24 members appointed under clause (i), one Chairperson of the Board (referred to in this section as the “Chairperson”) and one Vice Chairperson.

(B) Terms

(i) In general

Each member shall be appointed to serve a 4-year term, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member’s predecessor was appointed shall be appointed for the remainder of such term.

(ii) Consecutive appointments; maximum terms

A member may be appointed to serve not more than 3 terms on the Board, and may not serve more than 2 such terms consecutively.

(C) Qualifications

(i) In general

The Secretary shall appoint individuals to the Board based solely upon the individual’s established record of distinguished service in one of the areas of expertise described in clause (ii). Each individual appointed to the Board shall be of distinguished achievement and have a broad range of disciplinary interests.

(ii) Expertise

The Secretary shall select individuals based upon the following requirements:

(I) For each of the fields of—

(aa) basic research;

(bb) medicine;

(cc) biopharmaceuticals;

(dd) discovery and delivery of medical products;

(ee) bioinformatics and gene therapy;

(ff) medical instrumentation; and

(gg) regulatory review and approval of medical products,

the Secretary shall select at least 1 individual who is eminent in such fields.

(II) At least 4 individuals shall be recognized leaders in professional venture capital or private equity organizations and have demonstrated experience in private equity investing.

(III) At least 8 individuals shall represent disease advocacy organizations.

(3) Ex-officio members

(A) Appointment

In addition to the 24 Board members described in paragraph (2), the Secretary shall appoint as ex-officio members of the Board—

(i) a representative of the National Institutes of Health, recommended by the Secretary of the Department of Health and Human Services;

(ii) a representative of the Office of the Assistant Secretary of Defense for Health Affairs, recommended by the Secretary of Defense;

(iii) a representative of the Office of the Under Secretary for Health for the Veterans Health Administration, recommended by the Secretary of Veterans Affairs;

(iv) a representative of the National Science Foundation, recommended by the Chair of the National Science Board; and

(v) a representative of the Food and Drug Administration, recommended by the Commissioner of Food and Drugs.

(B) Terms

Each ex-officio member shall serve a 3-year term on the Board, except that the Chairperson may adjust the terms of the initial ex-officio members in order to provide for a staggered term of appointment for all such members.

(4) Responsibilities of the Board and the Director of the Center

(A) Responsibilities of the Board

(i) In general

The Board shall advise, and provide recommendations to, the Director of the Center with respect to—

(I) policies, programs, and procedures for carrying out the duties of the Director of the Center under this section; and

(II) significant barriers to successful translation of basic science into clinical application (including issues under the purview of other agencies and departments).

(ii) Report

In the case that the Board identifies a significant barrier, as described in clause (i)(II), the Board shall submit to the Secretary a report regarding such barrier.

(B) Responsibilities of the Director of the Center

With respect to each recommendation provided by the Board under subparagraph

(A)(i), the Director of the Center shall respond in writing to the Board, indicating whether such Director will implement such recommendation. In the case that the Director of the Center indicates a recommendation of the Board will not be implemented, such Director shall provide an explanation of the reasons for not implementing such recommendation.

(5) Meetings

(A) In general

The Board shall meet 4 times per calendar year, at the call of the Chairperson.

(B) Quorum; requirements; limitations

(i) Quorum

A quorum shall consist of a total of 13 members of the Board, excluding ex-officio members, with diverse representation as described in clause (iii).

(ii) Chairperson or Vice Chairperson

Each meeting of the Board shall be attended by either the Chairperson or the Vice Chairperson.

(iii) Diverse representation

At each meeting of the Board, there shall be not less than one scientist, one representative of a disease advocacy organization, and one representative of a professional venture capital or private equity organization.

(6) Compensation and travel expenses

(A) Compensation

Members shall receive compensation at a rate to be fixed by the Chairperson but not to exceed a rate equal to the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5 for each day (including travel time) during which the member is engaged in the performance of the duties of the Board. All members of the Board who are officers or employees of the United States shall serve without compensation in addition to that received for their services as officers or employees of the United States.

(B) Travel expenses

Members of the Board shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for persons employed intermittently by the Federal Government under section 5703(b)³ of title 5, while away from their homes or regular places of business in the performance of services for the Board.

(e) Grant program

(1) Supporting innovation

To carry out the purposes described in this section, the Director of the Center shall award contracts, grants, or cooperative agreements to the entities described in paragraph (2), to—

(A) promote innovation in technologies supporting the advanced research and devel-

opment and production of high need cures, including through the development of medical products and behavioral therapies.

(B) accelerate the development of high need cures, including through the development of medical products, behavioral therapies, and biomarkers that demonstrate the safety or effectiveness of medical products; or

(C) help the award recipient establish protocols that comply with Food and Drug Administration standards and otherwise permit the recipient to meet regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product.

(2) Eligible entities

To receive assistance under paragraph (1), an entity shall—

(A) be a public or private entity, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a disease advocacy organization, a patient advocacy organization, or an academic research institution;

(B) submit an application containing—

(i) a detailed description of the project for which the entity seeks such grant or contract;

(ii) a timetable for such project;

(iii) an assurance that the entity will submit—

(I) interim reports describing the entity's—

(aa) progress in carrying out the project; and

(bb) compliance with all provisions of this section and conditions of receipt of such grant or contract; and

(II) a final report at the conclusion of the grant period, describing the outcomes of the project; and

(iv) a description of the protocols the entity will follow to comply with Food and Drug Administration standards and regulatory requirements at all stages of development, manufacturing, review, approval, and safety surveillance of a medical product; and

(C) provide such additional information as the Director of the Center may require.

(3) Awards

(A) The cures acceleration partnership 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 Director of the Center the information

³So in original. Section 5703 of title 5 does not contain a subsec. (b).

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, non-compliance 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