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117TH CONGRESS
2D SESSION

H. R. 9676

To expand and improve the programs and activities of the Department of Health and Human Services for awareness, education, research, surveillance, diagnosis, and treatment concerning rare diseases and conditions.

IN THE HOUSE OF REPRESENTATIVES

DECEMBER 22, 2022

Mr. CARSON introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To expand and improve the programs and activities of the Department of Health and Human Services for awareness, education, research, surveillance, diagnosis, and treatment concerning rare diseases and conditions.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Rare disease Advancement, surveillance Research, and Education Act of 2022" or the "RARE Act of 2022".

SEC. 2. NIH RARE DISEASE REGIONAL CENTERS OF EXCELLENCE.

Paragraph (1) of section 402A(a) of the Public Health Service Act (42 U.S.C. 282a(a)) is amended by adding at the end the following: ''In addition to the amounts authorized to be appropriated by the preceding sentence, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2024 through 2028 for carrying out section 481A (relating to rare disease regional centers of excellence).''.

SEC. 3. CDC SURVEILLANCE OF RARE DISEASES AND CONDITIONS.

Title III of the Public Health Service Act is amended by inserting after section 317U of such Act (42 U.S.C. 247b–23) the following:

''SEC. 317V. CDC SURVEILLANCE OF RARE DISEASES AND CONDITIONS.

''(a) IN GENERAL.—The Secretary may, as appropriate—

''(1) enhance and expand infrastructure and activities to track the epidemiology of up to 4 rare diseases and conditions selected under subsection (c)(1); and

''(2) incorporate information obtained through such activities into an integrated surveillance system to be known as the National Rare Disease or Condition Surveillance System.

''(b) RESEARCH.—The Secretary shall ensure that the National Rare Disease or Condition Surveillance System is designed in a manner that provides information that facilitates further research on rare diseases and conditions.

''(c) CONTENT.—In carrying out subsection (a), the Secretary—

''(1) shall select up to 4 rare diseases and conditions that are determined by the Secretary to have—

''(A) a high rate of mortality or morbidity; or

''(B) potential for meaningful research and treatment;

''(2) shall provide for the collection and storage of information on the incidence and prevalence of such rare diseases and conditions in the United States;

''(3) to the extent practicable, shall provide for the collection and storage of other available information on such rare diseases and conditions, including information related to persons living with such a rare disease or condition who choose to participate in surveillance activities, and including information on—

''(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 the rare disease or condition, such as genetic and environmental risk factors and other information, as appropriate; and

''(C) diagnosis and progression markers;

''(4) to the extent practicable, shall provide for the collection and storage of information relevant to analysis on such rare diseases and conditions, such as information concerning—

''(A) the natural history of the diseases and conditions;

''(B) the prevention of the disease or condition, including secondary diseases and conditions;

''(C) the detection, management, and treatment approaches for the diseases and conditions; and

''(D) the development of outcomes measures; and

“(5) may address issues identified during the consultation process under subsection (d).

“(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;

“(2) representatives of national voluntary health associations that—

“(A) focus on rare diseases or conditions; 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 rare diseases or conditions;

“(5) research scientists with expertise in rare diseases or conditions, or experience conducting translational research or utilizing surveillance systems for scientific research purposes; and

“(6) patients and caregivers of patients with rare diseases or conditions.

“(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 Rare Disease or Condition 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 Rare Disease or 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 Rare Disease or Condition 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) SUPPLEMENT NOT SUPPLANT.—The activities under this section may supplement, but shall not supplant, any activities with respect to spina bifida, muscular dystrophy, or fragile X syndrome that are ongoing as of the date of enactment of this section.

"(j) REPORTS.—

"(1) REPORT ON INFORMATION AND ANALYSES.—Not later than 2 years 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 the date of the enactment of this section, 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 Rare Disease or Condition 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 rare diseases or conditions.

“(k) DEFINITIONS.—In this section:

“(1) NATIONAL VOLUNTARY HEALTH ASSOCIATION.—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 a rare disease or condition and have demonstrated experience in rare disease or condition research, care, and patient services.

“(2) RARE.—The term ‘rare’, with respect to a disease or condition, means having a prevalence of fewer than 200,000 individuals in the United States.

"(l) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2024 through 2029.".

SEC. 4. INCREASING HEALTH PROFESSIONALS' AWARENESS OF RARE DISEASES.

(a) IN GENERAL.—The Director of the Agency for Healthcare Research and Quality shall expand and intensify the activities of the Agency to increase the awareness and knowledge of health care providers about rare diseases and conditions.

(b) DEFINITION.—In this section, the term "rare diseases and conditions", with respect to a disease or condition, means having a prevalence of fewer than 200,000 individuals in the United States.

SEC. 5. REPORT.

(a) IN GENERAL.—The Secretary of Health and Human Services shall seek to enter into an arrangement with the National Academies (or another appropriate entity if the National Academies decline) to update and republish, by not later than 3 years after the date of enactment of this Act, the 2010 report of the National Academies entitled "Rare Diseases and Orphan Products: Accelerating Research and Development".

(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $1,000,000.

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