

(D) Evaluation

During the 6-month period following the end of the first fiscal year for which the total amount reserved under subparagraph (B) is equal to 5 percent of the total amount appropriated under subsection (a) for such fiscal year, the Secretary, acting through the Director of NIH, in consultation with the advisory council established under section 282(k) of this title, shall submit recommendations to the Congress for changes regarding amounts for the Common Fund.

(2) Trans-NIH research reporting**(A) Limitation**

With respect to the total amount appropriated under subsection (a) for fiscal year 2008 or any subsequent fiscal year, if the head of a national research institute or national center fails to submit the report required by subparagraph (B) for the preceding fiscal year, the amount made available for the institute or center for the fiscal year involved may not exceed the amount made available for the institute or center for fiscal year 2006.

(B) Reporting

Not later than January 1, 2008, and each January 1st thereafter—

(i) the head of each national research institute or national center shall submit to the Director of NIH a report on the amount made available by the institute or center for conducting or supporting research that involves collaboration between the institute or center and 1 or more other national research institutes or national centers; and

(ii) the Secretary shall submit a report to the Congress identifying the percentage of funds made available by each national research institute and national center with respect to such fiscal year for conducting or supporting research described in clause (i).

(C) Determination

For purposes of determining the amount or percentage of funds to be reported under subparagraph (B), any amounts made available to an institute or center under section 282(b)(7)(B) of this title shall be included.

(D) Verification of amounts

Upon receipt of each report submitted under subparagraph (B)(i), the Director of NIH shall review and, in cases of discrepancy, verify the accuracy of the amounts specified in the report.

(E) Waiver

At the request of any national research institute or national center, the Director of NIH may waive the application of this paragraph to such institute or center if the Director finds that the conduct or support of research described in subparagraph (B)(i) is inconsistent with the mission of such institute or center.

(d) Transfer authority

Of the total amount appropriated under subsection (a) for a fiscal year, the Director of NIH

may (in addition to the reservation under subsection (c)(1) for such year) transfer not more than 1 percent for programs or activities that are authorized in this subchapter and identified by the Director to receive funds pursuant to this subsection. In making such transfers, the Director may not decrease any appropriation account under subsection (a) by more than 1 percent.

(e) Rule of construction

This section may not be construed as affecting the authorities of the Director of NIH under section 281 of this title.

(July 1, 1944, ch. 373, title IV, §402A, as added Pub. L. 109-482, title I, §103(a), Jan. 15, 2007, 120 Stat. 3685.)

EFFECTIVE DATE

Section 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 an Effective Date of 2007 Amendment note under section 281 of this title.

§ 282b. Electronic coding of grants and activities

The Secretary, acting through the Director of NIH, shall establish an electronic system to uniformly code research grants and activities of the Office of the Director and of all the national research institutes and national centers. The electronic system shall be searchable by a variety of codes, such as the type of research grant, the research entity managing the grant, and the public health area of interest. When permissible, the Secretary, acting through the Director of NIH, shall provide information on relevant literature and patents that are associated with research activities of the National Institutes of Health.

(July 1, 1944, ch. 373, title IV, §402B, as added Pub. L. 109-482, title I, §104(a)(3), Jan. 15, 2007, 120 Stat. 3689.)

EFFECTIVE DATE

Section 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 an Effective Date of 2007 Amendment note under section 281 of this title.

§ 282c. Public access to funded investigators' final manuscripts

The Director of the National Institutes of Health (“NIH”) shall require in the current fiscal year and thereafter that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: *Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.

(Pub. L. 111-8, div. F, title II, §217, Mar. 11, 2009, 123 Stat. 782.)

CODIFICATION

Section was enacted as part of the Department of Health and Human Services Appropriations Act, 2009, and also as part of the Departments of Labor, Health

and Human Services, and Education, and Related Agencies Appropriations Act, 2009, and the Omnibus Appropriations Act, 2009, and not as part of the Public Health Service Act which comprises this chapter.

§ 282d. 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 NIH—

(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 Office of the Director of NIH 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 NIH, 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—

(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 NIH 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 distin-

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

² See References in Text note below.