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112TH CONGRESS
2D SESSION

H. R. 3891

To amend the Public Health Service Act to speed American innovation in research and drug development for the leading causes of death that are the most costly chronic conditions for our Nation, to save American families and the Federal and State governments money, and to help family caregivers.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 2, 2012

Mr. MARKEY (for himself and Mr. SMITH of New Jersey) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Public Health Service Act to speed American innovation in research and drug development for the leading causes of death that are the most costly chronic conditions for our Nation, to save American families and the Federal and State governments money, and to help family caregivers.

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 ''Spending Reductions through Innovations in Therapies Agenda Act of 2012'' or the ''SPRINT Act''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Half of health care expenses in the United States are spent on 5 percent of the population. Many of the most expensive health conditions to treat are also the leading causes of death.

(2) Improving a patient's quality of life by developing innovative treatments that improve health outcomes and lead to a cure will improve productivity in the United States, reduce government spending, and enhance public health.

(3) More than a quarter of all Americans—and 2 out of 3 older Americans—have multiple chronic conditions, and treatment for these individuals accounts for 66 percent of the health care budget of the United States.

(4) Alzheimer's disease and related dementias, for instance, have a disproportionate health and economic impact on patients, particularly those suffering from multiple chronic conditions. In 2004, Medicare payments per person for beneficiaries aged 65 and older with Alzheimer's disease and other dementias were almost 3 times as high as average Medicare payments for other Medicare beneficiaries in the same age group. In addition, Alzheimer's patients often depend on full-time at home or institu-

tional care. Medicaid payments per person for Medicare beneficiaries aged 65 and older with Alzheimer's disease and other dementias were more than 9 times as great as average Medicaid payments for other Medicare beneficiaries in the same age group.

(5) The Medicare program under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) and the Medicaid program under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) cover about 70 percent of the total costs of caring for people with Alzheimer's disease. In 2011, Medicare is expected to spend approximately $93,000,000,000 for the care of individuals with Alzheimer's disease and other dementias, and this amount is projected to increase to $627,000,000,000 in 2050. Medicaid costs are expected to increase nearly 400 percent, from $34,000,000,000 in 2011 to $178,000,000,000 in 2050.

(6) Researchers believe sustained and targeted investment in outcomes oriented research for the leading causes of death will improve health treatments and make cures more obtainable.

(7) The United States Government has, in the past, successfully addressed major research chal-

lenges by committing resources in high-risk and high-reward basic and applied research.

SEC. 3. SPRINT PROGRAM.

Part A of title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"SEC. 230. SPRINT PROGRAM.

''(a) DEFINITIONS.—In this section:

''(1) ADVANCED RESEARCH AND DEVELOPMENT.—The term 'advanced research and development' means activities that predominantly are conducted after basic research through early clinical development of novel therapies, naturally occurring compounds, and repurposed or reformulated drugs, biological products, and devices in use to treat chronic conditions.

''(2) BIOLOGICAL PRODUCT.—The term 'biological product' has the meaning given such term in section 351.

''(3) DEVICE; DRUG.—The terms 'device' and 'drug' have the meanings given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act.

''(4) EARLY-STAGE COMPANY.—The term 'early-stage company' means a business enterprise

with a limited operating history, such as a start-up enterprise.

''(5) FEDERAL HEALTH CARE PROGRAM.—The term 'Federal health care program' has the meaning given such term in section 1128B(f) of the Social Security Act.

''(6) GROWTH COMPANY.—The term 'growth company' means a business enterprise that grows at a greater rate than the United States economy as a whole and that usually directs a relatively high proportion of income back into the business.

''(7) HIGH-COST CHRONIC CONDITION.—The term 'high-cost chronic condition' means a condition as determined by the Secretary under subsection (c)(1).

''(8) THERAPY.—The term 'therapy' means any drug, device, biological product, or diagnostic identified by the Secretary to treat, prevent, diagnose, delay-onset, cure, or aid recovery of a high-cost chronic condition.

''(b) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish the Spending Reductions through Innovations in Therapies Program (referred to in this section as the 'SPRINT Program') to support development of thera-

pies to reduce spending by Federal health care programs for high-cost chronic conditions.

''(c) HIGH-COST CHRONIC CONDITIONS.—

''(1) IN GENERAL.—The Secretary shall determine the high-cost chronic conditions that shall be the focus of the SPRINT Program. In making such determination, the Secretary shall select chronic conditions, from the top 10 leading causes of death designated by the Centers for Disease Control and Prevention, that have—

''(A) the highest current and projected cost to Federal health care programs and high long-term care costs;

''(B) a likelihood of reducing the day-to-day functioning of an individual and impairing the ability of the individual to carry out activities of daily living, which can result in the individual becoming dependent on caregivers;

''(C) a death rate that has increased and is projected to increase significantly in future years; and

''(D) a lack of existing therapies to prevent, control, or cure the condition or delay cognitive decline, if applicable.

''(2) ALLOCATION.—In carrying out the SPRINT Program, the Secretary shall allocate funding towards the chronic conditions as determined in paragraph (1).

''(d) GOALS.—The SPRINT Program shall be guided by national plans and strategies, as appropriate, and shall—

''(1) accelerate advanced research and development of therapies for high-cost chronic conditions; and

''(2) encourage innovation in technologies that may assist advanced research and development to reduce the time and cost of therapy development.

''(e) DUTIES.—The Secretary shall carry out the following duties under this section:

''(1) Convene meetings and working groups with representatives from relevant industries, academia, other Federal agencies, States, patients, patient and consumer advocacy organizations, international agencies (as appropriate), and other interested persons as the Secretary deems necessary.

''(2) Ensure that the activities described in paragraph (1) are coordinated among agencies within the Department of Health and Human Services.

''(3) Partner with a nonprofit strategic investment entity or entities that will advise the Department of Health and Human Services regarding, and may make on behalf of such Department, investments in public entities, nonprofit entities, early-stage companies, or growth companies with expertise in advanced research and development of therapies for high-cost chronic conditions that can demonstrate a reasonable likelihood of reducing net spending under the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of such Act within 10 years after the date of enactment of the Spending Reductions through Innovations in Therapies Agenda Act of 2012.

''(4) Award contracts, grants, cooperative agreements, or enter into other transactions, such as prize payments, to accelerate advanced research and development of therapies that have the potential to prevent, diagnose, delay-onset, cure, aid recovery, or improve health outcomes for high-cost chronic conditions, through the SPRINT Award Program under subsection (f).

''(5) Reduce the time and cost barriers between laboratory discoveries and clinical trials for therapies used to treat high-cost chronic conditions.

''(6) Facilitate innovative and expedited review by the Food and Drug Administration of the therapies developed under subsection (f), which may include—

''(A) facilitating regular and ongoing communication between the sponsors of such drugs, devices, diagnostics, and biological products and the Food and Drug Administration regarding the status of activities related to such drugs, devices, diagnostics, and biological products;

''(B) ensuring that such activities are coordinated with the approval requirements of the Food and Drug Administration, with the goal of expediting the development and approval of therapies; and

''(C) developing regulatory science, processes, and mechanisms to provide clear, efficient pathways for developing and manufacturing therapies for high-cost chronic conditions.

''(f) SPRINT AWARD PROGRAM.—

''(1) IN GENERAL.—There is established a SPRINT Award Program, under which the Secretary may, in consultation or partnership with a nonprofit strategic investment entity, award contracts, grants, cooperative agreements, or enter into other transactions, such as prize payments, to support advanced research and the development of therapies, in order to carry out paragraphs (4) and (6) of subsection (e). Awards granted through the SPRINT Award Program shall be funded by the SPRINT Program.

''(2) ELIGIBILITY; APPLICATION.—

''(A) ELIGIBILITY.—To be eligible to receive an award under this section, an entity shall be a public, nonprofit, early stage company, or growth company, which may include a private or public research institution, an institution of higher education, a medical center, a biotechnology company, a pharmaceutical company, a medical device company, an academic research institution, or other organization specializing in advanced research and development, and shall submit an application to the Secretary as described in subparagraph (B).

''(B) APPLICATION.—An entity desiring an award under this subsection shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require, such as—

''(i) a detailed description of the project for which the entity seeks an award;

''(ii) a timetable for carrying out such project;

''(iii) an assurance that the entity will submit interim reports and a final report at the conclusion of the award period, as determined appropriate by the Secretary under paragraph (3);

''(iv) a description of how the project will lead to the development of therapies aimed at preventing, curing, reversing, or slowing the progression of an underlying chronic condition; and

''(v) a description of how the project will support efforts to reduce long-term Federal spending on health care.

''(3) AWARDEE REPORTING REQUIREMENTS.—An entity that receives an award under this sub-

section shall submit reports to the Secretary which may include—

"(A) interim reports describing the progress in carrying out the project and compliance with all conditions of receipt of such award;

"(B) a final report at the conclusion of the award period describing—

"(i) the outcomes of the project, including whether the entity achieved the goals set forth in the application;

"(ii) the protocols the entity followed to carry out the research and comply with the research and ethical standards of the National Institutes of Health, if applicable; and

"(iii) the standards and regulatory requirements of the Food and Drug Administration at all stages of development, manufacturing, review, approval, and safety surveillance, if applicable; and

"(C) such additional information required by the Secretary.

"(4) TERMINATION OF FUNDING.—The Secretary may modify or terminate a contract, grant,

cooperative agreement, other transaction, or prize to an awardee that does not meet milestones that are conditions of the contract, grant, cooperative agreement, other transaction, or prize.

"(5) CONSULTATION WITH NONPROFIT STRATEGIC INVESTMENT ENTITY.—In making awards under this subsection, the Secretary may consult or partner with a nonprofit strategic investment entity or entities that—

"(A) operate independently of the Department of Health and Human Services and consist of experts in neurology, biomedical research, drug and medical technology innovation and discovery, economics, and venture financing; and

"(B) have a record of—

"(i) promoting the development of therapies; and

"(ii) supporting novel technologies that have the potential to improve the development of therapies.

"(6) MATCHING FUNDS.—

"(A) IN GENERAL.—The Secretary may not make an award under this section unless the recipient involved agrees to make available

non-Federal contributions, in cash or in-kind, toward the costs of the project in an amount equal to not less than $2 for each $1 of Federal funds provided in the award. Such contributions may be made directly or through donations from public or private entities. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

''(B) EXCEPTION.—The Secretary may waive or modify the matching requirement under subparagraph (A) on a case-by-case basis for each award if the Secretary determines that the goals and objectives of the SPRINT Award Program cannot adequately be carried out unless such requirement is waived.

''(g) NON-DUPLICATION OF EFFORTS.—The Secretary shall ensure that the activities under this section complement and extend other efforts of the Department of Health and Human Services.

''(h) GIFTS IN SUPPORT OF THE SPRINT AWARD PROGRAM.—The Secretary may accept on behalf of the United States money gifts and bequests made uncondi-

tionally to the SPRINT Award Program under subsection (f) for the benefit of the Award Program or any activity financed through such Award Program.

''(i) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2013, and such sums as may be necessary for each of fiscal years 2014 through 2017. Funds appropriated under this section shall be available until expended.''.

SEC. 4. EVALUATION AND REPORT.

(a) EVALUATION.—The Secretary of Health and Human Services shall evaluate the projects funded under section 230 of the Public Health Service Act (as added by section 3) as necessary and shall make publicly available and disseminate the results of such evaluations on as wide a basis as practicable.

(b) REPORTS.—Not later than 2 years after the date of enactment of this Act, and annually thereafter, the Secretary of Health and Human Services shall submit to Congress a report that—

(1) describes the specific projects supported under section 230 of the Public Health Service Act (as added by section 3) and progress towards meeting science-based metrics;

(2) provides recommendations for Congress to improve the effectiveness of the programs under such section 230;

(3) explains why the Secretary waived or modified matching funds requirements for an award under subsection (f) of such section 230, if applicable; and

(4) describes how advanced research and development supported through the SPRINT Program under such section 230 is directed towards reducing Federal spending on high-cost chronic conditions (as defined in such section).

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