

(4) development of programs and enhancement of strategies to recruit, train, and provide continuing education opportunities for the personnel of the Centers with expertise related to the major disease area of focus of the Institute;

(5) enhancement of the interactions of the Centers with patients, sponsors, and the external biomedical community regarding the major disease area of focus of the Institute; and

(6) facilitation of the collaborative relationships of the Centers with other agencies within the Department of Health and Human Services regarding the major disease area of focus of the Institute.

(b) Public process

The Secretary shall provide a period for public comment during the time that each Institute is being implemented.

(c) Timing

The Secretary shall establish at least one Institute under subsection (a) before the date that is 1 year after December 13, 2016.

(d) Termination of Institutes

The Secretary may terminate any Institute established pursuant to this section if the Secretary determines such Institute is no longer benefitting the public health. Not less than 60 days prior to so terminating an Institute, the Secretary shall provide public notice, including the rationale for such termination.

(June 25, 1938, ch. 675, §1014, as added Pub. L. 114-255, div. A, title III, §3073(a), Dec. 13, 2016, 130 Stat. 1136.)

§ 399h. National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing

(a) In general

The Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs—

(1) may, to support the advancement, development, and implementation of advanced and continuous pharmaceutical manufacturing—

(A) solicit requests for designation as National Centers of Excellence in Advanced and Continuous Pharmaceutical Manufacturing (in this section referred to as a “National Center of Excellence”);

(B) beginning not later than one year after December 29, 2022, designate as National Centers of Excellence institutions of higher education or consortia of institutions of higher education that—

- (i) request such designation; and
- (ii) meet the eligibility criteria specified in subsection (c); and

(C) award grants to such institutions or consortia of institutions; and

(2) shall so designate not more than 5 institutions of higher education or consortia of such institutions.

(b) Request for designation

A request for designation under subsection (a) shall be made to the Secretary at such time, in

such manner, and containing such information as the Secretary may require.

(c) Eligibility criteria for designation

To be eligible to receive a designation under this section, an institution of higher education or consortium of institutions of higher education shall include in its request for designation a description of the institution’s or consortium’s—

(1) physical capacity and technical capabilities to conduct advanced research on, and to develop and implement, advanced and continuous pharmaceutical manufacturing;

(2) collaboration or partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities;

(3) proven capacity to design, develop, implement, and demonstrate new, highly effective technologies for use in advanced and continuous pharmaceutical manufacturing;

(4) proven ability to facilitate training of a qualified workforce for advanced research on, and development and implementation of, advanced and continuous pharmaceutical manufacturing; and

(5)(A) experience in participating in and leading advanced and continuous pharmaceutical manufacturing technology partnerships with other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, contract manufacturers, and other relevant entities to—

(i) support the implementation of advanced or continuous pharmaceutical manufacturing for companies manufacturing or seeking to manufacture in the United States;

(ii) support Federal agencies with technical assistance and workforce training, which may include regulatory and quality metric guidance as applicable, and hands-on training, for advanced and continuous pharmaceutical manufacturing;

(iii) organize and conduct advanced research and development activities, with respect to advanced or continuous pharmaceutical manufacturing, needed to develop new and more effective technology, and to develop and support technological leadership;

(iv) develop best practices for designing, developing, and implementing advanced and continuous pharmaceutical manufacturing processes; and

(v) identify and assess workforce needs for advanced and continuous pharmaceutical manufacturing, and address such workforce needs, which may include the development and implementing of training programs; or

(B) a plan, to be implemented within 2 years, to establish partnerships described in subparagraph (A).

(d) Termination of designation

The Secretary may terminate the designation of any National Center of Excellence designated

under this section if the Secretary determines such National Center of Excellence no longer meets the criteria specified in subsection (c). Not later than 90 days before the effective date of such a termination, the Secretary shall provide written notice to the National Center of Excellence, including the rationale for such termination.

(e) Conditions for designation

As a condition of designation as a National Center of Excellence under this section, the Secretary shall require that an institution of higher education or consortium of institutions of higher education enter into an agreement with the Secretary under which the institution or consortium agrees—

(1) to collaborate directly with the Food and Drug Administration to publish the reports required by subsection (g);

(2) to share data with the Food and Drug Administration regarding best practices and research generated through the funding under subsection (f);

(3) to develop, along with industry partners (which may include large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, and contract research organizations or contract manufacturers that carry out drug development and manufacturing activities) and another institution or consortium designated under this section, if any, a strategic plan for developing an advanced and continuous pharmaceutical manufacturing workforce;

(4) to develop, along with industry partners and other institutions or consortia of such institutions designated under this section, a strategic plan for strengthening existing, and developing new, partnerships with other institutions of higher education or consortia thereof, or nonprofit organizations; and

(5) to provide an annual report to the Food and Drug Administration regarding the designee's activities under this section, including a description of how the designee continues to meet and make progress on the criteria specified in subsection (c).

(f) Funding

(1) In general

The Secretary shall award funding, through grants, contracts, or cooperative agreements, to the entities designated as National Centers of Excellence under this section for the purposes of supporting the advanced research on, and development and implementation of, advanced and continuous pharmaceutical manufacturing, and recommending improvements to advanced and continuous pharmaceutical manufacturing, including—

(A) expanding capacity for advanced research on, and development of, advanced and continuous pharmaceutical manufacturing; and

(B) implementing advanced research capacity and capabilities in advanced and continuous pharmaceutical manufacturing suitable for accelerating the development of drug products needed to respond to public health threats, mitigate or prevent drug

shortages, address drug quality issues and supply chain disruptions, and other circumstances with respect to which the Secretary may determine the rapid development of new products or new manufacturing processes may be appropriate.

(2) Consistency with FDA mission

As a condition on receipt of funding under this subsection, a National Center of Excellence shall consider any input from the Secretary regarding the use of funding related to—

(A) best practices to increase, and provide for the advancement of, advanced and continuous pharmaceutical manufacturing through the National Center of Excellence; and

(B) the extent to which activities conducted by the National Center of Excellence are consistent with the mission of the Food and Drug Administration.

(3) Rule of construction

Nothing in this section shall be construed as precluding a National Center for Excellence designated under this section from receiving funds under any other provision of this Act or any other Federal law.

(g) Annual review and reports

(1) Annual report to Congress

Beginning not later than one year after the date on which the first designation is made under subsection (a), and annually thereafter, the Secretary shall—

(A) submit to Congress a report describing the activities, partnerships and collaborations, Federal policy recommendations, previous and continuing funding, and findings of, and any other applicable information from, the National Centers of Excellence designated under this section;

(B) include in such report an accounting of the Federal administrative expenses described in subsection (i)(2) over the reporting period; and

(C) make such report available to the public in an easily accessible electronic format on the website of the Food and Drug Administration.

(2) Center of Excellence report

An entity receiving a grant under this section shall, not later than 1 year after receiving such grant, and annually thereafter for the duration of the grant period, submit to the Secretary a summary of programs and activities funded under the grant.

(3) Periodic review

The Secretary shall periodically review the National Centers of Excellence designated under this section to ensure that such National Centers of Excellence continue to meet the criteria for designation under this section.

(4) Additional report to Congress

Not later than 1 year after the date on which the first designation is made under subsection (a), the Secretary, in consultation with the National Centers of Excellence designated under this section, shall submit a report to the

Congress on the role of the Food and Drug Administration in supporting advanced and continuous pharmaceutical manufacturing, including—

(A) a national framework of principles related to the implementation of advanced and continuous pharmaceutical manufacturing;

(B) a plan for the development of Federal regulations and guidance to support and facilitate the incorporation of advanced or continuous manufacturing into the development of pharmaceuticals;

(C) a plan for development of Federal regulations or guidance related to the review of advanced and continuous pharmaceutical manufacturing, including how such manufacturing practices may be incorporated into the review of medical product applications; and

(D) a summary of relevant feedback related to improving advanced and continuous pharmaceutical manufacturing solicited from the public, which may include other institutions of higher education, nonprofit organizations, and large and small pharmaceutical manufacturers, including generic and nonprescription manufacturers, and contract manufacturers, and other relevant entities.

(h) Definitions

In this section:

(1) Advanced and continuous pharmaceutical manufacturing

The term “advanced and continuous pharmaceutical manufacturing” refers to a method of pharmaceutical manufacturing, or a combination of pharmaceutical manufacturing methods—

(A) that incorporates a novel technology, or uses an established technique or technology in a new or innovative way, that enhances drug quality or improves the manufacturing process for a drug, including processes that may apply to advanced therapies and the production of biological products, such as cell and gene therapies; or

(B) for which the input materials are continuously fed into and transformed within the process, and the output materials are continuously removed from the system, utilizing an integrated manufacturing process that consists of a series of 2 or more simultaneous unit operations.

(2) Biological product

The term “biological product” has the meaning given such term in section 262(i) of title 42.

(3) Drug

The term “drug” has the meaning given such term in section 321(g) of this title.

(4) Institution of higher education

The term “institution of higher education” has the meaning given such term in section 1001(a) of title 20.

(5) Secretary

The term “Secretary” means the Secretary of Health and Human Services.

(i) Authorization of appropriations

(1) In general

There is authorized to be appropriated to carry out this section \$100,000,000 for the period of fiscal years 2023 through 2027.

(2) Federal administrative expenses

Of the amounts made available to carry out this section for a fiscal year, the Secretary shall not use more than 8 percent for Federal administrative expenses, including training, technical assistance, reporting, and evaluation.

(Pub. L. 114-255, div. A, title III, §3016, Dec. 13, 2016, 130 Stat. 1095; Pub. L. 117-328, div. FF, title III, §3204(a), Dec. 29, 2022, 136 Stat. 5815.)

Editorial Notes

REFERENCES IN TEXT

This Act, referred to in subsec. (f)(3), is Pub. L. 114-255, Dec. 13, 2016, 130 Stat. 1033, known as the 21st Century Cures Act. For complete classification of this Act to the Code, see Short Title of 2016 Amendment note set out under section 201 of Title 42, The Public Health and Welfare, and Tables.

CODIFICATION

Section was enacted as part of the 21st Century Cures Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

AMENDMENTS

2022—Pub. L. 117-328 amended section generally. Prior to amendment, section related to grants for studying continuous drug manufacturing.

Statutory Notes and Related Subsidiaries

TRANSITION RULE

Pub. L. 117-328, div. FF, title III, §3204(b), Dec. 29, 2022, 136 Stat. 5819, provided that: “Section 3016 of the 21st Century Cures Act (21 U.S.C. 399h), as in effect on the day before the date of the enactment of this section [Dec. 29, 2022], shall apply with respect to grants awarded under such section before such date of enactment.”

§ 399i. Food and Drug Administration Working Capital Fund

(a) In general

There is hereby established in the Treasury of the United States a Working Capital Fund (the Fund) to be administered by the Food and Drug Administration (FDA), without fiscal year limitation, for the payment of salaries, travel, and other expenses necessary to the maintenance and operation of (1) a supply service for the purchase, storage, handling, issuance, packing, or shipping of stationery, supplies, materials, equipment, and blank forms, for which stocks may be maintained to meet, in whole or in part, the needs of the FDA and requisitions of other Government Offices, and (2) such other services as the Commissioner of the FDA, subject to review by the Secretary of Health and Human Services, determines may be performed more advantageously as central services. The Fund shall be reimbursed from applicable discretionary resources, notwithstanding any otherwise applicable purpose limitations, available when services are performed or stock furnished, or in advance, on a basis of rates which shall include estimated