(i) Reports

(1) Report on information and analyses

Not later than 1 year after the date on which any system is established under this section, the Secretary shall submit an interim report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding aggregate information collected pursuant to this section and epidemiological analyses, as appropriate. Such report shall be posted on the Internet website of the Department of Health and Human Services and shall be updated biennially.

(2) Implementation report

Not later than 4 years after December 13, 2016, the Secretary shall submit a report to the Congress concerning the implementation of this section. Such report shall include information on—

(A) the development and maintenance of the National Neurological Conditions Surveillance System;

(B) the type of information collected and stored in the surveillance system;

(C) the use and availability of such information, including guidelines for such use; and

(D) the use and coordination of databases that collect or maintain information on neurological diseases.

(j) Definition

In this section, the term ''national voluntary health association'' means a national nonprofit organization with chapters, other affiliated organizations, or networks in States throughout the United States with experience serving the population of individuals with neurological disease and have demonstrated experience in neurological disease research, care, and patient services.

(k) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2018 through 2022.

(July 1, 1944, ch. 373, title III, § 399S–1, as added Pub. L. 114–255, div. A, title II, § 2061, Dec. 13, 2016, 130 Stat. 1076.)

§ 280g–7b. HHS public-private partnership for rare neurodegenerative diseases

(a) Establishment

Not later than one year after December 23, 2021, the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish and implement a Public-Private Partnership for Neurodegenerative Diseases between the National Institutes of Health, the Food and Drug Administration, and one or more eligible entities (to be known and referred to in this section as the ''Partnership'') through cooperative agreements, contracts, or other appropriate mechanisms with such eligible entities, for the purpose of advancing the understanding of neurodegenerative diseases and fostering the development of treatments for amytrophic lateral sclerosis and other rare neurodegenerative diseases. The Partnership shall—

(1) establish partnerships and consortia with other public and private entities and individuals with expertise in amyotrophic lateral sclerosis and other rare neurodegenerative diseases for the purposes described in this subsection;

(2) focus on advancing regulatory science and scientific research that will support and accelerate the development and review of drugs for patients with amyotrophic lateral sclerosis and other rare neurodegenerative diseases; and

(3) foster the development of effective drugs that improve the lives of people that suffer from amyotrophic lateral sclerosis and other rare neurodegenerative diseases.

(b) Eligible entity

In this section, the term ''eligible entity'' means an entity that—

(1) is—

(A) an institution of higher education (as such term is defined in section 1001[1] of title 20) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of title 26 and exempt from tax under subsection (a) of such section;

(2) has experienced personnel with clinical and other technical expertise in the field of biomedical sciences and demonstrated connection to the patient population;

(3) demonstrates to the Secretary's satisfaction that the entity is capable of identifying and establishing collaborations between public and private entities and individuals with expertise in neurodegenerative diseases, including patients, in order to facilitate—

(A) development and critical evaluation of tools, methods, and processes—

(i) to characterize neurodegenerative diseases and their natural history;

(ii) to identify molecular targets for neurodegenerative diseases; and

(iii) to increase efficiency, predictability, and productivity of clinical development of therapies, including advancement of rational therapeutic development and establishment of clinical trial networks; and

(B) securing funding for the Partnership from Federal and non-Federal governmental sources, foundations, and private individuals; and

(4) provides an assurance that the entity will not accept funding for a Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Secretary that the results of the project will not be influenced by any source of funding.

(c) Gifts

(1) In general

The Partnership may solicit and accept gifts, grants, and other donations, establish

[1] See References in Text note below.

accounts, and invest and expend funds in support of basic research and research associated with phase 3 clinical trials conducted with respect to investigational drugs that are the subjects of expanded access requests under section 360bbb of title 21.

(2) Use

In addition to any amounts appropriated for purposes of carrying out this section, the Partnership may use, without further appropriation, any funds derived from a gift, grant, or other donation accepted pursuant to paragraph (1).

(Pub. L. 117–79, § 3, Dec. 23, 2021, 135 Stat. 1535.)

Editorial Notes

REFERENCES IN TEXT

Section 1001 of title 20, referred to in subsec. (b)(1)(A), was in the original ''section 1001 of the Higher Education Act of 1965'' and was translated as if it had read ''section 101 of the Higher Education Act of 1965'' to reflect the probable intent of Congress. Section 101 of the Higher Education Act of 1965 is classified to section 1001 of Title 20, Education, and defines ''institution of higher education''.

CODIFICATION

Section was enacted as part of the Accelerating Access to Critical Therapies for ALS Act, and not as part of the Public Health Service Act which comprises this chapter.

§ 280g–8. Support for patients receiving a positive diagnosis of Down syndrome or other prenatally or postnatally diagnosed conditions

(a) Definitions

In this section:

(1) Down syndrome

The term ''Down syndrome'' refers to a chromosomal disorder caused by an error in cell division that results in the presence of an extra whole or partial copy of chromosome 21.

(2) Health care provider

The term ''health care provider'' means any person or entity required by State or Federal law or regulation to be licensed, registered, or certified to provide health care services, and who is so licensed, registered, or certified.

(3) Postnatally diagnosed condition

The term ''postnatally diagnosed condition'' means any health condition identified during the 12-month period beginning at birth.

(4) Prenatally diagnosed condition

The term ''prenatally diagnosed condition'' means any fetal health condition identified by prenatal genetic testing or prenatal screening procedures.

(5) Prenatal test

The term ''prenatal test'' means diagnostic or screening tests offered to pregnant women seeking routine prenatal care that are administered on a required or recommended basis by a health care provider based on medical history, family background, ethnic background, previous test results, or other risk factors.

(b) Information and support services

(1) In general

The Secretary, acting through the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, or the Administrator of the Health Resources and Services Administration, may authorize and oversee certain activities, including the awarding of grants, contracts or cooperative agreements to eligible entities, to—

(A) collect, synthesize, and disseminate current evidence-based information relating to Down syndrome or other prenatally or postnatally diagnosed conditions; and

(B) coordinate the provision of, and access to, new or existing supportive services for patients receiving a positive diagnosis for Down syndrome or other prenatally or postnatally diagnosed conditions, including—

(i) the establishment of a resource telephone hotline accessible to patients receiving a positive test result or to the parents of newly diagnosed infants with Down syndrome and other diagnosed conditions;

(ii) the expansion and further development of the National Dissemination Center for Children with Disabilities, so that such Center can more effectively conduct outreach to new and expecting parents and provide them with up-to-date information on the range of outcomes for individuals living with the diagnosed condition, including physical, developmental, educational, and psychosocial outcomes;

(iii) the expansion and further development of national and local peer-support programs, so that such programs can more effectively serve women who receive a positive diagnosis for Down syndrome or other prenatal conditions or parents of infants with a postnatally diagnosed condition;

(iv) the establishment of a national registry, or network of local registries, of families willing to adopt newborns with Down syndrome or other prenatally or postnatally diagnosed conditions, and links to adoption agencies willing to place babies with Down syndrome or other prenatally or postnatally diagnosed conditions, with families willing to adopt; and

(v) the establishment of awareness and education programs for health care providers who provide, interpret, or inform parents of the results of prenatal tests for Down syndrome or other prenatally or postnatally diagnosed conditions, to patients, consistent with the purpose described in section 2(b)(1)[1] of the Prenatally and Postnatally Diagnosed Conditions Awareness Act.

(2) Eligible entity

In this subsection, the term ''eligible entity'' means—

(A) a State or a political subdivision of a State;

[1] See References in Text note below.