115TH CONGRESS
2D SESSION

# S. _____

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 SENATE OF THE UNITED STATES

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Mrs. CAPITO (for herself and Ms. STABENOW) introduced the following bill; which was read twice and referred to the Committee on _____

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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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

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

(a) SHORT TITLE.—This Act may be cited as the ''Concentrating on High-Value Alzheimer's Needs to Get to an End (CHANGE) Act of 2018''.

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



(c) FINDINGS.—Congress finds as follows:

(1) The number of individuals in the United States with Alzheimer's disease and related dementias has more than doubled since 1980 and, based on the trajectory of Alzheimer's, as many as 14 to 16 million individuals in the United States will have Alzheimer's by 2050.

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

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

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

(5) Alzheimer's disease disproportionately impacts women and people of color. Women are twice as likely to develop Alzheimer's as they are breast cancer. African Americans are about two times more likely than White Americans to have Alzheimer's disease and other dementias. Latinos are about one and one-half times more likely than White Americans to have Alzheimer's disease and other dementias. This higher prevalence translates into a higher death rate: Alzheimer's deaths increased 55 percent among all Americans between 1999 and 2014, while the number was 107 percent for Latinos and 99 percent for African Americans.

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

(7) An early, documented diagnosis, communicated to the patient and caregiver, enables early access to care planning services and available medical and nonmedical treatments, and optimizes patients' ability to build a care team, participate in support services, and enroll in clinical trials.

(8) The lack of uniform, reliable cognitive impairment detection methodologies in the Medicare annual wellness visit, and appropriate follow-up,

delays diagnosis, resulting in decreased opportunities for patients to access timely treatment options, including clinical trial participation.

(9) African Americans represent 13 percent of the U.S. population but only 5 percent of clinical trial participants and Latinos represent 17 percent of the U.S. population but less than one percent of clinical trial participants. Further, Latinos and African Americans account for only 3.5 percent and 1.2 percent, respectively, of principal investigators supported by the National Institutes of Health funding, limiting this perspective in research. Better recruitment and trial designs are critical to addressing innovation in Alzheimer's generally, including the underrepresentation of African Americans and Latinos.

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

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

(12) Continued Federal investment in Alzheimer's research and the implementation of innova-

tive programs, such as the breakthrough EUREKA prize competition authorized in the 21st Century Cures Act, are critical to advance the search to identify, treat, cure, and prevent Alzheimer's disease.

(13) Existing health care systems—

(A) are costly;

(B) do not adequately meet the needs of Alzheimer's patients;

(C) overburden familial caregivers; and

(D) perpetuate hurdles to efficient Alzheimer's research.

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

(15) Section 1115A of the Social Security Act, as amended by the PACE Innovation Act of 2015, enables identification of Alzheimer's disease care models that focus on improving patient-centered outcomes, reduce the burden on informal and familial caregivers, and facilitate clinical trial participation.

**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 care setting, and other validated cognitive detection tools as the Secretary determines;

''(ii) include documentation of the tool used for detecting cognitive impairment and results of the assessment in the patient's medical record; and

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

formed cognitive impairment detection assessment.'';

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

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

''(G) Referral of patients with detected cognitive impairment or potential cognitive decline to—

''(i) appropriate Alzheimer's disease and dementia diagnostic services, including amyloid positron emission tomography, and other medically accepted diagnostic tests that the Secretary determines are safe and effective;

''(ii) specialists and other clinicians with expertise in diagnosing or treating Alzheimer's disease and related dementias;

''(iii) available community-based services, including patient and caregiver counseling and social support services; and

''(iv) appropriate clinical trials.''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to annual wellness visits furnished on or after January 1, 2019.

(b) INITIAL PREVENTIVE PHYSICAL EXAMINATION.—

(1) IN GENERAL.—Section 1861(ww)(1) of the Social Security Act (42 U.S.C. 1395x(ww)(1)) is amended by striking ''paragraph (2) and'' and inserting ''paragraph (2), detection of any cognitive impairment or progression of cognitive impairment as described in subparagraph (D) of subsection (hhh)(2) and referrals as described in subparagraph (G) of such subsection, and''.

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

**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.**

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

(1) in subsection (b)(2)(A), by adding at the end the following new sentence: ''The models selected under this subparagraph shall include the model described in subsection (h), which shall be im-

plemented by not later than 6 months after the date of the enactment of the Concentrating on High-Value Alzheimer's Needs to Get to an End (CHANGE) Act of 2018.'';

(2) by adding at the end the following new subsection:

''(h) DELIVERY MODELS OFFERING A CONTINUUM OF COMPREHENSIVE CARE, AND CAREGIVER SUPPORT SERVICES, FOR PATIENTS WITH ALZHEIMER'S DISEASE AND OTHER DEMENTIAS.—

''(1) IN GENERAL.—The models described in this subsection are Medicare, Medicaid, or multi-payer models that incorporate a comprehensive continuum of care framework, such as that contained in the Program of All-Inclusive Care for the Elderly (PACE), to individuals diagnosed with Alzheimer's disease or related dementia, at any stage.

''(2) REQUIREMENTS FOR MODELS.—The models described in this subsection shall include the following:

''(A) The enrollment of patients diagnosed with Alzheimer's disease, at any stage, without regard to medical need for skilled nursing facility care or Medicaid eligibility.

"(B) Through case management and care coordination services, the offering of a flexible menu of services, based upon identified patient needs over time, for high-quality, appropriate care from diagnosis through disease progression, including identification of appropriate clinical trials;

"(C) The employment of a comprehensive approach to caring for patients with Alzheimer's disease or related dementia that integrates treatment of such patients with training and support services for their families and caregivers, and facilitates participation in clinical trials. Such services may include—

"(i) day healthcare, including health care services and dementia-specific social, rehabilitative, recreational, memory, exercise, nutritional counseling, occupational therapy, and personal care services;

"(ii) physician care, including referred specialists;

"(iii) respite care and, for clinical trial participants, care partner surrogate services as needed;

"(iv) medications and medication management, including for clinical trial compliance;

"(v) nursing care, and occupational, physical, and speech therapy as prescribed;

"(vi) identification and management of comorbidities;

"(vii) social worker services;

"(viii) meals at day health care and, if needed, at home;

"(ix) transportation to and from day health care and clinical trial study visits; and

"(x) personal care, skilled nursing services, and other services the Secretary determines appropriate that—

"(I) incorporate caregiver training, support, and counseling services successfully evaluated and implemented in previous or existing models tested under such section 1115A and that are specific to Alzheimer's disease patients and their caregivers;

"(II) maintain documentation and data likely to further scientific

understanding of Alzheimer's disease natural history, taking into account gender, race, ethnicity, age of onset, and other factors; and

"(III) provide outreach activities to inform the public of the services of the program, and provide information on Alzheimer's disease and related dementias to the primary care community and general public.

"(3) MODEL SELECTION AND EVALUATION.—

"(A) REQUESTS FOR PROPOSALS.—In implementing the models described in this subsection, the Secretary shall seek requests for proposals from States, PACE programs (as defined in section 1894(a)(2), Alzheimer's disease and dementia care centers, and specialized MA plans for special needs individuals (as defined in section 1859(b)(6)) that have the demonstrated ability to deliver the comprehensive continuum of dementia care described in paragraph (2).

"(B) PHASE I MODELS.—In selecting models under this subsection to be tested under 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

room visits, and skilled nursing facility stays, without increasing spending under the applicable title.''.

**SEC. 4. STATE INNOVATION MODELS FOR FAMILY CAREGIVERS OF PATIENTS WITH ALZHEIMER'S AND RELATED DEMENTIAS.**

Section 1115A(b)(2)(B) of the Social Security Act (42 U.S.C. 1315(b)(2)(B)) is amended by adding the following new clause:

''(xxv) Allowing States to develop and test programs that increase an Alzheimer's disease patient's ability to remain in the community by reducing the financial burden to family caregivers, and that include—

''(I) familial caregiver support services, including training necessary to enable such caregivers to provide services at the level of a home health aide;

''(II) certification of familial caregiver training and satisfactory completion of testing or other requirements demonstrating caregiver competence;

"(III) appropriate familial caregiver oversight, including home visits or other activities; and

"(IV) for familial caregivers of Alzheimer's disease and other dementia patients for whom a care plan includes home health aide services, payment to the caregiver for the hours of one-on-one services provided in the care plan, and performed by the familial caregivers, in an amount that is not below the then-applicable minimum wage in that State and does not exceed the prevailing hourly rate paid to a home health aide.".

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

Not later than January 1, 2019, the Secretary of Health and Human Services shall implement Medicare policies under title XVIII of the Social Security Act, including quality measures and Medicare Advantage plan rating and risk adjustment mechanisms, that reflect the public health imperative of—

(1) promoting healthy brain lifestyle choices;

(2) identifying and responding to patient risk factors for Alzheimer's disease and related dementias; and

(3) incentivizing providers for—

(A) adequate and reliable cognitive impairment detection in the primary care setting, that is documented in the patient's electronic health record and communicated to the patient;

(B) timely Alzheimer's disease diagnosis; and

(C) appropriate care planning services, including identification of, and communication with patients and caregivers about, the potential for clinical trial participation.

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

Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to Congress on the implementation of the provisions of, and amendments made by, this Act, including—

(1) the increased use of validated tools for detection of cognitive impairment and Alzheimer's disease;

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

(3) utilization of Alzheimer's disease diagnostic and care planning services; and

(4) outreach efforts in the primary care and patient communities.

**SEC. 7. STUDY AND REPORT ON REGULATORY AND LEGISLATIVE CHANGES OR REFINEMENTS THAT WOULD ACCELERATE ALZHEIMER'S DISEASE RESEARCH PROGRESS.**

(a) IN GENERAL.—The Comptroller General of the United States (in this section referred to as the ''Comptroller General'') shall conduct a study on regulatory and legislative changes or refinements that would accelerate Alzheimer's disease research progress. In conducting such study, the Comptroller General shall consult with interested stakeholders, including industry leaders, researchers, clinical experts, patient advocacy groups, caregivers, patients, providers, and State leaders. Such study shall include an analysis of—

(1) innovative public-private partnerships, innovative financing tools, incentives and other mechanisms to enhance the quality of care for individuals diagnosed with Alzheimer's disease, reduce the emo-

tional, financial, and physical burden on familial care partners, and accelerate development of preventative, curative, and disease-modifying therapies; and

(2) the results of any models under the provisions of, and amendments made by, sections 3 and 4 and the feasibility of incorporating into such models innovative arrangements with research sponsors, through a user fee or otherwise, to facilitate budget neutrality or incentivize providers through a shared-savings approach.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.