

115TH CONGRESS
2D SESSION

S. 2387

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

FEBRUARY 7, 2018

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

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 2018”.

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. Test of care delivery models offering a continuum of comprehensive care, and caregiver support services, for patients with Alzheimer's disease and other dementias.
- Sec. 4. State innovation models for family caregivers of patients with Alzheimer's and related dementias.
- Sec. 5. Medicare quality payment program.
- Sec. 6. Report to Congress on implementation of this Act.
- Sec. 7. 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) The number of individuals in the United
 5 States with Alzheimer's disease and related demen-
 6 tias has more than doubled since 1980 and, based
 7 on the trajectory of Alzheimer's, as many as 14 to
 8 16 million individuals in the United States will have
 9 Alzheimer's by 2050.

10 (2) Alzheimer's is the only disease among the
 11 top 10 causes of death in the United States without
 12 an effective means of prevention, treatment, or cure.

13 (3) In 2017, Alzheimer's care will cost Medicare
 14 and Medicaid an estimated \$175,000,000,000 and
 15 by 2050, Alzheimer's disease will cost Medicare and
 16 Medicaid as much as \$758,000,000,000.

17 (4) Alzheimer's exacts an emotional and phys-
 18 ical toll on caregivers, resulting in higher incidence
 19 of heart disease, cancer, depression, and other health
 20 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 two times more
5 likely than White Americans to have Alzheimer’s dis-
6 ease and other dementias. Latinos are about one
7 and one-half times more likely than White Ameri-
8 cans to have Alzheimer’s disease and other demen-
9 tias. This higher prevalence translates into a higher
10 death rate: Alzheimer’s deaths increased 55 percent
11 among all Americans between 1999 and 2014, while
12 the number was 107 percent for Latinos and 99 per-
13 cent for African Americans.

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

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

23 (8) The lack of uniform, reliable cognitive im-
24 pairment detection methodologies in the Medicare
25 annual wellness visit, and appropriate follow-up,

1 delays diagnosis, resulting in decreased opportunities
2 for patients to access timely treatment options, in-
3 cluding clinical trial participation.

4 (9) African Americans represent 13 percent of
5 the U.S. population but only 5 percent of clinical
6 trial participants and Latinos represent 17 percent
7 of the U.S. population but less than one percent of
8 clinical trial participants. Further, Latinos and Afri-
9 can Americans account for only 3.5 percent and 1.2
10 percent, respectively, of principal investigators sup-
11 ported by the National Institutes of Health funding,
12 limiting this perspective in research. Better recruit-
13 ment and trial designs are critical to addressing in-
14 novation in Alzheimer's generally, including the
15 underrepresentation of African Americans and
16 Latinos.

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

21 (11) Advancing treatment options to prevent,
22 treat, or cure Alzheimer's is an urgent national pri-
23 ority.

24 (12) Continued Federal investment in Alz-
25 heimer's research and the implementation of innova-

1 tive programs, such as the breakthrough EUREKA
2 prize competition authorized in the 21st Century
3 Cures Act, are critical to advance the search to iden-
4 tify, treat, cure, and prevent Alzheimer’s disease.

5 (13) Existing health care systems—

6 (A) are costly;

7 (B) do not adequately meet the needs of
8 Alzheimer’s patients;

9 (C) overburden familial caregivers; and

10 (D) perpetuate hurdles to efficient Alz-
11 heimer’s research.

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

16 (15) Section 1115A of the Social Security Act,
17 as amended by the PACE Innovation Act of 2015,
18 enables identification of Alzheimer’s disease care
19 models that focus on improving patient-centered out-
20 comes, reduce the burden on informal and familial
21 caregivers, and facilitate clinical trial participation.

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

5 (a) ANNUAL WELLNESS VISIT.—

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

9 (A) by striking subparagraph (D) and in-
 10 serting the following:

11 “(D) Detection of any cognitive impair-
 12 ment or progression of cognitive impairment
 13 that shall—

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

21 “(ii) include documentation of the tool
 22 used for detecting cognitive impairment
 23 and results of the assessment in the pa-
 24 tient’s medical record; and

25 “(iii) take into consideration the tool
 26 used, and results of, any previously per-

1 formed cognitive impairment detection as-
2 sessment.”;

3 (B) by redesignating subparagraph (G) as
4 subparagraph (H); and

5 (C) by inserting after subparagraph (F)
6 the following new subparagraph:

7 “(G) Referral of patients with detected
8 cognitive impairment or potential cognitive de-
9 cline to—

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

16 “(ii) specialists and other clinicians
17 with expertise in diagnosing or treating
18 Alzheimer’s disease and related dementias;

19 “(iii) available community-based serv-
20 ices, including patient and caregiver coun-
21 seling and social support services; and

22 “(iv) appropriate clinical trials.”.

23 (2) EFFECTIVE DATE.—The amendments made
24 by paragraph (1) shall apply to annual wellness vis-
25 its furnished on or after January 1, 2019.

1 (b) INITIAL PREVENTIVE PHYSICAL EXAMINA-
2 TION.—

3 (1) IN GENERAL.—Section 1861(w)(1) of the
4 Social Security Act (42 U.S.C. 1395x(w)(1)) is
5 amended by striking “paragraph (2) and” and in-
6 serting “paragraph (2), detection of any cognitive
7 impairment or progression of cognitive impairment
8 as described in subparagraph (D) of subsection
9 (h)(2) and referrals as described in subparagraph
10 (G) of such subsection, and”.

11 (2) EFFECTIVE DATE.—The amendments made
12 by paragraph (1) shall apply to initial preventive
13 physical examinations furnished on or after January
14 1, 2019.

15 **SEC. 3. TEST OF CARE DELIVERY MODELS OFFERING A**
16 **CONTINUUM OF COMPREHENSIVE CARE, AND**
17 **CAREGIVER SUPPORT SERVICES, FOR PA-**
18 **TIENTS WITH ALZHEIMER’S DISEASE AND**
19 **OTHER DEMENTIAS.**

20 Section 1115A of the Social Security Act (42 U.S.C.
21 1315a) is amended—

22 (1) in subsection (b)(2)(A), by adding at the
23 end the following new sentence: “The models se-
24 lected under this subparagraph shall include the
25 model described in subsection (h), which shall be im-

1 plemented by not later than 6 months after the date
 2 of the enactment of the Concentrating on High-value
 3 Alzheimer’s Needs to Get to an End (CHANGE)
 4 Act of 2018.”;

5 (2) by adding at the end the following new sub-
 6 section:

7 “(h) DELIVERY MODELS OFFERING A CONTINUUM
 8 OF COMPREHENSIVE CARE, AND CAREGIVER SUPPORT
 9 SERVICES, FOR PATIENTS WITH ALZHEIMER’S DISEASE
 10 AND OTHER DEMENTIAS.—

11 “(1) IN GENERAL.—The models described in
 12 this subsection are Medicare, Medicaid, or multi-
 13 payer models that incorporate a comprehensive con-
 14 tinuum of care framework, such as that contained in
 15 the Program of All-Inclusive Care for the Elderly
 16 (PACE), to individuals diagnosed with Alzheimer’s
 17 disease or related dementia, at any stage.

18 “(2) REQUIREMENTS FOR MODELS.—The mod-
 19 els described in this subsection shall include the fol-
 20 lowing:

21 “(A) The enrollment of patients diagnosed
 22 with Alzheimer’s disease, at any stage, without
 23 regard to medical need for skilled nursing facil-
 24 ity care or Medicaid eligibility.

1 “(B) Through case management and care
2 coordination services, the offering of a flexible
3 menu of services, based upon identified patient
4 needs over time, for high-quality, appropriate
5 care from diagnosis through disease progres-
6 sion, including identification of appropriate clin-
7 ical trials.

8 “(C) The employment of a comprehensive
9 approach to caring for patients with Alz-
10 heimer’s disease or related dementia that inte-
11 grates treatment of such patients with training
12 and support services for their families and care-
13 givers, and facilitates participation in clinical
14 trials. Such services may include—

15 “(i) day healthcare, including health
16 care services and dementia-specific social,
17 rehabilitative, recreational, memory, exer-
18 cise, nutritional counseling, occupational
19 therapy, and personal care services;

20 “(ii) physician care, including referred
21 specialists;

22 “(iii) respite care and, for clinical trial
23 participants, care partner surrogate serv-
24 ices as needed;

1 “(iv) medications and medication
2 management, including for clinical trial
3 compliance;

4 “(v) nursing care, and occupational,
5 physical, and speech therapy as prescribed;

6 “(vi) identification and management
7 of comorbidities;

8 “(vii) social worker services;

9 “(viii) meals at day health care and,
10 if needed, at home;

11 “(ix) transportation to and from day
12 health care and clinical trial study visits;
13 and

14 “(x) personal care, skilled nursing
15 services, and other services the Secretary
16 determines appropriate that—

17 “(I) incorporate caregiver train-
18 ing, support, and counseling services
19 successfully evaluated and imple-
20 mented in previous or existing models
21 tested under such section 1115A and
22 that are specific to Alzheimer’s dis-
23 ease patients and their caregivers;

24 “(II) maintain documentation
25 and data likely to further scientific

1 understanding of Alzheimer’s disease
 2 natural history, taking into account
 3 gender, race, ethnicity, age of onset,
 4 and other factors; and

5 “(III) provide outreach activities
 6 to inform the public of the services of
 7 the program, and provide information
 8 on Alzheimer’s disease and related de-
 9 mentias to the primary care commu-
 10 nity and general public.

11 “(3) MODEL SELECTION AND EVALUATION.—

12 “(A) REQUESTS FOR PROPOSALS.—In im-
 13 plementing the models described in this sub-
 14 section, the Secretary shall seek requests for
 15 proposals from States, PACE programs (as de-
 16 fined in section 1894(a)(2)), Alzheimer’s dis-
 17 ease and dementia care centers, and specialized
 18 MA plans for special needs individuals (as de-
 19 fined in section 1859(b)(6)) that have the dem-
 20 onstrated ability to deliver the comprehensive
 21 continuum of dementia care described in para-
 22 graph (2).

23 “(B) PHASE I MODELS.—In selecting mod-
 24 els under this subsection to be tested under
 25 subsection (b), and in evaluating models, the

Secretary shall primarily focus on patient and caregiver outcomes, such as—

“(i) improved quality of life;

“(ii) maintaining functional or cognitive performance;

“(iii) management of comorbidities and behavioral and safety concerns; and

“(iv) continued ability to remain in the community.

“(C) PHASE II.—Subject to the requirements under subsection (c), in determining which models under this subsection to expand under subsection (c), the Secretary shall take into account—

“(i) any recommendations or strategies identified in the report under section 8 of the Concentrating on High-value Alzheimer’s Needs to Get to an End (CHANGE) Act of 2018; and

“(ii) whether the model incorporates care delivery, payment, and evaluation strategies that are likely to demonstrate improved patient outcomes, including the outcomes described in subparagraph (B) and reduced hospitalizations, emergency

1 room visits, and skilled nursing facility
 2 stays, without increasing spending under
 3 the applicable title.”.

4 **SEC. 4. STATE INNOVATION MODELS FOR FAMILY CARE-**
 5 **GIVERS OF PATIENTS WITH ALZHEIMER’S**
 6 **AND RELATED DEMENTIAS.**

7 Section 1115A(b)(2)(B) of the Social Security Act
 8 (42 U.S.C. 1315(b)(2)(B)) is amended by adding the fol-
 9 lowing new clause:

10 “(xxv) Allowing States to develop and
 11 test programs that increase an Alzheimer’s
 12 disease patient’s ability to remain in the
 13 community by reducing the financial bur-
 14 den to family caregivers, and that in-
 15 clude—

16 “(I) familial caregiver support
 17 services, including training necessary
 18 to enable such caregivers to provide
 19 services at the level of a home health
 20 aide;

21 “(II) certification of familial
 22 caregiver training and satisfactory
 23 completion of testing or other require-
 24 ments demonstrating caregiver com-
 25 petence;

1 “(III) appropriate familial care-
 2 giver oversight, including home visits
 3 or other activities; and

4 “(IV) for familial caregivers of
 5 Alzheimer’s disease and other demen-
 6 tia patients for whom a care plan in-
 7 cludes home health aide services, pay-
 8 ment to the caregiver for the hours of
 9 one-on-one services provided in the
 10 care plan, and performed by the fa-
 11 miliary caregivers, in an amount that is
 12 not below the then-applicable min-
 13 imum wage in that State and does not
 14 exceed the prevailing hourly rate paid
 15 to a home health aide.”.

16 **SEC. 5. MEDICARE QUALITY PAYMENT PROGRAM.**

17 Not later than January 1, 2019, the Secretary of
 18 Health and Human Services shall implement Medicare
 19 policies under title XVIII of the Social Security Act, in-
 20 cluding quality measures and Medicare Advantage plan
 21 rating and risk adjustment mechanisms, that reflect the
 22 public health imperative of—

23 (1) promoting healthy brain lifestyle choices;

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

4 (3) incentivizing providers for—

5 (A) adequate and reliable cognitive impair-
6 ment detection in the primary care setting, that
7 is documented in the patient’s electronic health
8 record and communicated to the patient;

9 (B) timely Alzheimer’s disease diagnosis;
10 and

11 (C) appropriate care planning services, in-
12 cluding identification of, and communication
13 with patients and caregivers about, the poten-
14 tial for clinical trial participation.

15 **SEC. 6. REPORT TO CONGRESS ON IMPLEMENTATION OF**
16 **THIS ACT.**

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

22 (1) the increased use of validated tools for de-
23 tection of cognitive impairment and Alzheimer’s dis-
24 ease;

1 (2) models undergoing testing and evaluation
 2 under the provisions of, and amendments made by,
 3 sections 3 and 4;

4 (3) utilization of Alzheimer’s disease diagnostic
 5 and care planning services; and

6 (4) outreach efforts in the primary care and pa-
 7 tient communities.

8 **SEC. 7. STUDY AND REPORT ON REGULATORY AND LEGIS-**
 9 **LATIVE CHANGES OR REFINEMENTS THAT**
 10 **WOULD ACCELERATE ALZHEIMER’S DISEASE**
 11 **RESEARCH PROGRESS.**

12 (a) IN GENERAL.—The Comptroller General of the
 13 United States (in this section referred to as the “Comp-
 14 troller General”) shall conduct a study on regulatory and
 15 legislative changes or refinements that would accelerate
 16 Alzheimer’s disease research progress. In conducting such
 17 study, the Comptroller General shall consult with inter-
 18 ested stakeholders, including industry leaders, researchers,
 19 clinical experts, patient advocacy groups, caregivers, pa-
 20 tients, providers, and State leaders. Such study shall in-
 21 clude an analysis of—

22 (1) innovative public-private partnerships, inno-
 23 vative financing tools, incentives and other mecha-
 24 nisms to enhance the quality of care for individuals
 25 diagnosed with Alzheimer’s disease, reduce the emo-

1 tional, financial, and physical burden on familial
2 care partners, and accelerate development of pre-
3 ventative, curative, and disease-modifying therapies;
4 and

5 (2) the results of any models under the provi-
6 sions of, and amendments made by, sections 3 and
7 4 and the feasibility of incorporating into such mod-
8 els innovative arrangements with research sponsors,
9 through a user fee or otherwise, to facilitate budget
10 neutrality or incentivize providers through a shared-
11 savings approach.

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

○