

116TH CONGRESS  
1ST SESSION

# 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.

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## 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.

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

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

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

5 (b) TABLE OF CONTENTS.—The table of contents of  
6 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.

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

8 (1) It is estimated that 5.8 million Americans  
9 are living with Alzheimer’s disease in 2019. This in-  
10 cludes an estimated 5.6 million people age 65 and  
11 older and approximately 200,000 individuals under  
12 age 65 who have younger-onset Alzheimer’s. By  
13 2050, the number of people age 65 and older with  
14 Alzheimer’s dementia is projected to increase to 13.8  
15 million Americans.

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

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

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

3           (4) Alzheimer's exacts an emotional and phys-  
4       ical toll on caregivers, resulting in higher incidence  
5       of heart disease, cancer, depression, and other health  
6       consequences.

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

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

3           (6) There are evidence-based, reliable, and  
4       NIH-identified cognitive impairment detection tools  
5       available at the National Institute on Aging's Alz-  
6       heimer's and Dementia Resources for Professionals  
7       website that must replace detection by direct obser-  
8       vation in the Medicare Annual visits and Welcome to  
9       Medicare visits. The NIH-identified tools will allow  
10      for appropriate follow-up instead of delaying diag-  
11      nosis or impeding opportunities for patients to ac-  
12      cess timely treatment options, including clinical trial  
13      participation.

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

20          (8) African Americans represent 13 percent of  
21      the population of the United States but only 5 per-  
22      cent of clinical trial participants, and Latinos rep-  
23      resent 17 percent of the population of the United  
24      States but less than one percent of clinical trial par-  
25      ticipants. Further, Latinos and African Americans

1 account for only 3.5 percent and 1.2 percent, respec-  
2 tively, of principal investigators supported by the  
3 National Institutes of Health funding, limiting this  
4 perspective in research. Better recruitment and trial  
5 designs are critical to addressing innovation in Alz-  
6 heimer's generally, including the underrepresentation  
7 of African Americans and Latinos.

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

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

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

20 **SEC. 2. COGNITIVE IMPAIRMENT DETECTION BENEFIT IN**  
21 **THE MEDICARE ANNUAL WELLNESS VISIT**  
22 **AND INITIAL PREVENTIVE PHYSICAL EXAM-**  
23 **INATION.**

24 (a) ANNUAL WELLNESS VISIT.—

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

4           (A) by striking subparagraph (D) and in-  
5       serting the following:

6           “(D) Detection of any cognitive impair-  
7       ment or progression of cognitive impairment  
8       that shall—

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

16          “(ii) include documentation of the tool  
17       used for detecting cognitive impairment  
18       and results of the assessment in the pa-  
19       tient’s medical record; and

20          “(iii) take into consideration the tool  
21       used, and results of, any previously per-  
22       formed cognitive impairment detection as-  
23       sessment.”;

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

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

3 “(I) Referral of patients with detected cog-  
 4 nitive impairment or potential cognitive decline  
 5 to—

6 “(i) appropriate Alzheimer’s disease  
 7 and dementia diagnostic services, including  
 8 amyloid positron emission tomography, and  
 9 other medically accepted diagnostic tests  
 10 that the Secretary determines are safe and  
 11 effective;

12 “(ii) specialists and other clinicians  
 13 with expertise in diagnosing or treating  
 14 Alzheimer’s disease and related dementias;

15 “(iii) available community-based serv-  
 16 ices, including patient and caregiver coun-  
 17 seling and social support services; and

18 “(iv) appropriate clinical trials.”.

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

22 (b) INITIAL PREVENTIVE PHYSICAL EXAMINA-  
 23 TION.—

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

1 amended by striking “agreement with the individual,  
2 and” and inserting “agreement with the individual,  
3 detection of any cognitive impairment or progression  
4 of cognitive impairment as described in subpara-  
5 graph (D) of subsection (hhh)(2) and referrals as  
6 described in subparagraph (I) of such subsection,  
7 and”.

8 (2) EFFECTIVE DATE.—The amendments made  
9 by paragraph (1) shall apply to initial preventive  
10 physical examinations furnished on or after January  
11 1, 2020.

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

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

19 (1) promoting healthy brain lifestyle choices;

20 (2) identifying and responding to patient risk  
21 factors for Alzheimer’s disease and related demen-  
22 tias; and

23 (3) incentivizing providers for—

24 (A) adequate and reliable cognitive impair-  
25 ment detection in the primary care setting, that

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

3 (B) timely Alzheimer's disease diagnosis;  
4 and

5 (C) appropriate care planning services, in-  
6 cluding identification of, and communication  
7 with patients and caregivers about, the poten-  
8 tial for clinical trial participation.

9 **SEC. 4. REPORT TO CONGRESS ON IMPLEMENTATION OF**  
10 **THIS ACT.**

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

16 (1) the increased use of validated tools for de-  
17 tection of cognitive impairment and Alzheimer's dis-  
18 ease;

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

21 (3) outreach efforts in the primary care and pa-  
22 tient communities.

1 **SEC. 5. STUDY AND REPORT ON REGULATORY AND LEGIS-**  
2 **LATIVE CHANGES OR REFINEMENTS THAT**  
3 **WOULD ACCELERATE ALZHEIMER’S DISEASE**  
4 **RESEARCH PROGRESS.**

5 (a) IN GENERAL.—The Comptroller General of the  
6 United States (in this section referred to as the “Comp-  
7 troller General”) shall conduct a study on regulatory and  
8 legislative changes or refinements that would accelerate  
9 Alzheimer’s disease research progress. In conducting such  
10 study, the Comptroller General shall consult with inter-  
11 ested stakeholders, including industry leaders, researchers,  
12 clinical experts, patient advocacy groups, caregivers, pa-  
13 tients, providers, and State leaders. Such study shall in-  
14 clude an analysis of innovative public-private partnerships,  
15 innovative financing tools, incentives, and other mecha-  
16 nisms to enhance the quality of care for individuals diag-  
17 nosed with Alzheimer’s disease, reduce the emotional, fi-  
18 nancial, and physical burden on familial care partners,  
19 and accelerate development of preventative, curative, and  
20 disease-modifying therapies.

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

1 ommendations for such legislation and administrative ac-  
2 tion as the Comptroller General determines appropriate.

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