

115TH CONGRESS
1ST SESSION

S. 1191

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

MAY 22, 2017

Mr. GRASSLEY 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 2017”.

7 (b) TABLE OF CONTENTS.—The table of contents for
8 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, 2018, 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 2018, 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), in the matter preceding sub-
 13 clause (I), by striking “an item of custom-fabricated
 14 orthotics described in clause (ii) or for an item of
 15 prosthetics unless such item is” and inserting “an
 16 item of orthotics or prosthetics, including an item of
 17 custom-fabricated orthotics described in clause (ii),
 18 unless such item is”;

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

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

1 provide or manage the provision of orthotics and
 2 prosthetics (and custom-designed or -fabricated
 3 orthotics, in the case of an item described in clause
 4 (ii))”; and

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

7 “(v) EXEMPTION OF OFF-THE-SHELF
 8 ORTHOTICS INCLUDED IN A COMPETITIVE
 9 ACQUISITION PROGRAM.—This subpara-
 10 graph shall not apply to an item of
 11 orthotics described in paragraph (2)(C) of
 12 section 1847(a) furnished on or after Jan-
 13 uary 1, 2018, that is included in a com-
 14 petitive acquisition area under such sec-
 15 tion.”.

16 (b) EFFECTIVE DATE.—The amendments made by
 17 subsection (a) shall apply to orthotics and prosthetics fur-
 18 nished on or after January 1, 2018.

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

23 Section 1834(h) of the Social Security Act (42 U.S.C.
 24 1395m(h)) is amended—

(1) in paragraph (1)(F)(iii), in the matter preceding subclause (I), by striking “other individual who” and inserting “other individual who, with respect to the provision of orthotics and prosthetics furnished on or after January 1, 2018, and subject to paragraph (5)(A), satisfies all applicable criteria of the provider qualification designation for such orthotic or prosthetic, and who”;

(2) in paragraph (1)(F)(iv), by inserting before the period the following: “and, with respect to the provision of orthotics and prosthetics furnished on or after January 1, 2018, and subject to paragraph (5)(A), satisfies all applicable criteria of the provider qualification designation for such orthotic or prosthetic”; and

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

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

“(A) CONSIDERATIONS FOR ELIGIBILITY FOR PAYMENTS.—

“(i) IN GENERAL.—In applying clauses (iii) and (iv) of paragraph (1)(F) for purposes of determining whether pay-

1 ment may be made under this subsection
2 for orthotics and prosthetics furnished on
3 or after January 1, 2018, the Secretary
4 shall take into account the complexity of
5 the respective item and, subject to clauses
6 (ii), (iii), and (iv), the qualifications of the
7 individual or entity furnishing and fabri-
8 cating such respective item in accordance
9 with this paragraph.

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

22 “(iii) SUPPLIERS MEDICARE-ELIGIBLE
23 PRIOR TO JANUARY 1, 2018, EXEMPTED.—
24 In the case of a qualified supplier who is
25 eligible to receive payment under this title

1 before January 1, 2018, with respect to
2 the provision of orthotics and prosthetics,
3 any new criteria for provider qualifications
4 established after such date shall not apply
5 to such supplier, for the furnishing or fab-
6 rication of such an item.

7 “(iv) MODIFICATIONS.—The Secretary
8 shall, in consultation with the Boards and
9 programs described in paragraph
10 (1)(F)(iv), periodically review the criteria
11 for supplier qualifications and may imple-
12 ment by regulation any modifications to
13 such criteria, as determined appropriate in
14 accordance with such consultation. Any
15 such modifications shall take effect no ear-
16 lier than January 1, 2018.

17 “(B) ASSIGNMENT OF BILLING CODES.—
18 For purposes of subparagraph (A), the Sec-
19 retary, in consultation with representatives of
20 the fields of occupational therapy, physical ther-
21 apy, orthotics, and prosthetics, shall utilize and
22 incorporate the set of L-codes listed, as of the
23 date of enactment of this paragraph, in the
24 Centers for Medicare & Medicaid Services docu-
25 ment entitled ‘Transmittal 656’ (CMS Pub.

1 100–04, Change Request 3959, August 19,
 2 2005). Transmittal 656 shall be the controlling
 3 source of category, product, and code assign-
 4 ments for the orthotics and prosthetics care,
 5 using the supplier qualification designation for
 6 each HCPCS code as stated in such document.
 7 In the case that Transmittal 656 is updated,
 8 reissued, or replaced by a subsequent document,
 9 the preceding sentence shall be applied with re-
 10 spect to the most recent update, reissuance, or
 11 replacement of such document.”.

12 **SEC. 5. ORTHOTIST’S AND PROSTHETIST’S CLINICAL NOTES**
 13 **AS PART OF THE PATIENT’S MEDICAL**
 14 **RECORD.**

15 Section 1834(h) of the Social Security Act (42 U.S.C.
 16 1395m(h)), as amended by section 4, is amended by add-
 17 ing at the end the following new paragraph:

18 “(6) DOCUMENTATION CREATED BY
 19 ORTHOTISTS AND PROSTHETISTS.—With respect to
 20 claims filed after the date of the enactment of the
 21 Medicare Orthotics and Prosthetics Improvement
 22 Act of 2017, for purposes of determining the reason-
 23 ableness, medical necessity, and functional level (ap-
 24 plicable to prosthetics) of orthotics and prosthetics,
 25 documentation created by an orthotist or prosthetist

1 shall be considered part of the patient’s medical
 2 record and, consistent with the treatment of orthotic
 3 and prosthetic patient care delivery stated in the
 4 health care professional exception provided in clause
 5 (ii) of subsection (a)(20)(F), shall be considered
 6 along with documentation created by other health
 7 professionals, including physicians, nurse practi-
 8 tioners, occupational therapists, and physical thera-
 9 pists.”.

10 **SEC. 6. DISTINGUISHING ORTHOTISTS AND PROSTHETISTS**
 11 **FROM SUPPLIERS OF DURABLE MEDICAL**
 12 **EQUIPMENT AND SUPPLIES.**

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

17 (b) REQUIREMENTS FOR ORTHOTISTS AND
 18 PROSTHETISTS.—

19 (1) IN GENERAL.—Section 1834 of the Social
 20 Security Act (42 U.S.C. 1395m) is amended by add-
 21 ing at the end the following new subsection:

22 “(v) REQUIREMENTS FOR ORTHOTISTS AND
 23 PROSTHETISTS.—

24 “(1) ISSUANCE AND RENEWAL OF SUPPLIER
 25 NUMBER.—

1 “(A) PAYMENT.—

2 “(i) IN GENERAL.—No payment may
3 be made under this part to an orthotic or
4 prosthetic supplier unless such orthotic or
5 prosthetic supplier obtains (and renews at
6 such intervals as the Secretary may re-
7 quire) a supplier number.

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

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

22 “(i) licensure or accreditation—

23 “(I) complies with all applicable
24 State and Federal licensure and regu-
25 latory requirements; or

1 “(II) acquires accreditation from
2 the American Board for Certification
3 in Orthotics, Prosthetics and
4 Pedorthics, Inc. (ABC) or the Board
5 of Certification/Accreditation, Inter-
6 national (BOC), or other accreditation
7 entity that the Secretary determines
8 has standards that are essentially
9 equivalent to the standards of such
10 Boards;

11 “(ii) maintains a physical facility on
12 an appropriate site;

13 “(iii) has proof of appropriate liability
14 insurance; and

15 “(iv) meets such other requirements
16 as the Secretary shall specify.

17 “(C) PROHIBITION AGAINST MULTIPLE
18 SUPPLIER NUMBERS.—The Secretary may not
19 issue more than one supplier number to any
20 orthotic or prosthetic supplier unless the Sec-
21 retary finds that the issuance of more than one
22 number is appropriate to identify other entities
23 under the ownership or control of the orthotic
24 or prosthetic supplier.

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

3 “(A) INFORMATION PROVIDED BY
4 ORTHOTISTS AND PROSTHETISTS ON DETAILED
5 WRITTEN ORDERS FOR ORTHOTICS AND PROS-
6 THETICS.—An orthotist or prosthetist may dis-
7 tribute to physicians, or to an individual en-
8 rolled under this part, a detailed written order
9 for orthotics or prosthetics (as defined in para-
10 graph (5)) for commercial purposes that con-
11 tains the following information:

12 “(i) The identification of—

13 “(I) the orthotic or prosthetic
14 supplier; and

15 “(II) the individual to whom the
16 orthotics or prosthetics are furnished.

17 “(ii) The identification of the treating
18 physician, including the name, address,
19 and telephone number of the physician.

20 “(iii) A description of the orthotics or
21 prosthetics ordered.

22 “(iv) Any billing code identifying the
23 orthotics or prosthetics.

24 “(v) Diagnosis codes, a description of
25 the individual’s medical and functional

1 condition, and information about the need
2 for the orthotics or prosthetics.

3 “(B) INFORMATION ON CODING AND
4 DESCRIPTORS OF COMPONENTS PROVIDED.—If
5 an orthotist or prosthetist distributes a detailed
6 written order for orthotics or prosthetics de-
7 scribed in subparagraph (A), the orthotist or
8 prosthetist shall also list on the order the
9 HCPCS codes and summary descriptors of the
10 items and services being recommended prior to
11 submission of the order to the treating physi-
12 cian for approval.

13 “(C) SIGNATURE BY TREATING PHYSI-
14 CIAN.—A detailed written order for orthotics or
15 prosthetics described in subparagraph (A) shall
16 be signed by the treating physician.

17 “(3) LIMITATION ON INDIVIDUAL LIABILITY.—
18 Except as provided in paragraph (4), if an orthotist
19 or prosthetist—

20 “(A) furnishes an orthosis or prosthesis to
21 an individual for which no payment may be
22 made under this part; or

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

1 any expenses incurred for the orthosis or prosthesis
 2 furnished to an individual by the orthotist or pros-
 3 thetist not on an assigned basis shall be the respon-
 4 sibility of such orthotist or prosthetist. The indi-
 5 vidual shall have no financial responsibility for such
 6 expenses and the orthotist or prosthetist shall refund
 7 on a timely basis to the individual (and shall be lia-
 8 ble to the individual for) any amounts collected from
 9 the individual for such items and services. The pro-
 10 visions of subsection (a)(18) shall apply to refunds
 11 required under the previous sentence in the same
 12 manner as such provisions apply to refunds under
 13 such subsection.

14 “(4) INDIVIDUAL LIABILITY.—If an orthotist or
 15 prosthetist furnishes an orthosis or prosthesis to an
 16 individual for which payment is denied in advance
 17 under subsection (a)(15), expenses incurred for such
 18 orthosis or prosthesis furnished to the individual by
 19 the orthotist or prosthetist shall be the responsibility
 20 of the individual.

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

22 “(A) DETAILED WRITTEN ORDER FOR
 23 ORTHOTICS OR PROSTHETICS.—

24 “(i) IN GENERAL.—The term ‘detailed
 25 written order for orthotics or prosthetics’

1 means a form or other document prepared
2 by an orthotist or prosthetist and signed
3 by the physician (as defined by section
4 1861(r)) that contains information re-
5 quired by the Secretary to be submitted to
6 show that an orthosis or prosthesis is rea-
7 sonable and necessary for the treatment of
8 an illness or injury or to improve the func-
9 tioning of a malformed body member.

10 “(ii) CLARIFICATION.—The detailed
11 written work order for orthotics or pros-
12 thetic shall not be considered alone for
13 purposes of determining the reasonable-
14 ness, medical necessity, and functional
15 level (applicable to prosthetics) of pros-
16 thetic devices and orthotics.

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

20 “(C) ORTHOTIST OR PROSTHETIST.—The
21 term ‘orthotist or prosthetist’ means an indi-
22 vidual who is specifically trained and educated
23 in the provision of, and patient care manage-
24 ment related to, prosthetics and custom-fab-
25 ricated or custom-fit orthotics, and—

1 “(i) in the case of a State that pro-
 2 vides for the licensing of orthotists and
 3 prosthetists, is licensed by the State in
 4 which the orthotics or prosthetics were
 5 supplied; or

6 “(ii) in the case of a State that does
 7 not provide for the licensing of orthotists
 8 and prosthetists, is certified by the Amer-
 9 ican Board of Certification in Orthotics,
 10 Prosthetics and Pedorthics, Inc. or by the
 11 Board of Certification/Accreditation, Inter-
 12 national, or is certified and approved by an
 13 entity that the Secretary determines has
 14 certification and approval standards that
 15 are essentially equivalent to the certifi-
 16 cation and approval standards of such
 17 Boards.”.

18 (2) IMPACT ON DMEPOS BENEFIT.—The
 19 amendment made by paragraph (1)—

20 (A) shall not be construed to create a sepa-
 21 rate benefit category under title XVIII of the
 22 Social Security Act for orthotic and prosthetic
 23 devices; but

24 (B) shall be construed as differentiating
 25 the manner in which orthotic and prosthetic de-

1 vices and services are provided in contrast to
 2 other durable medical equipment and supplies
 3 services covered under such title.

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

10 (d) LIMITATION OF COMPETITIVE ACQUISITION FOR
 11 OFF-THE-SHELF ORTHOTICS.—Section 1847(a)(7)(A)(i)
 12 of the Social Security Act (42 U.S.C. 1395w-
 13 3(a)(7)(A)(i)) is amended—

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

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

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

21 (e) EFFECTIVE DATE.—The amendments made by
 22 this section shall take effect on the date of enactment of
 23 this Act, and apply to items and services furnished on or
 24 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)”;

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 at the end and
 20 inserting “; 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 The Secretary shall promulgate—

3 (1) not later than 1 year after the enactment
4 of this Act, final regulations to implement the provi-
5 sions of, and amendments made by, this Act; and

6 (2) not later than 120 days after the enactment
7 of this Act, final regulations to implement the provi-
8 sions of, and amendments made by, section 427 of
9 the Medicare, Medicaid, and SCHIP Benefits Im-
10 provement and Protections Act of 2000, as enacted
11 into law by section 1(a)(6) of Public Law 106–554.

○