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H. R. 2283

To provide better care and outcomes for Americans living with Alzheimer's disease and related dementias and their caregivers while accelerating progress toward prevention strategies, disease modifying treatments, and, ultimately, a cure.

IN THE HOUSE OF REPRESENTATIVES

APRIL 10, 2019

Ms. SÁNCHEZ (for herself, Mr. LAHOOD, Ms. MATSUI, and Mrs. RODGERS of Washington) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To provide better care and outcomes for Americans living with Alzheimer's disease and related dementias and their caregivers while accelerating progress toward prevention strategies, disease modifying treatments, and, ultimately, a cure.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS; FINDINGS.

(a) SHORT TITLE.—This Act may be cited as the ''Concentrating on High-value Alzheimer's Needs to Get to an End Act of 2019'' or the ''CHANGE Act of 2019''.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

(c) FINDINGS.—Congress finds as follows:

(1) It is estimated that 5.8 million Americans are living with Alzheimer's disease in 2019. This includes an estimated 5.6 million people age 65 and older and approximately 200,000 individuals under age 65 who have younger-onset Alzheimer's. By 2050, the number of people age 65 and older with Alzheimer's dementia is projected to increase to 13.8 million Americans.

(2) As many as half of the estimated 5,100,000 American seniors with Alzheimer's disease and other dementias have never received a diagnosis.

(3) In 2019, it is estimated that Alzheimer's and related dementias will have cost the Medicare and Medicaid programs $195 billion. By 2050, it is

estimated that these direct costs will increase to as much as $1.1 trillion.

(4) Alzheimer's exacts an emotional and physical toll on caregivers, resulting in higher incidence of heart disease, cancer, depression, and other health consequences.

(5) Alzheimer's disease disproportionately impacts women and people of color. Women are twice as likely to develop Alzheimer's as they are breast cancer. African Americans are about two times more likely than White Americans to have Alzheimer's disease and other dementias. Latinos are about one and one-half times more likely than White Americans to have Alzheimer's disease and other dementias. According to the Centers for Disease Control and Prevention, among people ages 65 and older, African Americans have the highest prevalence of Alzheimer's disease and related dementias (13.8 percent), followed by Hispanics (12.2 percent), and non-Hispanic Whites (10.3 percent), American Indian and Alaska Natives (9.1 percent), and Asian and Pacific Islanders (8.4 percent). This higher prevalence translates into a higher death rate: Alzheimer's deaths increased 55 percent among all Americans between 1999 and 2014, while the num-

ber was 107 percent for Latinos and 99 percent for African Americans.

(6) There are evidence-based, reliable, and NIH-identified cognitive impairment detection tools available at the National Institute on Aging's Alzheimer's and Dementia Resources for Professionals website that must replace detection by direct observation in the Medicare Annual visits and Welcome to Medicare visits. The NIH-identified tools will allow for appropriate follow-up instead of delaying diagnosis or impeding opportunities for patients to access timely treatment options, including clinical trial participation.

(7) An early, documented diagnosis, communicated to the patient and caregiver, enables early access to care planning services and available medical and nonmedical treatments, and optimizes patients' ability to build a care team, participate in support services, and enroll in clinical trials.

(8) African Americans represent 13 percent of the population of the United States but only 5 percent of clinical trial participants, and Latinos represent 17 percent of the population of the United States but less than one percent of clinical trial participants. Further, Latinos and African Americans

account for only 3.5 percent and 1.2 percent, respectively, of principal investigators supported by the National Institutes of Health funding, limiting this perspective in research. Better recruitment and trial designs are critical to addressing innovation in Alzheimer's generally, including the underrepresentation of African Americans and Latinos.

(9) Inability to identify eligible patients at the earliest stages of disease is a substantial impediment to efficient research toward Alzheimer's disease prevention, treatment, and cure.

(10) Advancing treatment options to prevent, treat, or cure Alzheimer's is an urgent national priority.

(11) A paradigm shift to drive synergies between high-value patient care, caregiver support, brain health promotion, and research initiatives is our best hope for preventing, treating, and curing Alzheimer's disease.

SEC. 2. COGNITIVE IMPAIRMENT DETECTION BENEFIT IN THE MEDICARE ANNUAL WELLNESS VISIT AND INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) ANNUAL WELLNESS VISIT.—

(1) IN GENERAL.—Section 1861(hhh)(2) of the Social Security Act (42 U.S.C. 1395x(hhh)(2)) is amended—

(A) by striking subparagraph (D) and inserting the following:

''(D) Detection of any cognitive impairment or progression of cognitive impairment that shall—

''(i) be performed using a cognitive impairment detection tool identified by the National Institute on Aging as meeting its criteria for selecting instruments to detect cognitive impairment in the primary care setting, and other validated cognitive detection tools as the Secretary determines;

''(ii) include documentation of the tool used for detecting cognitive impairment and results of the assessment in the patient's medical record; and

''(iii) take into consideration the tool used, and results of, any previously performed cognitive impairment detection assessment.'';

(B) by redesignating subparagraph (I) as subparagraph (J); and

(C) by inserting after subparagraph (H) the following new subparagraph:

''(I) Referral of patients with detected cognitive impairment or potential cognitive decline to—

''(i) appropriate Alzheimer's disease and dementia diagnostic services, including amyloid positron emission tomography, and other medically accepted diagnostic tests that the Secretary determines are safe and effective;

''(ii) specialists and other clinicians with expertise in diagnosing or treating Alzheimer's disease and related dementias;

''(iii) available community-based services, including patient and caregiver counseling and social support services; and

''(iv) appropriate clinical trials.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to annual wellness visits furnished on or after January 1, 2020.

(b) INITIAL PREVENTIVE PHYSICAL EXAMINATION.—

(1) IN GENERAL.—Section 1861(ww)(1) of the Social Security Act (42 U.S.C. 1395x(ww)(1)) is

amended by striking ''agreement with the individual, and'' and inserting ''agreement with the individual, detection of any cognitive impairment or progression of cognitive impairment as described in subparagraph (D) of subsection (hhh)(2) and referrals as described in subparagraph (I) of such subsection, and''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to initial preventive physical examinations furnished on or after January 1, 2020.

SEC. 3. MEDICARE QUALITY PAYMENT PROGRAM.

Not later than January 1, 2020, the Secretary of Health and Human Services shall implement Medicare policies under title XVIII of the Social Security Act, including quality measures and Medicare Advantage plan rating and risk adjustment mechanisms, that reflect the public health imperative of—

(1) promoting healthy brain lifestyle choices;

(2) identifying and responding to patient risk factors for Alzheimer's disease and related dementias; and

(3) incentivizing providers for—

(A) adequate and reliable cognitive impairment detection in the primary care setting, that

is documented in the patient's electronic health record and communicated to the patient;

(B) timely Alzheimer's disease diagnosis; and

(C) appropriate care planning services, including identification of, and communication with patients and caregivers about, the potential for clinical trial participation.

SEC. 4. REPORT TO CONGRESS ON IMPLEMENTATION OF THIS ACT.

Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to Congress on the implementation of the provisions of, and amendments made by, this Act, including—

(1) the increased use of validated tools for detection of cognitive impairment and Alzheimer's disease;

(2) utilization of Alzheimer's disease diagnostic and care planning services; and

(3) outreach efforts in the primary care and patient communities.

SEC. 5. STUDY AND REPORT ON REGULATORY AND LEGISLATIVE CHANGES OR REFINEMENTS THAT WOULD ACCELERATE ALZHEIMER'S DISEASE RESEARCH PROGRESS.

(a) IN GENERAL.—The Comptroller General of the United States (in this section referred to as the ''Comptroller General'') shall conduct a study on regulatory and legislative changes or refinements that would accelerate Alzheimer's disease research progress. In conducting such study, the Comptroller General shall consult with interested stakeholders, including industry leaders, researchers, clinical experts, patient advocacy groups, caregivers, patients, providers, and State leaders. Such study shall include an analysis of innovative public-private partnerships, innovative financing tools, incentives, and other mechanisms to enhance the quality of care for individuals diagnosed with Alzheimer's disease, reduce the emotional, financial, and physical burden on familial care partners, and accelerate development of preventative, curative, and disease-modifying therapies.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the study conducted under subsection (a), together with rec-

ommendations for such legislation and administrative action as the Comptroller General determines appropriate.

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