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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R.

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

Ms. SÁNCHEZ introduced the following bill; which was referred to the Committee on _____

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 Act of 2019” or the “CHANGE Act”.

1 (b) TABLE OF CONTENTS.—The table of contents of
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 of this Act.
- Sec. 5. Study and report on regulatory and legislative changes or refinements that would accelerate Alzheimer's disease research progress.

3 (c) FINDINGS.—Congress finds as follows:

4 (1) It is estimated that 5.8 million Americans
5 are living with Alzheimer's disease in 2019. This in-
6 cludes an estimated 5.6 million people age 65 and
7 older and approximately 200,000 individuals under
8 age 65 who have younger-onset Alzheimer's. By
9 2050, the number of people age 65 and older with
10 Alzheimer's dementia is projected to increase to 13.8
11 million 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 2018 it is estimated that Alzheimer's
16 and related dementias will have cost the Medicare
17 and Medicaid programs \$186 billion. By 2050, it is
18 estimated that these direct costs will increase to as
19 much as \$750 billion.

20 (4) Alzheimer's exacts an emotional and phys-
21 ical toll on caregivers, resulting in higher incidence

1 of heart disease, cancer, depression, and other health
2 consequences.

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

24 (6) There are evidence-based, reliable, and
25 NIH-identified cognitive impairment detection tools

1 available at the National Institute on Aging's Alz-
2 heimer's and Dementia Resources for Professionals
3 website that must replace detection by direct obser-
4 vation in the Medicare Annual visits and Welcome to
5 Medicare visits. The NIH-identified tools will allow
6 for appropriate follow-up instead of delaying diag-
7 nosis or opportunities for patients to access timely
8 treatment options, including clinical trial participa-
9 tion.

10 (7) An early, documented diagnosis, commu-
11 nicated to the patient and caregiver, enables early
12 access to care planning services and available med-
13 ical and nonmedical treatments, and optimizes pa-
14 tients' ability to build a care team, participate in
15 support services, and enroll in clinical trials.

16 (8) African Americans represent 13 percent of
17 the population of the United States but only 5 per-
18 cent of clinical trial participants, and Latinos rep-
19 resent 17 percent of the population of the United
20 States but less than one percent of clinical trial par-
21 ticipants. Further, Latinos and African Americans
22 account for only 3.5 percent and 1.2 percent, respec-
23 tively, of principal investigators supported by the
24 National Institutes of Health funding, limiting this
25 perspective in research. Better recruitment and trial

1 designs are critical to addressing innovation in Alz-
2 heimer's generally, including the underrepresentation
3 of African Americans and Latinos.

4 (9) Inability to identify eligible patients at the
5 earliest stages of disease is a substantial impediment
6 to efficient research toward Alzheimer's disease pre-
7 vention, treatment, and cure.

8 (10) Advancing treatment options to prevent,
9 treat, or cure Alzheimer's is an urgent national pri-
10 ority.

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

16 **SEC. 2. COGNITIVE IMPAIRMENT DETECTION BENEFIT IN**
17 **THE MEDICARE ANNUAL WELLNESS VISIT**
18 **AND INITIAL PREVENTIVE PHYSICAL EXAM-**
19 **INATION.**

20 (a) ANNUAL WELLNESS VISIT.—

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

24 (A) by striking subparagraph (D) and in-
25 serting the following:

1 “(D) Detection of any cognitive impair-
2 ment or progression of cognitive impairment
3 that shall—

4 “(i) be performed using a cognitive
5 impairment detection tool identified by the
6 National Institute on Aging as meeting its
7 criteria for selecting instruments to detect
8 cognitive impairment in the primary care
9 setting, and other validated cognitive de-
10 tection tools as the Secretary determines;

11 “(ii) include documentation of the tool
12 used for detecting cognitive impairment
13 and results of the assessment in the pa-
14 tient’s medical record; and

15 “(iii) take into consideration the tool
16 used, and results of, any previously per-
17 formed cognitive impairment detection as-
18 sessment.”;

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

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

23 “(I) Referral of patients with detected cog-
24 nitive impairment or potential cognitive decline
25 to—

1 “(i) appropriate Alzheimer’s disease
2 and dementia diagnostic services, including
3 amyloid positron emission tomography, and
4 other medically accepted diagnostic tests
5 that the Secretary determines are safe and
6 effective;

7 “(ii) specialists and other clinicians
8 with expertise in diagnosing or treating
9 Alzheimer’s disease and related dementias;

10 “(iii) available community-based serv-
11 ices, including patient and caregiver coun-
12 seling and social support services; and

13 “(iv) appropriate clinical trials.”.

14 (2) EFFECTIVE DATE.—The amendments made
15 by paragraph (1) shall apply to annual wellness vis-
16 its furnished on or after January 1, 2020.

17 (b) INITIAL PREVENTIVE PHYSICAL EXAMINA-
18 TION.—

19 (1) IN GENERAL.—Section 1861(ww)(1) of the
20 Social Security Act (42 U.S.C. 1395x(ww)(1)) is
21 amended by striking “agreement with the individual,
22 and” and inserting “agreement with the individual,
23 detection of any cognitive impairment or progression
24 of cognitive impairment as described in subpara-
25 graph (D) of subsection (hhh)(2) and referrals as

1 described in subparagraph (I) of such subsection,
2 and”.

3 (2) EFFECTIVE DATE.—The amendments made
4 by paragraph (1) shall apply to initial preventive
5 physical examinations furnished on or after January
6 1, 2020.

7 **SEC. 3. MEDICARE QUALITY PAYMENT PROGRAM.**

8 Not later than January 1, 2020, the Secretary of
9 Health and Human Services shall implement Medicare
10 policies under title XVIII of the Social Security Act, in-
11 cluding quality measures and Medicare Advantage plan
12 rating and risk adjustment mechanisms, that reflect the
13 public health imperative of—

14 (1) promoting healthy brain lifestyle choices;

15 (2) identifying and responding to patient risk
16 factors for Alzheimer’s disease and related demen-
17 tias; and

18 (3) incentivizing providers for—

19 (A) adequate and reliable cognitive impair-
20 ment detection in the primary care setting, that
21 is documented in the patient’s electronic health
22 record and communicated to the patient;

23 (B) timely Alzheimer’s disease diagnosis;
24 and

1 (C) appropriate care planning services, in-
2 cluding identification of, and communication
3 with patients and caregivers about, the poten-
4 tial for clinical trial participation.

5 **SEC. 4. REPORT TO CONGRESS ON IMPLEMENTATION OF**
6 **THIS ACT.**

7 Not later than 3 years after the date of the enact-
8 ment of this Act, the Secretary of Health and Human
9 Services shall submit a report to Congress on the imple-
10 mentation of the provisions of, and amendments made by,
11 this Act, including—

12 (1) the increased use of validated tools for de-
13 tection of cognitive impairment and Alzheimer’s dis-
14 ease;

15 (2) utilization of Alzheimer’s disease diagnostic
16 and care planning services; and

17 (3) outreach efforts in the primary care and pa-
18 tient communities.

19 **SEC. 5. STUDY AND REPORT ON REGULATORY AND LEGIS-**
20 **LATIVE CHANGES OR REFINEMENTS THAT**
21 **WOULD ACCELERATE ALZHEIMER’S DISEASE**
22 **RESEARCH PROGRESS.**

23 (a) IN GENERAL.—The Comptroller General of the
24 United States (in this section referred to as the “Comp-
25 troller General”) shall conduct a study on regulatory and

1 legislative changes or refinements that would accelerate
2 Alzheimer's disease research progress. In conducting such
3 study, the Comptroller General shall consult with inter-
4 ested stakeholders, including industry leaders, researchers,
5 clinical experts, patient advocacy groups, caregivers, pa-
6 tients, providers, and State leaders. Such study shall in-
7 clude an analysis of innovative public-private partnerships,
8 innovative financing tools, incentives and other mecha-
9 nisms to enhance the quality of care for individuals diag-
10 nosed with Alzheimer's disease, reduce the emotional, fi-
11 nancial, and physical burden on familial care partners,
12 and accelerate development of preventative, curative, and
13 disease-modifying therapies.

14 (b) REPORT.—Not later than 1 year after the date
15 of the enactment of this Act, the Comptroller General shall
16 submit to Congress a report containing the results of the
17 study conducted under subsection (a), together with rec-
18 ommendations for such legislation and administrative ac-
19 tion as the Comptroller General determines appropriate.