118TH CONGRESS
1ST SESSION

S. 3258

To amend title XVIII of the Social Security Act to provide coverage of ALS-related services under the Medicare program for individuals diagnosed with amyotrophic lateral sclerosis, and for other purposes.

IN THE SENATE OF THE UNITED STATES

NOVEMBER 8, 2023

Mr. COONS (for himself and Ms. MURKOWSKI) introduced the following bill; which was read twice and referred to the Committee on Finance

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A BILL

To amend title XVIII of the Social Security Act to provide coverage of ALS-related services under the Medicare program for individuals diagnosed with amyotrophic lateral sclerosis, and for other purposes.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''ALS Better Care Act''.

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Amyotrophic lateral sclerosis (in this section, referred to as ''ALS'') is a progressive and debilitating neurodegenerative disease.

(2) Key services, that include (but are not limited to) providing specialized physician or nurse practitioner support, occupational therapy support, speech pathology support, physical therapy, dietary support, respiratory support, registered nurse support, and coordination of the furnishing of durable medical equipment, are crucial for managing the complex medical needs of ALS patients.

(3) Studies have shown ALS clinics that provide these key services to ALS patients extend these patients' lifespans and improve the quality of their lives.

(4) These key services are furnished by a range of healthcare professionals.

(5) Facilities providing care to ALS patients currently face inadequate Medicare reimbursement for the key services they offer to these patients.

(6) Insufficient reimbursement creates significant challenges for facilities specializing in ALS care, resulting in extended wait times for patients in need of crucial services and hampering the ability of

these facilities to innovate and improve the quality of care provided to ALS patients.

(7) Improved reimbursement rates would encourage facilities to invest in research, innovation, and technology, leading to enhanced treatment options for ALS and improved patient outcomes.

(8) Remote medical management options for individuals suffering from ALS must be an essential part of access to care for such individuals, especially those living in rural areas or care deserts.

(9) Telehealth is one of the essential management options referred to in paragraph (8) and can assist in delivering timely and comprehensive care, as ALS patients living in rural areas or care deserts often face challenges in accessing specialized ALS care and could otherwise be required to travel long travel distances, often with caregivers or family members.

(10) Telehealth is especially important in maintaining access to care for ALS patients as the disease progresses and causes ALS patients to have more limited mobility, which may make it challenging to attend in-person appointments regularly.

(11) Low funding and difficulty in staffing for ALS clinical trials delay the development and avail-

ability of potential treatments and therapies for individuals living with the disease.

(12) Inadequate funding for ALS clinical trials also impedes the ability to attract and retain qualified researchers, clinicians, and support staff, limiting the overall progress and success of these trials.

SEC. 3. PROVIDING FOR COVERAGE OF ALS-RELATED SERVICES UNDER THE MEDICARE PROGRAM FOR INDIVIDUALS DIAGNOSED WITH AMYOTROPHIC LATERAL SCLEROSIS.

(a) IN GENERAL.—Part E of title XVIII of the Social Security Act (42 U.S.C. 1395 et. seq.) is amended by inserting after section 1881A the following new section:

"SEC. 1881B. MEDICARE COVERAGE OF ALS-RELATED SERVICES FOR INDIVIDUALS DIAGNOSED WITH AMYOTROPHIC LATERAL SCLEROSIS.

''(a) IN GENERAL.—In the case of a covered ALS individual, the Secretary shall establish a supplemental facility-based payment system described in subsection (d) for ALS-related services provided to such an individual.

''(b) COVERED ALS INDIVIDUAL.—For purposes of this section, the term 'covered ALS individual' means an individual who is medically determined to have amyotrophic lateral sclerosis (as described in section 226(h)).

''(c) ALS-RELATED SERVICES.—For purposes of this section, the term 'ALS-related services' means items and services that are furnished to a covered ALS individual in an outpatient setting by a qualified provider (or by others under arrangements with them made by the qualified provider) for the care and treatment of such an individual with respect to the progression of amyotrophic lateral sclerosis.

''(d) PAYMENT SYSTEM.—

''(1) AUTHORITY.—The Secretary shall establish a payment system under which a single payment determined in accordance with the succeeding paragraphs is made to a qualified provider for ALS-related services furnished to a covered ALS individual during a visit beginning on or after January 1, 2025, for the purpose of reimbursing the qualified provider for furnishing ALS-related services.

''(2) BASE PAYMENT AMOUNT.—

''(A) 2025.—For coverage year 2025, the Secretary shall establish a single payment amount for ALS-related services equal to $800 for such services furnished for each visit during such year.

''(B) 2026.—For coverage year 2026, the Secretary shall establish a single payment

amount for ALS-related services furnished for each visit during such year that is the greater of—

"(i) the payment amount recommended by the Comptroller General in the report described in subparagraph (D); or

"(ii) the amount specified in subparagraph (A).

"(C) SUBSEQUENT YEARS.—The Secretary shall do each of the following:

"(i) ANNUAL INCREASE.—For each coverage year beginning with coverage year 2027, the Secretary shall annually increase the payment amount for each visit determined under this paragraph by an ALS services market basket percentage increase (as determined by the Secretary) for the purpose of reflecting the year-to-year changes in the prices of an appropriate mix of goods and services that are ALS-related services.

"(ii) REESTABLISHMENT OF AMOUNT.—For each coverage year beginning with coverage year 2028, and every 3

coverage years thereafter, for the purpose of ensuring that the range of ALS-related services is modernized over time, the Secretary shall reestablish a single payment amount for ALS-related services furnished for each visit during such year that is the greater of—

"(I) the payment amount recommended by the Comptroller General in the report described in clause (i) or (ii) of subparagraph (E), as applicable; or

"(II) the payment amount specified pursuant to clause (i).

"(D) REPORT BY THE COMPTROLLER GENERAL.—Not later than January 1, 2025, the Comptroller General shall, in consultation with qualified providers that are representative of the types of qualified providers eligible for payment under this subsection, submit to the Secretary of Health and Human Services a report that recommends a single payment amount for ALS-related services that takes into account the average amount of payment for each item or service included in ALS-related services that

the Comptroller General estimates would have been payable—

"(i) under this title for such a service based on per patient utilization data from whichever single coverage year from 2021 through 2023 has the highest per patient utilization of ALS-related services, even if such service is not payable for a particular ALS individual because of the application of section 1862(a)(1)(A) with respect to an item or service provided to such individual;

"(ii) in the case that an estimate is unable to be determined pursuant to clause (i), by health insurance issuers and group health plans (as such terms are defined in section 2791 of the Public Health Service Act) and MA plans under part C for such a service, based on such data from whichever single coverage year from 2021 through 2023 has the highest per patient utilization of ALS-related services; and

"(iii) in the case that an estimate is unable to be determined pursuant to clause (ii), based on the recommendation of the Specialty Society Relative Value Scale Up-

date Committee of the American Medical Association or the estimate of the Comptroller General for such a service.

''(E) SUBSEQUENT REPORTS.—For the purpose of subparagraph (C)(ii)(I), the Comptroller General shall, not later than—

''(i) January 1, 2028, submit a report to the Secretary in accordance with subparagraph (D), except such subparagraph shall be applied by substituting '2024 through 2026' for '2021 through 2023' each place it appears; and

''(ii) January 1, 2031, and every 3 years thereafter, submit a report to the Secretary in accordance with subparagraph (D), after application of clause (i), except clause (i) shall be applied by substituting coverage years that are 3 years later than the coverage years previously applicable for reports under clause (i) or this clause for '2024 through 2026'.

''(3) PAYMENT ADJUSTMENTS.—The payment system under this subsection shall include a payment adjustment—

''(A) for a qualified provider that is participating in at least 1 clinical trial identified on the clinicaltrials.gov database (or any successor database) of the National Institutes of Health to account for the increased costs borne by such a qualified provider during such a clinical trial; and

''(B) to account for a medical service or technology that is furnished as a part of ALS-related services for which, as determined by the Secretary—

''(i) payment for the service or technology as part of ALS-related services under this section was not being made in the preceding coverage year; and

''(ii) the cost of the service or technology is not insignificant in relation to the payment amount (as determined under this subsection) payable for ALS-related services.

''(4) MECHANISM FOR PAYMENTS.—For purposes of making payments for ALS-related services, the Secretary shall establish a mechanism under the payment system under this subsection which makes payment when a qualified provider submits a claim

for reimbursement which includes, with respect to a covered ALS individual, an alphanumeric code issued under the International Classification of Diseases, 10th Revision, Clinical Modification (commonly referred to as 'ICD–10–CM') and its subsequent revisions that is for the treatment of a diagnosis of amyotrophic lateral sclerosis.

''(5) NO COST SHARING.—Payment under this subsection shall be made only on an assignment-related basis without any cost sharing.

''(6) QUALIFIED PROVIDER DEFINED.—In this section, the term 'qualified provider' means a provider of services or a clinic which—

''(A) is capable of furnishing care to a covered ALS individual, including by providing such services as providing specialized physician or nurse practitioner support, occupational therapy support, speech pathology support, physical therapy, dietary support, respiratory support, registered nurse support, and coordination of the furnishing of durable medical equipment; and

''(B) meets such requirements as the Secretary may prescribe by regulation to implement subparagraph (A), in consultation with—

''(i) covered ALS individuals and their representatives;

''(ii) physicians who provide ALS-related services and their representatives; and

''(iii) professional and non-profit organizations with expertise in amyotrophic lateral sclerosis.

''(e) CLARIFICATION.—Payment under subsection (d) shall be in addition to, and shall not supplant, any payment that would be otherwise made to a provider of services, physician, practitioner, supplier, or laboratory under any other provision of this title for an item or service furnished to a covered ALS individual.

''(f) IMPLEMENTATION.—

''(1) IN GENERAL.—Except as provided under paragraph (2), the Secretary may implement the provisions of this section by program instruction or otherwise.

''(2) RULEMAKING.—The Secretary shall implement subsections (c) and (d)(6) through notice and comment rulemaking.

''(g) FUNDING.—For purposes of carrying out this section and subject to subsection (e), payment under this section shall be made from the Federal Supplementary

Medical Insurance Trust Fund under section 1841 or from the Federal Hospital Insurance Trust Fund under section 1817.''.

(b) CONFORMING AMENDMENTS.—

(1) ENSURING SUPPLEMENTAL PAYMENTS FOR ALS-RELATED SERVICES.—Section 1833(t) of the Social Security Act (42 U.S.C. 1395(t) is amended by adding at the end the following new paragraph:

''(23) ENSURING SUPPLEMENTAL PAYMENTS FOR ALS-RELATED SERVICES.—Any covered OPD service furnished to a covered ALS individual (as defined in section 1881B(b)) that is otherwise payable to a qualified provider (as defined in section 1881B(d)(6)) pursuant to paragraph (4) shall be payable under such paragraph notwithstanding any payment made under section 1881B(d).''.

(2) DEFINITION OF ''ARRANGEMENTS''.—Section 1861(w)(1) of the Social Security Act (42 U.S.C. 1395x(w)(1)) is amended by inserting ''qualified provider (as defined in section 1881B(d)(6)) with respect to ALS-related services (as defined in section 1881B(c)),'' before ''or hospice program''.

SEC. 4. REPORT ON CHALLENGES WITH RESPECT TO THE ADMINISTRATION AND STAFFING OF AMYOTROPHIC LATERAL SCLEROSIS CLINICAL TRIALS.

Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services, acting through the Director of the National Institute of Neurological Disorders and Stroke, shall submit to Congress and publish on the Internet website of the agency a report that identifies—

(1) any challenges with respect to the administration and staffing of clinical trials for the prevention, diagnosis, mitigation, treatment, or cure of amyotrophic lateral sclerosis;

(2) actions that the Director of the National Institute of Neurological Disorders and Stroke will take to address such challenges; and

(3) any legislative recommendations (including requests for appropriations) to further improve the administration of such clinical trials.

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