

**(b) Activities**

Activities to be carried out under the demonstration project under subsection (a) may include the establishment of—

(1) programs to test and evaluate various strategies to provide information and education to health professionals, other health care providers, and the public concerning—

(A) the signs of preterm labor, updated as new research results become available;

(B) the screening for and the treating of infections;

(c)<sup>1</sup> counseling on optimal weight and good nutrition, including folic acid;

(D) smoking cessation education and counseling;

(E) stress management; and

(F) appropriate prenatal care;

(2) programs to improve the treatment and outcomes for babies born premature, including the use of evidence-based standards of care by health care professionals for pregnant women at risk of preterm labor or other serious complications and for infants born preterm and at a low birthweight;

(3) programs to respond to the informational needs of families during the stay of an infant in a neonatal intensive care unit, during the transition of the infant to the home, and in the event of a newborn death; and

(4) such other programs as the Secretary determines appropriate to achieve the purpose specified in subsection (a).

**(c) Authorization of appropriations**

There is authorized to be appropriated to carry out this section \$5,000,000 for each of fiscal years 2007 through 2011.

(July 1, 1944, ch. 373, title III, §399Q, as added Pub. L. 109-450, §4(2), Dec. 22, 2006, 120 Stat. 3342.)

**§ 280g-6. Chronic kidney disease initiatives****(a) In general**

The Secretary shall establish pilot projects to—

(1) increase public and medical community awareness (particularly of those who treat patients with diabetes and hypertension) regarding chronic kidney disease, focusing on prevention;

(2) increase screening for chronic kidney disease, focusing on Medicare beneficiaries at risk of chronic kidney disease; and

(3) enhance surveillance systems to better assess the prevalence and incidence of chronic kidney disease.

**(b) Scope and duration****(1) Scope**

The Secretary shall select at least 3 States in which to conduct pilot projects under this section.

**(2) Duration**

The pilot projects under this section shall be conducted for a period that is not longer than 5 years and shall begin on January 1, 2009.

**(c) Evaluation and report**

The Comptroller General of the United States shall conduct an evaluation of the pilot projects conducted under this section. Not later than 12 months after the date on which the pilot projects are completed, the Comptroller General shall submit to Congress a report on the evaluation.

**(d) Authorization of appropriations**

There are authorized to be appropriated such sums as may be necessary for the purpose of carrying out this section.

(July 1, 1944, ch. 373, title III, §399R, as added Pub. L. 110-275, title I, §152(a), July 15, 2008, 122 Stat. 2551.)

## CODIFICATION

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110-373, §2, Oct. 8, 2008, 122 Stat. 4047, was renumbered section 399S and is classified to section 280g-7 of this title.

Another section 399R of act July 1, 1944, ch. 373, as added by Pub. L. 110-374, §3, Oct. 8, 2008, 122 Stat. 4051, was renumbered section 399T and is classified to section 280g-8 of this title.

**§ 280g-7. Amyotrophic lateral sclerosis registry****(a) Establishment****(1) In general**

Not later than 1 year after the receipt of the report described in subsection (b)(2)(A), the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, if scientifically advisable—

(A) develop a system to collect data on amyotrophic lateral sclerosis (referred to in this section as “ALS”) and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS, including information with respect to the incidence and prevalence of the disease in the United States; and

(B) establish a national registry for the collection and storage of such data to develop a population-based registry of cases in the United States of ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS.

**(2) Purpose**

It is the purpose of the registry established under paragraph (1)(B) to—

(A) better describe the incidence and prevalence of ALS in the United States;

(B) examine appropriate factors, such as environmental and occupational, that may be associated with the disease;

(C) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease;

(D) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS; and

(E) other matters as recommended by the Advisory Committee established under subsection (b).

<sup>1</sup> So in original. Probably should be “(C)”.

**(b) Advisory Committee****(1) Establishment**

Not later than 180 days after October 8, 2008, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, may establish a committee to be known as the Advisory Committee on the National ALS Registry (referred to in this section as the “Advisory Committee”). The Advisory Committee shall be composed of not more than 27 members to be appointed by the Secretary, acting through the Centers for Disease Control and Prevention, of which—

(A) two-thirds of such members shall represent governmental agencies—

(i) including at least one member representing—

(I) the National Institutes of Health, to include, upon the recommendation of the Director of the National Institutes of Health, representatives from the National Institute of Neurological Disorders and Stroke and the National Institute of Environmental Health Sciences;

(II) the Department of Veterans Affairs;

(III) the Agency for Toxic Substances and Disease Registry; and

(IV) the Centers for Disease Control and Prevention; and

(ii) of which at least one such member shall be a clinician with expertise on ALS and related diseases, an epidemiologist with experience in data registries, a statistician, an ethicist, and a privacy expert (relating to the privacy regulations under the Health Insurance Portability and Accountability Act of 1996); and

(B) one-third of such members shall be public members, including at least one member representing—

(i) national and voluntary health associations;<sup>1</sup>

(ii) patients with ALS or their family members;

(iii) clinicians with expertise on ALS and related diseases;

(iv) epidemiologists with experience in data registries;

(v) geneticists or experts in genetics who have experience with the genetics of ALS or other neurological diseases<sup>2</sup> and

(vi) other individuals with an interest in developing and maintaining the National ALS Registry.

**(2) Duties**

The Advisory Committee may review information and make recommendations to the Secretary concerning—

(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

<sup>1</sup> So in original. Probably should be “national voluntary health associations;”.

<sup>2</sup> So in original. Probably should be followed by a semicolon.

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

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-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)<sup>1</sup> 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;

<sup>1</sup> See References in Text note below.