

- (A) the development and maintenance of the National ALS Registry;
- (B) the type of information to be collected and stored in the Registry;
- (C) the manner in which such data is to be collected;
- (D) the use and availability of such data including guidelines for such use; and
- (E) the collection of information about diseases and disorders that primarily affect motor neurons that are considered essential to furthering the study and cure of ALS.

**(3) Report**

Not later than 270 days after the date on which the Advisory Committee is established, the Advisory Committee may submit a report to the Secretary concerning the review conducted under paragraph (2) that contains the recommendations of the Advisory Committee with respect to the results of such review.

**(c) Grants**

The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may award grants to, and enter into contracts and cooperative agreements with, public or private nonprofit entities for the collection, analysis, and reporting of data on ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS after receiving the report under subsection (b)(3).

**(d) Coordination with State, local, and Federal registries**

**(1)<sup>3</sup> In general**

In establishing the National ALS Registry under subsection (a), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may—

- (A) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure wherever possible, which may include—
  - (i) any registry pilot projects previously supported by the Centers for Disease Control and Prevention;
  - (ii) the Department of Veterans Affairs ALS Registry;
  - (iii) the DNA and Cell Line Repository of the National Institute of Neurological Disorders and Stroke Human Genetics Resource Center at the National Institutes of Health;
  - (iv) Agency for Toxic Substances and Disease Registry studies, including studies conducted in Illinois, Missouri, El Paso and San Antonio, Texas, and Massachusetts;
  - (v) State-based ALS registries;
  - (vi) the National Vital Statistics System; and
  - (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.)

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—

<sup>3</sup>So in original. No par. (2) has been enacted.

(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 systems, 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-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 di-