

117TH CONGRESS
1ST SESSION

H. R. 3354

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

MAY 19, 2021

Ms. SÁNCHEZ (for herself, Mr. LAHOOD, Ms. MATSUI, Mr. UPTON, Ms. SHERRILL, Ms. BARRAGÁN, Mr. POSEY, Ms. STEVENS, Mr. FITZPATRICK, Mr. LOWENTHAL, Ms. NORTON, Mr. WELCH, Mr. KINZINGER, Ms. WATERS, Ms. NEWMAN, Mr. DEFazio, Mr. COLE, Mr. SUOZZI, Mrs. DEMINGS, Mr. GROTHMAN, Mr. MICHAEL F. DOYLE of Pennsylvania, Mr. KEATING, Ms. KUSTER, and Mr. GRIJALVA) 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

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 2021” or the “CHANGE Act of 2021”.

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 6.2 million Americans
9 age 65 and older are living with Alzheimer’s disease
10 in 2021. More than one in nine people age 65 and
11 older has Alzheimer’s. By 2050, the number of
12 Americans age 65 and older with Alzheimer’s de-
13 mentia is projected to reach 12.7 million.

14 (2) Alzheimer’s disease disproportionately im-
15 pacts women and people of color.

16 (3) Almost two-thirds of Americans with Alz-
17 heimer’s disease are women.

18 (4) According to the Centers for Disease Con-
19 trol and Prevention, among people ages 65 and
20 older, African Americans have the highest prevalence
21 of Alzheimer’s disease and related dementias (13.8
22 percent), followed by Hispanics (12.2 percent), and

1 non-Hispanic Whites (10.3 percent), American In-
2 dian and Alaska Natives (9.1 percent), and Asian
3 and Pacific Islanders (8.4 percent). This higher
4 prevalence translates into a higher death rate: Alz-
5 heimer's deaths increased 55 percent among all
6 Americans between 1999 and 2014, while the num-
7 ber was 107 percent for Latinos and 99 percent for
8 African Americans.

9 (5) Currently available data shows that about
10 half of individuals age 65 and older with mild cog-
11 nitive impairment (MCI)—roughly 5 million Ameri-
12 cans—have MCI due to Alzheimer's disease. Ap-
13 proximately 15 percent of individuals with MCI de-
14 velop dementia after two years and 32 percent de-
15 velop Alzheimer's dementia within five years' follow-
16 up.

17 (6) Addressing modifiable risk factors such as
18 physical activity, smoking, education, staying socially
19 and mentally active, blood pressure, and diet might
20 prevent or delay up to 40 percent of dementia cases.

21 (7) An early, documented diagnosis, commu-
22 nicated to the patient and caregiver, enables early
23 access to care planning services and available med-
24 ical and nonmedical treatments, and optimizes pa-

tients' ability to build a care team, participate in support services, and enroll in clinical trials.

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

(9) More than 11 million Americans provide unpaid care for people with Alzheimer's or other dementia and provided nearly \$257 billion in unpaid care to people living with Alzheimer's and other dementias in 2020.

(10) In 2021, it is estimated that Alzheimer's and related dementias will have cost Medicare and Medicaid programs \$239 billion. By 2050, it is estimated that these direct costs will increase to as much as \$1.1 trillion.

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

(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—

1 (A) by striking subparagraph (D) and in-
2 serting the following:

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

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

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

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

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

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

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

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

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

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

16 “(iv) appropriate clinical trials.”.

17 (2) EFFECTIVE DATE.—The amendments made
18 by paragraph (1) shall apply to annual wellness vis-
19 its furnished on or after January 1, 2022.

20 (b) INITIAL PREVENTIVE PHYSICAL EXAMINA-
21 TION.—

22 (1) IN GENERAL.—Section 1861(ww)(1) of the
23 Social Security Act (42 U.S.C. 1395x(ww)(1)) is
24 amended by striking “agreement with the individual,
25 and” and inserting “agreement with the individual,

1 detection of any cognitive impairment or progression
 2 of cognitive impairment as described in subpara-
 3 graph (D) of subsection (hhh)(2) and referrals as
 4 described in subparagraph (I) of such subsection,
 5 and”.

6 (2) EFFECTIVE DATE.—The amendments made
 7 by paragraph (1) shall apply to initial preventive
 8 physical examinations furnished on or after January
 9 1, 2022.

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

11 Not later than January 1, 2022, the Secretary of
 12 Health and Human Services shall implement Medicare
 13 policies under title XVIII of the Social Security Act, in-
 14 cluding quality measures and Medicare Advantage plan
 15 rating and risk adjustment mechanisms, that reflect the
 16 public health imperative of—

- 17 (1) promoting healthy brain lifestyle choices;
- 18 (2) identifying and responding to patient risk
- 19 factors for Alzheimer’s disease and related demen-
- 20 tias; and
- 21 (3) incentivizing providers for—
 - 22 (A) adequate and reliable cognitive impair-
 - 23 ment detection in the primary care setting, that
 - 24 is documented in the patient’s electronic health
 - 25 record and communicated to the patient;

1 (B) timely Alzheimer’s disease diagnosis;
2 and

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

7 **SEC. 4. REPORT TO CONGRESS ON IMPLEMENTATION OF**
8 **THIS ACT.**

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

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

17 (2) utilization of Alzheimer’s disease diagnostic
18 and care planning services; and

19 (3) outreach efforts in the primary care and pa-
20 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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