

118TH CONGRESS
1ST SESSION

H. R. 5663

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 21, 2023

Ms. SCHAKOWSKY (for herself, Mr. QUIGLEY, Mr. FITZPATRICK, Mr. CROW, Mr. BACON, Mr. JACKSON of Illinois, and Mr. BISHOP of Georgia) 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 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) evidence of providing specialized physician
6 or nurse practitioner support, occupational therapy
7 support, speech pathology support, physical therapy,
8 dietary support, respiratory support, registered
9 nurse support, and coordination of the furnishing of
10 durable medical equipment are crucial for managing
11 the 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 a crucial part
9 of access to care for such individuals, especially
10 those living in rural areas or care deserts.

11 (9) Telehealth is an essential management op-
12 tion referred to in paragraph (6) and can assist in
13 delivering timely and comprehensive care, as ALS
14 patients living in rural areas or care deserts often
15 face challenges in accessing specialized ALS care
16 and could otherwise be required to travel long travel
17 distances—often with caregivers or family members.

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

23 (11) Low funding and difficulty in staffing for
24 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.—Subtitle E of title XVIII of the
 12 Social Security Act (42 U.S.C. 1395 et seq.) is amended
 13 by inserting 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 and after January 1,
16 2025, for the purpose of reimbursing the qualified
17 provider (or clinic, if applicable) for furnishing ALS-
18 related services.

19 “(2) BASE PAYMENT AMOUNT.—

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

1 “(B) 2026.—For coverage year 2026, the
2 Secretary shall establish a single payment
3 amount for ALS-related services furnished for
4 each visit during such year that is the greater
5 of—

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

10 “(ii) the amount specified in subpara-
11 graph (A).

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

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

1 “(ii) REESTABLISHMENT OF
2 AMOUNT.—For each coverage year begin-
3 ning with coverage year 2028, and every
4 three coverage years thereafter, the Sec-
5 retary shall reestablish a single payment
6 amount for ALS-related services furnished
7 for each visit during such year that is the
8 greater of—

9 “(I) the payment amount rec-
10 ommended by the Comptroller General
11 in the report described in subclause
12 (I) or (II) of subparagraph (D)(ii), as
13 appropriate; or

14 “(II) the payment amount speci-
15 fied pursuant to clause (i); for the
16 purpose of ensuring that the range of
17 ALS-related services is modernized
18 over time.

19 “(D) REPORT BY THE COMPTROLLER GEN-
20 ERAL.—Not later than January 1, 2025, the
21 Comptroller General shall, in consultation with
22 qualified providers that are representative of
23 the types of qualified providers eligible for pay-
24 ment under this subsection, submit to the Sec-
25 retary of Health and Human Services a report

1 that recommends a single payment amount for
2 ALS-related services that takes into account the
3 average amount of payment for each item or
4 service included in ALS-related services that
5 the Comptroller General estimates would have
6 been payable—

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

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

1 “(iii) in the case an estimate is unable
2 to be determined pursuant to subclause
3 (II), based on the recommendation of the
4 Specialty Society Relative Value Scale Up-
5 date Committee of the American Medical
6 Association or the estimate of the Comp-
7 troller General for such a service.

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

11 “(i) January 1, 2028, submit a report
12 to the Secretary in accordance with clause
13 (i), except by substituting ‘2021 through
14 2023’ for ‘2024 through 2026’; and

15 “(ii) three years after the date speci-
16 fied in subclause (I), and every three years
17 thereafter, submit a report to the Sec-
18 retary in accordance with such clause (i),
19 except by substituting the coverage years
20 for the previous report with coverage years
21 that are three years later.

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 one clinical trial identified
3 on the clinicaltrials.gov database (or any suc-
4 cessor database) of the National Institutes of
5 Health to account for the increased costs borne
6 by such a qualified provider during such a clin-
7 ical trial; and

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

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 ('ICD-
5 10-CM') and its subsequent revisions that is for the
6 treatment of a diagnosis of amyotrophic lateral sle-
7 rosis.

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 which—

14 “(A) is capable of furnishing care to a cov-
15 ered ALS individual that includes (but is not
16 limited to) evidence of providing specialized
17 physician or nurse practitioner support, occupa-
18 tional therapy support, speech pathology sup-
19 port, physical therapy, dietary support, res-
20 piratory support, registered nurse support, and
21 coordination of the furnishing of durable med-
22 ical equipment; and

23 “(B) meets requirements as the Secretary
24 prescribes by regulation to implement subpara-
25 graph (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, subject to subsection (e), payment under this sec-
25 tion shall be made from the Federal Supplementary Med-

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

4 (b) CONFORMING AMENDMENTS.—

5 (1) Section 1833(t) of the Social Security Act
6 (42 U.S.C. 1395(t)) is amended by adding at the
7 end the following new paragraph:

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

16 (2) Section 1861(w)(1) of the Social Security
17 Act (42 U.S.C. 1395x(w)(1)) is amended by insert-
18 ing “qualified provider (as defined in section
19 1881B(d)(6)(A)) with respect to ALS-related serv-
20 ices (as defined in section 1881B(c)),” before “or
21 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 of the Na-
9 tional Institutes of Health, shall submit to Congress and
10 publish on the internet website of the agency a report that
11 identifies—

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

16 (2) actions that the Director of the National In-
17 stitute of Neurological Disorders and Stroke to ad-
18 dress such challenges; and

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

22 **SEC. 5. EFFECTIVE DATE.**

23 The amendments made by this Act shall take effect
24 on the date of the enactment of this Act.

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