

114TH CONGRESS
1ST SESSION

S. 829

To amend title XVIII of the Social Security Act to refine how Medicare pays for orthotics and prosthetics and to improve beneficiary experience and outcomes with orthotic and prosthetic care, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 23, 2015

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

A BILL

To amend title XVIII of the Social Security Act to refine how Medicare pays for orthotics and prosthetics and to improve beneficiary experience and outcomes with orthotic and prosthetic care, 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; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Orthotics and Prosthetics Improvement Act of
6 2015”.

7 (b) TABLE OF CONTENTS.—The Table of Contents
8 for this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Modification of requirements applicable under Medicare to the designation of accreditation organizations for suppliers of orthotics and prosthetics.
- Sec. 3. Application of existing accreditation and licensure requirements to certain prosthetics and custom-fabricated or custom-fitted orthotics.
- Sec. 4. Eligibility for Medicare payment for orthotics and prosthetics based on supplier qualifications and complexity of care.
- Sec. 5. Orthotist's and prosthetist's clinical notes as part of the patient's medical record.
- Sec. 6. Distinguishing orthotists and prosthetists from suppliers of durable medical equipment and supplies.
- Sec. 7. Clarification about minimal self-adjustment for off-the-shelf orthotics.
- Sec. 8. Regulations.

1 **SEC. 2. MODIFICATION OF REQUIREMENTS APPLICABLE**
 2 **UNDER MEDICARE TO THE DESIGNATION OF**
 3 **ACCREDITATION ORGANIZATIONS FOR SUP-**
 4 **PLIERS OF ORTHOTICS AND PROSTHETICS.**

5 (a) IN GENERAL.—Section 1834(a)(20)(B) of the So-
 6 cial Security Act (42 U.S.C. 1395m(a)(20)(B)) is amend-
 7 ed—

8 (1) by striking “ORGANIZATIONS.—Not later
 9 than” and inserting: “ORGANIZATIONS.—

10 “(i) IN GENERAL.—Subject to clause
 11 (ii), not later than”; and

12 (2) by adding after clause (i), as added by
 13 paragraph (1), the following new clauses:

14 “(ii) SPECIAL REQUIREMENTS FOR
 15 ACCREDITATION OF SUPPLIERS OF
 16 ORTHOTICS AND PROSTHETICS.—For pur-
 17 poses of applying quality standards under
 18 subparagraph (A) for suppliers (other than

1 suppliers described in clause (iii)) of items
2 and services described in subparagraph
3 (D)(ii), the Secretary shall designate and
4 approve independent accreditation organi-
5 zations under clause (i) only if such orga-
6 nizations are Boards or programs de-
7 scribed in subsection (h)(1)(F)(iv). Not
8 later than January 1, 2016, the Secretary
9 shall ensure that at least one, and ideally
10 multiple, independent accreditation organi-
11 zations are designated and approved in ac-
12 cordance with this clause.

13 “(iii) EXCEPTION.—Suppliers de-
14 scribed in this clause are physicians, occu-
15 pational therapists, or physical therapists
16 who are licensed or otherwise regulated by
17 the State in which they are practicing and
18 who receive payment under this title, in-
19 cluding regulations promulgated pursuant
20 to this subsection.”.

21 (b) EFFECTIVE DATE.—Each organization must sat-
22 isfy the requirement of section 1834(a)(20)(B)(ii), as
23 added by subsection (a)(2), not later than January 1,
24 2016, regardless of whether the organization is designated

1 or approved as an independent accreditation organization
2 before, on, or after the date of the enactment of this Act.

3 **SEC. 3. APPLICATION OF EXISTING ACCREDITATION AND**
4 **LICENSURE REQUIREMENTS TO CERTAIN**
5 **PROSTHETICS AND CUSTOM-FABRICATED OR**
6 **CUSTOM-FITTED ORTHOTICS.**

7 (a) IN GENERAL.—Section 1834(h)(1)(F) of the So-
8 cial Security Act (42 U.S.C. 1395m(h)(1)(F)) is amend-
9 ed—

10 (1) in the heading, by inserting “OR CUSTOM-
11 FITTED” after “CUSTOM-FABRICATED”;

12 (2) in clause (i), by striking “an item of cus-
13 tom-fabricated orthotics described in clause (ii) or
14 for an item of prosthetics unless such item is” and
15 inserting “an item of orthotics or prosthetics, includ-
16 ing an item of custom-fabricated orthotics described
17 in clause (ii), unless such item is”;

18 (3) in clause (ii)(II), by striking “a list of items
19 to which this subparagraph applies” and inserting
20 “a list of items for purposes of clause (i)”;

21 (4) in clause (iii)(III), by striking “to provide
22 or manage the provision of prosthetics and custom-
23 designed or -fabricated orthotics” and inserting “to
24 provide or manage the provision of orthotics and
25 prosthetics (and custom-designed or -fabricated

1 orthotics, in the case of an item described in clause
2 (ii)”; and

3 (5) by adding at the end the following new
4 clause:

5 “(v) EXEMPTION OF OFF-THE-SHELF
6 ORTHOTICS INCLUDED IN A COMPETITIVE
7 ACQUISITION PROGRAM.—This subpara-
8 graph shall not apply to an item of
9 orthotics described in paragraph (2)(C) of
10 section 1847(a) furnished on or after Jan-
11 uary 1, 2016, that is included in a com-
12 petitive acquisition area under such sec-
13 tion.”.

14 (b) EFFECTIVE DATE.—The amendments made by
15 subsection (a) shall apply to orthotics and prosthetics fur-
16 nished on or after January 1, 2016.

17 **SEC. 4. ELIGIBILITY FOR MEDICARE PAYMENT FOR**
18 **ORTHOTICS AND PROSTHETICS BASED ON**
19 **SUPPLIER QUALIFICATIONS AND COM-**
20 **PLEXITY OF CARE.**

21 Section 1834(h) of the Social Security Act (42 U.S.C.
22 1395m(h)) is amended—

23 (1) in paragraph (1)(F)(iii), in the matter pre-
24 ceding subclause (I), by striking “other individual
25 who” and inserting “other individual who, with re-

1 spect to the provision of orthotics and prosthetics
2 furnished on or after January 1, 2016, and subject
3 to paragraph (5)(A), satisfies all applicable criteria
4 of the provider qualification designation for such
5 orthotic or prosthetic, and who”;

6 (2) in paragraph (1)(F)(iv), by inserting before
7 the period the following: “and, with respect to the
8 provision of orthotics and prosthetics furnished on
9 or after January 1, 2016, and subject to paragraph
10 (5)(A), satisfies all applicable criteria of the provider
11 qualification designation for such orthotic or pros-
12 thetic”; and

13 (3) by adding at the end the following new
14 paragraph:

15 “(5) ELIGIBILITY FOR PAYMENT BASED ON
16 SUPPLIER QUALIFICATIONS AND COMPLEXITY OF
17 CARE.—

18 “(A) CONSIDERATIONS FOR ELIGIBILITY
19 FOR PAYMENTS.—

20 “(i) IN GENERAL.—In applying
21 clauses (iii) and (iv) of paragraph (1)(F)
22 for purposes of determining whether pay-
23 ment may be made under this subsection
24 for orthotics and prosthetics furnished on
25 or after January 1, 2016, the Secretary

1 shall take into account the complexity of
2 the respective item and, subject to clauses
3 (ii), (iii), and (iv), the qualifications of the
4 individual or entity furnishing and fabri-
5 cating such respective item in accordance
6 with this paragraph.

7 “(ii) INDIVIDUALS AND ENTITIES EX-
8 EMPTED FROM SUPPLIER QUALIFICATION
9 CRITERIA.—With respect to the provision
10 of orthotics or prosthetics, any criteria for
11 supplier qualifications shall not apply to
12 physicians, occupational therapists, or
13 physical therapists who are licensed or oth-
14 erwise regulated by the State in which they
15 are practicing and who receive payment
16 under this title, including regulations pro-
17 mulgated pursuant to this subsection, for
18 the provision of orthotics and prosthetics.

19 “(iii) SUPPLIERS MEDICARE-ELIGIBLE
20 PRIOR TO JANUARY 1, 2016, EXEMPTED.—
21 In the case of a qualified supplier who is
22 eligible to receive payment under this title
23 before January 1, 2016, with respect to
24 the provision of orthotics and prosthetics,
25 any new criteria for provider qualifications

1 established after such date shall not apply
2 to such supplier, for the furnishing or fab-
3 rication of such an item.

4 “(iv) MODIFICATIONS.—The Secretary
5 shall, in consultation with the Boards and
6 programs described in paragraph
7 (1)(F)(iv), periodically review the criteria
8 for supplier qualifications and may imple-
9 ment by regulation any modifications to
10 such criteria, as determined appropriate in
11 accordance with such consultation. Any
12 such modifications shall take effect no ear-
13 lier than January 1, 2016.

14 “(B) ASSIGNMENT OF BILLING CODES.—
15 For purposes of subparagraph (A), the Sec-
16 retary, in consultation with representatives of
17 the fields of occupational therapy, physical ther-
18 apy, orthotics, and prosthetics, shall utilize and
19 incorporate the set of L-codes listed, as of the
20 date of enactment of this paragraph, in the
21 Centers for Medicare & Medicaid Services docu-
22 ment entitled ‘Transmittal 656’ (CMS Pub.
23 100–04, Change Request 3959, August 19,
24 2005). Transmittal 656 shall be the controlling
25 source of category, product, and code assign-

1 ments for the orthotics and prosthetics care,
 2 using the supplier qualification designation for
 3 each HCPCS code as stated in such document.
 4 In the case that Transmittal 656 is updated,
 5 reissued, or replaced by a subsequent document,
 6 the preceding sentence shall be applied with re-
 7 spect to the most recent update, reissuance, or
 8 replacement of such document.”.

9 **SEC. 5. ORTHOTIST’S AND PROSTHETIST’S CLINICAL NOTES**
 10 **AS PART OF THE PATIENT’S MEDICAL**
 11 **RECORD.**

12 Section 1834(h) of the Social Security Act (42 U.S.C.
 13 1395m(h)), as amended by section 4, is amended by add-
 14 ing at the end the following new paragraph:

15 “(6) DOCUMENTATION CREATED BY
 16 ORTHOTISTS AND PROSTHETISTS.—With respect to
 17 claims filed after August 11, 2011, for purposes of
 18 determining the reasonableness, medical necessity,
 19 and functional level (applicable to prosthetics) of
 20 prosthetic devices and orthotics and prosthetics, doc-
 21 umentation created by an orthotist or prosthetist
 22 shall be considered part of the patient’s medical
 23 record and, consistent with the treatment of orthotic
 24 and prosthetic patient care delivery stated in the
 25 health care professional exception provided in clause

1 (ii) of subsection (a)(20)(F), shall be given the same
 2 consideration as documentation created by other
 3 health professionals, including physicians, nurse
 4 practitioners, occupational therapists, and physical
 5 therapists.”.

6 **SEC. 6. DISTINGUISHING ORTHOTISTS AND PROSTHETISTS**
 7 **FROM SUPPLIERS OF DURABLE MEDICAL**
 8 **EQUIPMENT AND SUPPLIES.**

9 (a) REQUIREMENTS FOR SUPPLIERS OF MEDICAL
 10 EQUIPMENT AND SUPPLIES.—Section 1834(j)(5) of the
 11 Social Security Act (42 U.S.C. 1395m(j)(5)) is amended
 12 by striking subparagraph (C).

13 (b) REQUIREMENTS FOR ORTHOTISTS AND
 14 PROSTHETISTS.—Section 1834 of the Social Security Act
 15 (42 U.S.C. 1395m) is amended by adding at the end the
 16 following new subsection:

17 “(r) REQUIREMENTS FOR ORTHOTISTS AND
 18 PROSTHETISTS.—

19 “(1) ISSUANCE AND RENEWAL OF SUPPLIER
 20 NUMBER.—

21 “(A) PAYMENT.—

22 “(i) IN GENERAL.—No payment may
 23 be made under this part to an orthotic or
 24 prosthetic supplier unless such orthotic or
 25 prosthetic supplier obtains (and renews at

1 such intervals as the Secretary may re-
2 quire) a supplier number.

3 “(ii) CLARIFICATION REGARDING PRO-
4 VIDERS UNDER PART A.—Nothing in
5 clause (i) shall prohibit a provider other-
6 wise permitted to receive payment for
7 orthotics and prosthetics under part A
8 from continuing to receive payment under
9 such part without interruption.

10 “(B) STANDARDS FOR POSSESSING A SUP-
11 PLIER NUMBER.—An orthotic or prosthetic sup-
12 plier may only obtain a supplier number if the
13 supplier meets standards prescribed by the Sec-
14 retary that include requirements that the
15 orthotic or prosthetic supplier (and, where ap-
16 plicable, the orthotist or prosthetist)—

17 “(i) complies with all applicable State
18 and Federal licensure and regulatory re-
19 quirements;

20 “(ii) acquires accreditation from the
21 American Board for Certification in
22 Orthotics, Prosthetics and Pedorthics, Inc.
23 (ABC) or the Board of Certification/Ac-
24 creditation, International (BOC), or other
25 accreditation entity that the Secretary de-

1 termines has standards that are essentially
2 equivalent to the standards of such
3 Boards;

4 “(iii) maintains a physical facility on
5 an appropriate site;

6 “(iv) has proof of appropriate liability
7 insurance; and

8 “(v) meets such other requirements as
9 the Secretary shall specify.

10 “(C) PROHIBITION AGAINST MULTIPLE
11 SUPPLIER NUMBERS.—The Secretary may not
12 issue more than one supplier number to any
13 orthotic or prosthetic supplier unless the Sec-
14 retary finds that the issuance of more than one
15 number is appropriate to identify other entities
16 under the ownership or control of the orthotic
17 or prosthetic supplier.

18 “(2) ORDER FOR ORTHOTICS OR PROS-
19 THETICS.—

20 “(A) INFORMATION PROVIDED BY
21 ORTHOTISTS AND PROSTHETISTS ON DETAILED
22 WRITTEN ORDERS FOR ORTHOTICS AND PROS-
23 THETICS.—An orthotist or prosthetist may dis-
24 tribute to physicians, or to an individual en-
25 rolled under this part, a detailed written order

1 for orthotics or prosthetics (as defined in para-
2 graph (5)) for commercial purposes that con-
3 tains the following information:

4 “(i) The identification of—

5 “(I) the orthotic or prosthetic
6 supplier; and

7 “(II) the individual to whom the
8 orthotics or prosthetics are furnished.

9 “(ii) The identification of the treating
10 physician, including the name, address,
11 and telephone number of the physician.

12 “(iii) A description of the orthotics or
13 prosthetics ordered.

14 “(iv) Any billing code identifying the
15 orthotics or prosthetics.

16 “(v) Diagnosis codes, a description of
17 the individual’s medical and functional
18 condition, and information about the need
19 for the orthotics or prosthetics.

20 “(B) INFORMATION ON CODING AND
21 DESCRIPTORS OF COMPONENTS PROVIDED.—If
22 an orthotist or prosthetist distributes a detailed
23 written order for orthotics or prosthetics de-
24 scribed in subparagraph (A), the orthotist or
25 prosthetist shall also list on the order the

1 HCPCS codes and summary descriptors of the
2 items and services being recommended prior to
3 submission of the order to the treating physi-
4 cian for approval.

5 “(C) SIGNATURE BY TREATING PHYSI-
6 CIAN.—A detailed written order for orthotics or
7 prosthetics described in subparagraph (A) shall
8 be signed by the treating physician.

9 “(3) LIMITATION ON INDIVIDUAL LIABILITY.—
10 Except as provided in paragraph (4), if an orthotist
11 or prosthetist—

12 “(A) furnishes an orthosis or prosthesis to
13 an individual for which no payment may be
14 made under this part; or

15 “(B) subject to section 1879, furnishes an
16 orthosis or prosthesis to an individual for which
17 payment is denied under section 1862(a)(1),

18 any expenses incurred for the orthosis or prosthesis
19 furnished to an individual by the orthotist or pros-
20 thetist not on an assigned basis shall be the respon-
21 sibility of such orthotist or prosthetist. The indi-
22 vidual shall have no financial responsibility for such
23 expenses and the orthotist or prosthetist shall refund
24 on a timely basis to the individual (and shall be lia-
25 ble to the individual for) any amounts collected from

1 the individual for such items and services. The pro-
2 visions of subsection (a)(18) shall apply to refunds
3 required under the previous sentence in the same
4 manner as such provisions apply to refunds under
5 such subsection.

6 “(4) INDIVIDUAL LIABILITY.—If an orthotist or
7 prosthetist furnishes an orthosis or prosthesis to an
8 individual for which payment is denied in advance
9 under subsection (a)(15), expenses incurred for such
10 orthosis or prosthesis furnished to the individual by
11 the orthotist or prosthetist shall be the responsibility
12 of the individual.

13 “(5) DEFINITIONS.—In this subsection:

14 “(A) DETAILED WRITTEN ORDER FOR
15 ORTHOTICS OR PROSTHETICS.—The term ‘de-
16 tailed written order for orthotics or prosthetics’
17 means a form or other document prepared by
18 an orthotist or prosthetist and signed by the
19 physician (as defined by section 1861(r)) that
20 contains information required by the Secretary
21 to be submitted to show that an orthosis or
22 prosthesis is reasonable and necessary for the
23 treatment of an illness or injury or to improve
24 the functioning of a malformed body member.

1 “(B) ORTHOTICS AND PROSTHETICS.—The
2 term ‘orthotics and prosthetics’ has the mean-
3 ing given that term in section 1834(h)(4)(C).

4 “(C) ORTHOTIST OR PROSTHETIST.—The
5 term ‘orthotist or prosthetist’ means an indi-
6 vidual who is specifically trained and educated
7 in the provision of, and patient care manage-
8 ment related to, prosthetics and custom-fab-
9 ricated or custom-fit orthotics, and—

10 “(i) in the case of a State that pro-
11 vides for the licensing of orthotists and
12 prosthetists, is licensed by the State in
13 which the orthotics or prosthetics were
14 supplied; or

15 “(ii) in the case of a State that does
16 not provide for the licensing of orthotists
17 and prosthetists, is certified by the Amer-
18 ican Board of Certification in Orthotics,
19 Prosthetics and Pedorthics, Inc. or by the
20 Board of Certification/Accreditation, Inter-
21 national, or is certified and approved by an
22 entity that the Secretary determines has
23 certification and approval standards that
24 are essentially equivalent to the certifi-

1 cation and approval standards of such
2 Boards.”.

3 (c) DEFINITION OF ORTHOTICS AND PROSTHETICS
4 SYNONYMOUS WITH ORTHOSES AND PROSTHESES.—Sec-
5 tion 1834(h)(4)(C) of the Social Security Act (42 U.S.C.
6 1395m(h)(4)(C)) is amended by inserting “(which may
7 also be referred to without distinction as ‘orthoses and
8 prostheses’)” after “the term ‘orthotics and prosthetics’”.

9 (d) LIMITATION OF COMPETITIVE ACQUISITION FOR
10 OFF-THE-SHELF ORTHOTICS.—Section 1847(a)(7)(A)(i)
11 of the Social Security Act (42 U.S.C. 1395w-
12 3(a)(7)(A)(i)) is amended—

13 (1) by inserting “, orthotist or prosthetist (as
14 defined in section 1834(r)(5)(C)),” after “by a phy-
15 sician”;

16 (2) by inserting “, orthotist’s or prosthetist’s,”
17 after “to the physician’s”; and

18 (3) by inserting “, orthotist’s or prosthetist’s,”
19 after “of the physician’s”.

20 (e) EFFECTIVE DATE.—The amendments made by
21 this section shall take effect on the date of enactment of
22 this Act, and apply to items and services furnished on or
23 after such date.

1 **SEC. 7. CLARIFICATION ABOUT MINIMAL SELF-ADJUST-**
2 **MENT FOR OFF-THE-SHELF ORTHOTICS.**

3 (a) IN GENERAL.—Section 1847(a)(2)(C) of the So-
4 cial Security Act (42 U.S.C. 1395w–3(a)(2)(C)) is amend-
5 ed—

6 (1) by inserting “furnished to a patient” after
7 “section 1861(s)(9) of this title”;

8 (2) by inserting “by that patient (and not by
9 any other person)” after “minimal self-adjustment”;
10 and

11 (3) by striking “to fit to the individual” and in-
12 serting “to fit to that patient”.

13 (b) INCLUSION IN MEDICAL AND OTHER HEALTH
14 SERVICES.—Section 1861(s)(9) of the Social Security Act
15 (42 U.S.C. 1395x(s)(9)) is amended—

16 (1) by striking “leg, arm” and inserting “(A)
17 leg, arm”;

18 (2) in subparagraph (A), as added by para-
19 graph (1), by striking the semicolon and inserting “;
20 and”; and

21 (3) by adding the following new subparagraph:
22 “(B) off-the-shelf orthotics (as defined in sec-
23 tion 1847(a)(2)(C)).”.

24 (c) EFFECTIVE DATE.—The amendments made by
25 this section shall take effect on April 1, 2007, and apply
26 to items and services furnished on or after such date.

1 **SEC. 8. REGULATIONS.**

2 Not later than 120 days after the date of enactment
3 of this Act, the Secretary shall promulgate regulations to
4 implement—

5 (1) the provisions of, and amendments made
6 by, this Act; and

7 (2) the provisions of, and amendments made
8 by, section 427 of the Medicare, Medicaid, and
9 SCHIP Benefits Improvement and Protections Act
10 of 2000, as enacted into law by section 1(a)(6) of
11 Public Law 106–554.

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