

(vii) any other existing or relevant databases that collect or maintain information on those motor neuron diseases recommended by the Advisory Committee established in subsection (b); and

(B) provide for research access to ALS data as recommended by the Advisory Committee established in subsection (b) to the extent permitted by applicable statutes and regulations and in a manner that protects personal privacy consistent with applicable privacy statutes and regulations.

(C) COORDINATION WITH NIH AND DEPARTMENT OF VETERANS AFFAIRS.—Consistent with applicable privacy statutes and regulations, the Secretary may ensure that epidemiological and other types of information obtained under subsection (a) is made available to the National Institutes of Health and the Department of Veterans Affairs.

(e) Definition

For the purposes of this section, the term “national voluntary health association” means a national non-profit organization with chapters or other affiliated organizations in States throughout the United States with experience serving the population of individuals with ALS and have demonstrated experience in ALS research, care, and patient services.

(July 1, 1944, ch. 373, title III, § 399S, formerly § 399R, as added Pub. L. 110–373, § 2, Oct. 8, 2008, 122 Stat. 4047; renumbered § 399S, Pub. L. 111–148, title IV, § 4003(b)(2)(A), Mar. 23, 2010, 124 Stat. 544.)

Editorial Notes

REFERENCES IN TEXT

The Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (b)(1)(A)(ii), is Pub. L. 104–191, Aug. 21, 1996, 110 Stat. 1936. For complete classification of this Act to the Code, see Short Title of 1996 Amendments note set out under section 201 of this title and Tables.

§ 280g–7a. Surveillance of neurological diseases

(a) In general

The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in coordination with other agencies as the Secretary determines, shall, as appropriate—

- (1) enhance and expand infrastructure and activities to track the epidemiology of neurological diseases; and
- (2) incorporate information obtained through such activities into an integrated surveillance system, which may consist of or include a registry, to be known as the National Neurological Conditions Surveillance System.

(b) Research

The Secretary shall ensure that the National Neurological Conditions Surveillance System is designed in a manner that facilitates further research on neurological diseases.

(c) Content

- In carrying out subsection (a), the Secretary—
- (1) shall provide for the collection and storage of information on the incidence and prevalence

of neurological diseases in the United States;

(2) to the extent practicable, shall provide for the collection and storage of other available information on neurological diseases, including information related to persons living with neurological diseases who choose to participate, such as—

- (A) demographics, such as age, race, ethnicity, sex, geographic location, family history, and other information, as appropriate;
- (B) risk factors that may be associated with neurological diseases, such as genetic and environmental risk factors and other information, as appropriate; and
- (C) diagnosis and progression markers;

(3) may provide for the collection and storage of information relevant to analysis on neurological diseases, such as information concerning—

- (A) the natural history of the diseases;
- (B) the prevention of the diseases;
- (C) the detection, management, and treatment approaches for the diseases; and
- (D) the development of outcomes measures;

(4) may address issues identified during the consultation process under subsection (d); and

(5) initially may address a limited number of neurological diseases.

(d) Consultation

In carrying out this section, the Secretary shall consult with individuals with appropriate expertise, which may include—

- (1) epidemiologists with experience in disease surveillance or registries;
- (2) representatives of national voluntary health associations that—
 - (A) focus on neurological diseases; and
 - (B) have demonstrated experience in research, care, or patient services;
- (3) health information technology experts or other information management specialists;
- (4) clinicians with expertise in neurological diseases; and
- (5) research scientists with experience conducting translational research or utilizing surveillance systems for scientific research purposes.

(e) Grants

The Secretary may award grants to, or enter into contracts or cooperative agreements with, public or private nonprofit entities to carry out activities under this section.

(f) Coordination with other Federal, State, and local agencies

Subject to subsection (h), the Secretary shall—

- (1) make information and analysis in the National Neurological Conditions Surveillance System available, as appropriate—
 - (A) to Federal departments and agencies, such as the National Institutes of Health and the Department of Veterans Affairs; and
 - (B) to State and local agencies; and
- (2) identify, build upon, leverage, and coordinate among existing data and surveillance sys-

terms, surveys, registries, and other Federal public health infrastructure, wherever practicable.

(g) Public access

Subject to subsection (h), the Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are available, as appropriate, to the public, including researchers.

(h) Privacy

The Secretary shall ensure that information and analysis in the National Neurological Conditions Surveillance System are made available only to the extent permitted by applicable Federal and State law, and in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum.

(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 amyotrophic 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 1001¹ 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

¹ See References in Text note below.