116TH CONGRESS
1ST SESSION

S. 1126

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 SENATE OF THE UNITED STATES

APRIL 10, 2019

Mrs. CAPITO (for herself, Ms. STABENOW, Mr. WICKER, and Mr. MENENDEZ) introduced the following bill; which was read twice and referred to the Committee on Finance

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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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

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

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

Sec. 1. Short title; table of contents; findings.
Sec. 2. Cognitive impairment detection benefit in the Medicare annual wellness visit and initial preventive physical examination.
Sec. 3. Medicare quality payment program.
Sec. 4. Report to Congress on implementation.

3 (c) FINDINGS.—Congress finds the following:
4 (1) It is estimated that 5,800,000 million
5 Americans are living with Alzheimer's disease in
6 2019. This includes an estimated 5,600,000 million
7 people age 65 and older and approximately 200,000
8 individuals under age 65 who have younger-onset
9 Alzheimer's. By 2050, the number of people age 65
10 and older with Alzheimer's dementia is projected to
11 increase to 13,800,000 Americans.
12 (2) As many as half of the estimated 5,100,000
13 American seniors with Alzheimer's disease and other
14 dementias have never received a diagnosis.
15 (3) In 2019, it is expected that Alzheimer's and
16 related dementias will cost Medicare and Medicaid
17 $195,000,000,000. By 2050, it is estimated that
18 overall Alzheimer's costs will increase to more than
19 $1,100,000,000,000.
20 (4) Alzheimer's exacts an emotional and phys-
21 ical toll on caregivers, resulting in higher incidence
22 of heart disease, cancer, depression, and other health
23 consequences.

1 (5) Alzheimer's disease disproportionately im-
2 pacts women and people of color. Women are twice
3 as likely to develop Alzheimer's as they are breast
4 cancer. African Americans are about 2 times more
5 likely than White Americans to have Alzheimer's dis-
6 ease and other dementias. Latinos are about 1½
7 times more likely than White Americans to have Alz-
8 heimer's disease and other dementias. According to
9 the Centers for Disease Control, among people ages
10 65 and older, African Americans have the highest
11 prevalence of Alzheimer's disease and related demen-
12 tias (13.8 percent), followed by Hispanics (12.2 per-
13 cent), and non-Hispanic Whites (10.3 percent),
14 American Indian and Alaska Natives (9.1 percent),
15 and Asian and Pacific Islanders (8.4 percent). This
16 higher prevalence translates into a higher death
17 rate: Alzheimer's deaths increased 55 percent among
18 all Americans between 1999 and 2014, while the
19 number was 107 percent for Latinos and 99 percent
20 for African Americans.

21 (6) The latest science reveals there are actions
22 that can be taken both now and across the lifespan
23 of an individual to help optimize brain health, reduce
24 the risk of cognitive decline, and help mitigate symp-
25 toms. There are also important behavioral and social

1 dimensions that could delay cognitive decline and
2 build a resilient brain. For example, a 2016 study
3 supported by the National Institutes of Health
4 found that a diet high in natural plant-based foods
5 and limited in saturated fats was associated with re-
6 duced cognitive decline. A 2017 study published by
7 the Lancet Commission found that physical activity
8 had a significant protective effect against cognitive
9 decline. A study supported by the National Insti-
10 tutes of Health which was published in 2018 found
11 a connection between lower blood pressure and de-
12 creased cognitive impairment. An American Acad-
13 emy of Neurology study recently published found
14 that physical activity and cognitive activity were
15 both associated with reduced risk of total dementia.
16 (7) There are evidence-based, reliable, and Na-
17 tional Institutes of Health-identified cognitive im-
18 pairment detection tools that are available on the
19 Alzheimer's and Dementia Resources website of the
20 National Institute on Aging that must replace detec-
21 tion by direct observation in the Medicare Annual
22 visits and Welcome to Medicare visits. The National
23 Institutes of Health-identified tools will allow for ap-
24 propriate follow-up instead of delaying diagnosis or
25 impeding opportunities for patients to access timely

1 treatment options, including clinical trial participa-
2 tion.
3 (8) An early, documented diagnosis, commu-
4 nicated to the patient and caregiver, enables early
5 access to care planning services and available med-
6 ical and nonmedical treatments, and optimizes the
7 ability of patients to build a care team, participate
8 in support services, and enroll in clinical trials.
9 (9) African Americans represent 13 percent of
10 the United States population, but only 5 percent of
11 clinical trial participants, and Latinos represent 17
12 percent of the United States population, but less
13 than 1 percent of clinical trial participants. Further,
14 Latinos and African Americans account for only 3.5
15 percent and 1.2 percent, respectively, of principal in-
16 vestigators supported by the National Institutes of
17 Health funding, limiting this perspective in research.
18 Better recruitment and trial designs are critical to
19 addressing innovation in Alzheimer's generally, in-
20 cluding the underrepresentation of African Ameri-
21 cans and Latinos.
22 (10) Inability to identify eligible patients at the
23 earliest stages of disease is a substantial impediment
24 to efficient research toward Alzheimer's disease pre-
25 vention, treatment, and cure.

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

(12) 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

1 care setting, and other validated cognitive detection
2 tools as the Secretary determines;
3 "(ii) include documentation of the tool used for
4 detecting cognitive impairment and results of the as-
5 sessment in the medical record of the patient; and
6 "(iii) take into consideration the tool used, and
7 results of, any previously performed cognitive im-
8 pairment detection assessment.";
9 (B) by moving subparagraphs (G) and (H)
10 two ems to the left;
11 (C) by redesignating subparagraph (I) as
12 subparagraph (J); and
13 (D) by inserting after subparagraph (H)
14 the following new subparagraph:
15 "(I) Referral of patients with detected cognitive
16 impairment or potential cognitive decline to—
17 "(i) appropriate Alzheimer's disease and
18 dementia diagnostic services, including amyloid
19 positron emission tomography, and other medi-
20 cally accepted diagnostic tests that the Sec-
21 retary determines are safe and effective;
22 "(ii) specialists and other clinicians with
23 expertise in diagnosing or treating Alzheimer's
24 disease and related dementias;

1 “(iii) available community-based services,
2 including patient and caregiver counseling and
3 social support services; and
4 “(iv) appropriate clinical trials.”.
5 (2) EFFECTIVE DATE.—The amendments made
6 by paragraph (1) shall apply to annual wellness vis-
7 its furnished on or after January 1, 2020.
8 (b) INITIAL PREVENTIVE PHYSICAL EXAMINA-
9 TION.—
10 (1) IN GENERAL.—Section 1861(ww)(1) of the
11 Social Security Act (42 U.S.C. 1395x(ww)(1)) is
12 amended by inserting “detection of any cognitive im-
13 pairment or progression of cognitive impairment as
14 described in subparagraph (D) of subsection
15 (hhh)(2) and referrals as described in subparagraph
16 (I) of such subsection,” after “upon the agreement
17 with the individual,”.
18 (2) EFFECTIVE DATE.—The amendments made
19 by paragraph (1) shall apply to initial preventive
20 physical examinations furnished on or after January
21 1, 2020.
22 **SEC. 3. MEDICARE QUALITY PAYMENT PROGRAM.**
23 Not later than January 1, 2020, the Secretary of
24 Health and Human Services shall implement Medicare
25 policies under title XVIII of the Social Security Act (42

1 U.S.C. 1395 et seq.), including quality measures and
2 Medicare Advantage plan rating and risk adjustment
3 mechanisms, that reflect the public health imperative of—
4 (1) promoting healthy brain lifestyle choices;
5 (2) identifying and responding to patient risk
6 factors for Alzheimer's disease and related demen-
7 tias; and
8 (3) incentivizing providers for—
9 (A) adequate and reliable cognitive impair-
10 ment detection in the primary care setting, that
11 is documented in the electronic health record of
12 the patient and communicated to the patient;
13 (B) timely Alzheimer's disease diagnosis;
14 and
15 (C) appropriate care planning services, in-
16 cluding identification of, and communication
17 with patients and caregivers regarding, the po-
18 tential for clinical trial participation.

19 **SEC. 4. REPORT TO CONGRESS ON IMPLEMENTATION.**

20 Not later than 3 years after the date of the enact-
21 ment of this Act, the Secretary of Health and Human
22 Services shall submit to Congress a report on the imple-
23 mentation of the provisions of, and amendments made by,
24 this Act, including—

1 (1) the increased use of validated tools for de-
2 tection of cognitive impairment and Alzheimer's dis-
3 ease;
4 (2) utilization of Alzheimer's disease diagnostic
5 and care planning services; and
6 (3) outreach efforts in the primary care and pa-
7 tient communities.

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