

118TH CONGRESS  
1ST SESSION



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.

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IN THE SENATE OF THE UNITED STATES



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



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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.

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.**

4 This Act may be cited as the “ALS Better Care Act”.

5 **SEC. 2. FINDINGS.**

6 Congress makes the following findings:

1           (1) Amyotrophic lateral sclerosis (in this sec-  
2           tion, referred to as “ALS”) is a progressive and de-  
3           bilitating neurodegenerative disease.

4           (2) Key services, that include (but are not lim-  
5           ited to) providing specialized physician or nurse  
6           practitioner support, occupational therapy support,  
7           speech pathology support, physical therapy, dietary  
8           support, respiratory support, registered nurse sup-  
9           port, and coordination of the furnishing of durable  
10          medical equipment, are crucial for managing the  
11          complex medical needs of ALS patients.

12          (3) Studies have shown ALS clinics that pro-  
13          vide these key services to ALS patients extend these  
14          patients’ lifespans and improve the quality of their  
15          lives.

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

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

21          (6) Insufficient reimbursement creates signifi-  
22          cant challenges for facilities specializing in ALS  
23          care, resulting in extended wait times for patients in  
24          need of crucial services and hampering the ability of

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

3           (7) Improved reimbursement rates would en-  
4       courage facilities to invest in research, innovation,  
5       and technology, leading to enhanced treatment op-  
6       tions for ALS and improved patient outcomes.

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

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

19          (10) Telehealth is especially important in main-  
20      taining access to care for ALS patients as the dis-  
21      ease progresses and causes ALS patients to have  
22      more limited mobility, which may make it chal-  
23      lenging to attend in-person appointments regularly.

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

1 ability of potential treatments and therapies for indi-  
2 viduals living with the disease.

3 (12) Inadequate funding for ALS clinical trials  
4 also impedes the ability to attract and retain quali-  
5 fied researchers, clinicians, and support staff, lim-  
6 iting the overall progress and success of these trials.

7 **SEC. 3. PROVIDING FOR COVERAGE OF ALS-RELATED SERV-**  
8 **ICES UNDER THE MEDICARE PROGRAM FOR**  
9 **INDIVIDUALS DIAGNOSED WITH**  
10 **AMYOTROPHIC LATERAL SCLEROSIS.**

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

14 **“SEC. 1881B. MEDICARE COVERAGE OF ALS-RELATED SERV-**  
15 **ICES FOR INDIVIDUALS DIAGNOSED WITH**  
16 **AMYOTROPHIC LATERAL SCLEROSIS.**

17 “(a) **IN GENERAL.**—In the case of a covered ALS  
18 individual, the Secretary shall establish a supplemental fa-  
19 cility-based payment system described in subsection (d)  
20 for ALS-related services provided to such an individual.

21 “(b) **COVERED ALS INDIVIDUAL.**—For purposes of  
22 this section, the term ‘covered ALS individual’ means an  
23 individual who is medically determined to have  
24 amyotrophic lateral sclerosis (as described in section  
25 226(h)).

1           “(c) ALS-RELATED SERVICES.—For purposes of this  
2 section, the term ‘ALS-related services’ means items and  
3 services that are furnished to a covered ALS individual  
4 in an outpatient setting by a qualified provider (or by oth-  
5 ers under arrangements with them made by the qualified  
6 provider) for the care and treatment of such an individual  
7 with respect to the progression of amyotrophic lateral scler-  
8 rosis.

9           “(d) PAYMENT SYSTEM.—

10           “(1) AUTHORITY.—The Secretary shall estab-  
11 lish a payment system under which a single payment  
12 determined in accordance with the succeeding para-  
13 graphs is made to a qualified provider for ALS-re-  
14 lated services furnished to a covered ALS individual  
15 during a visit beginning on or after January 1,  
16 2025, for the purpose of reimbursing the qualified  
17 provider for furnishing ALS-related services.

18           “(2) BASE PAYMENT AMOUNT.—

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

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

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

4 “(i) the payment amount rec-  
5 ommended by the Comptroller General in  
6 the report described in subparagraph (D);  
7 or

8 “(ii) the amount specified in subpara-  
9 graph (A).

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

12 “(i) ANNUAL INCREASE.—For each  
13 coverage year beginning with coverage year  
14 2027, the Secretary shall annually increase  
15 the payment amount for each visit deter-  
16 mined under this paragraph by an ALS  
17 services market basket percentage increase  
18 (as determined by the Secretary) for the  
19 purpose of reflecting the year-to-year  
20 changes in the prices of an appropriate  
21 mix of goods and services that are ALS-re-  
22 lated services.

23 “(ii) REESTABLISHMENT OF  
24 AMOUNT.—For each coverage year begin-  
25 ning with coverage year 2028, and every 3

1 coverage years thereafter, for the purpose  
2 of ensuring that the range of ALS-related  
3 services is modernized over time, the Sec-  
4 retary shall reestablish a single payment  
5 amount for ALS-related services furnished  
6 for each visit during such year that is the  
7 greater of—

8 “(I) the payment amount rec-  
9 ommended by the Comptroller General  
10 in the report described in clause (i) or  
11 (ii) of subparagraph (E), as applica-  
12 ble; or

13 “(II) the payment amount speci-  
14 fied pursuant to clause (i).

15 “(D) REPORT BY THE COMPTROLLER GEN-  
16 ERAL.—Not later than January 1, 2025, the  
17 Comptroller General shall, in consultation with  
18 qualified providers that are representative of  
19 the types of qualified providers eligible for pay-  
20 ment under this subsection, submit to the Sec-  
21 retary of Health and Human Services a report  
22 that recommends a single payment amount for  
23 ALS-related services that takes into account the  
24 average amount of payment for each item or  
25 service included in ALS-related services that

1 the Comptroller General estimates would have  
2 been payable—

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

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

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



1 date Committee of the American Medical  
2 Association or the estimate of the Comp-  
3 troller General for such a service.

4 “(E) SUBSEQUENT REPORTS.—For the  
5 purpose of subparagraph (C)(ii)(I), the Comp-  
6 troller General shall, not later than—

7 “(i) January 1, 2028, submit a report  
8 to the Secretary in accordance with sub-  
9 paragraph (D), except such subparagraph  
10 shall be applied by substituting ‘2024  
11 through 2026’ for ‘2021 through 2023’  
12 each place it appears; and

13 “(ii) January 1, 2031, and every 3  
14 years thereafter, submit a report to the  
15 Secretary in accordance with subparagraph  
16 (D), after application of clause (i), except  
17 clause (i) shall be applied by substituting  
18 coverage years that are 3 years later than  
19 the coverage years previously applicable for  
20 reports under clause (i) or this clause for  
21 ‘2024 through 2026’.

22 “(3) PAYMENT ADJUSTMENTS.—The payment  
23 system under this subsection shall include a payment  
24 adjustment—

1           “(A) for a qualified provider that is par-  
2           ticipating in at least 1 clinical trial identified on  
3           the clinicaltrials.gov database (or any successor  
4           database) of the National Institutes of Health  
5           to account for the increased costs borne by such  
6           a qualified provider during such a clinical trial;  
7           and

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

12                 “(i) payment for the service or tech-  
13                 nology as part of ALS-related services  
14                 under this section was not being made in  
15                 the preceding coverage year; and

16                 “(ii) the cost of the service or tech-  
17                 nology is not insignificant in relation to the  
18                 payment amount (as determined under this  
19                 subsection) payable for ALS-related serv-  
20                 ices.

21           “(4) MECHANISM FOR PAYMENTS.—For pur-  
22           poses of making payments for ALS-related services,  
23           the Secretary shall establish a mechanism under the  
24           payment system under this subsection which makes  
25           payment when a qualified provider submits a claim

1 for reimbursement which includes, with respect to a  
2 covered ALS individual, an alphanumeric code  
3 issued under the International Classification of Dis-  
4 eases, 10th Revision, Clinical Modification (com-  
5 monly referred to as ‘ICD–10–CM’) and its subse-  
6 quent revisions that is for the treatment of a diag-  
7 nosis of amyotrophic lateral sclerosis.

8 “(5) NO COST SHARING.—Payment under this  
9 subsection shall be made only on an assignment-re-  
10 lated basis without any cost sharing.

11 “(6) QUALIFIED PROVIDER DEFINED.—In this  
12 section, the term ‘qualified provider’ means a pro-  
13 vider of services or a clinic which—

14 “(A) is capable of furnishing care to a cov-  
15 ered ALS individual, including by providing  
16 such services as providing specialized physician  
17 or nurse practitioner support, occupational  
18 therapy support, speech pathology support,  
19 physical therapy, dietary support, respiratory  
20 support, registered nurse support, and coordi-  
21 nation of the furnishing of durable medical  
22 equipment; and

23 “(B) meets such requirements as the Sec-  
24 retary may prescribe by regulation to imple-  
25 ment subparagraph (A), in consultation with—

1                   “(i) covered ALS individuals and their  
2                   representatives;

3                   “(ii) physicians who provide ALS-re-  
4                   lated services and their representatives;  
5                   and

6                   “(iii) professional and non-profit orga-  
7                   nizations with expertise in amyotrophic lat-  
8                   eral sclerosis.

9                   “(e) CLARIFICATION.—Payment under subsection (d)  
10 shall be in addition to, and shall not supplant, any pay-  
11 ment that would be otherwise made to a provider of serv-  
12 ices, physician, practitioner, supplier, or laboratory under  
13 any other provision of this title for an item or service fur-  
14 nished to a covered ALS individual.

15                   “(f) IMPLEMENTATION.—

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

20                   “(2) RULEMAKING.—The Secretary shall imple-  
21 ment subsections (c) and (d)(6) through notice and  
22 comment rulemaking.

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

1 Medical Insurance Trust Fund under section 1841 or  
2 from the Federal Hospital Insurance Trust Fund under  
3 section 1817.”.

4 (b) CONFORMING AMENDMENTS.—

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

9 “(23) ENSURING SUPPLEMENTAL PAYMENTS  
10 FOR ALS-RELATED SERVICES.—Any covered OPD  
11 service furnished to a covered ALS individual (as de-  
12 fined in section 1881B(b)) that is otherwise payable  
13 to a qualified provider (as defined in section  
14 1881B(d)(6)) pursuant to paragraph (4) shall be  
15 payable under such paragraph notwithstanding any  
16 payment made under section 1881B(d).”.

17 (2) DEFINITION OF “ARRANGEMENTS”.—Sec-  
18 tion 1861(w)(1) of the Social Security Act (42  
19 U.S.C. 1395x(w)(1)) is amended by inserting “quali-  
20 fied provider (as defined in section 1881B(d)(6))  
21 with respect to ALS-related services (as defined in  
22 section 1881B(c)),” before “or hospice program”.

1 SEC. 4. REPORT ON CHALLENGES WITH RESPECT TO THE  
2 ADMINISTRATION AND STAFFING OF  
3 AMYOTROPHIC LATERAL SCLEROSIS CLIN-  
4 ICAL TRIALS.

5 Not later than 90 days after the date of the enact-  
6 ment of this Act, the Secretary of Health and Human  
7 Services, acting through the Director of the National In-  
8 stitute of Neurological Disorders and Stroke, shall submit  
9 to Congress and publish on the Internet website of the  
10 agency a report that identifies—

11 (1) any challenges with respect to the adminis-  
12 tration and staffing of clinical trials for the preven-  
13 tion, diagnosis, mitigation, treatment, or cure of  
14 amyotrophic lateral sclerosis;

15 (2) actions that the Director of the National In-  
16 stitute of Neurological Disorders and Stroke will  
17 take to address such challenges; and

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