

116TH CONGRESS
2D SESSION

S. 4503

To amend title XVIII of the Social Security Act to protect beneficiaries with limb loss and other orthopedic conditions by providing access to appropriate, safe, effective, patient-centered orthotic and prosthetic care, to reduce fraud, waste, and abuse with respect to orthotics and prosthetics, and for other purposes.

IN THE SENATE OF THE UNITED STATES

AUGUST 6, 2020

Mr. WARNER (for himself, Mr. DAINES, Ms. DUCKWORTH, Mr. CASSIDY, and Mr. CORNYN) 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 protect beneficiaries with limb loss and other orthopedic conditions by providing access to appropriate, safe, effective, patient-centered orthotic and prosthetic care, to reduce fraud, waste, and abuse with respect to orthotics and prosthetics, 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 “Medicare Orthotics and
5 Prosthetics Patient-Centered Care Act”.

1 **SEC. 2. INCREASING PROTECTIONS FOR BENEFICIARIES**
 2 **RECEIVING ORTHOTIC AND PROSTHETIC**
 3 **CARE UNDER THE MEDICARE PROGRAM.**

4 (a) DISTINGUISHING ORTHOTISTS AND
 5 PROSTHETISTS FROM SUPPLIERS OF DURABLE MEDICAL
 6 EQUIPMENT AND SUPPLIES.—Section 1834 of the Social
 7 Security Act (42 U.S.C. 1395m) is amended—

8 (1) in subsection (j)(5), by striking subpara-
 9 graph (C) and redesignating the subsequent sub-
 10 paragraphs accordingly; and

11 (2) by adding at the end the following new sub-
 12 section:

13 “(x) REQUIREMENTS FOR ORTHOTISTS AND
 14 PROSTHETISTS.—

15 “(1) ISSUANCE AND RENEWAL OF SUPPLIER
 16 NUMBER.—

17 “(A) PAYMENT.—

18 “(i) IN GENERAL.—No payment may
 19 be made under this part to an orthotic or
 20 prosthetic supplier unless such orthotic or
 21 prosthetic supplier obtains (and renews at
 22 such intervals as the Secretary may re-
 23 quire) a supplier number.

24 “(ii) CLARIFICATION REGARDING PRO-
 25 VIDERS UNDER PART A.—Nothing in
 26 clause (i) shall prohibit a provider other-

1 wise permitted to receive payment for
2 orthotics and prosthetics under part A
3 from continuing to receive payment under
4 such part without interruption.

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

12 “(i) licensure and accreditation—

13 “(I) complies with all applicable
14 State and Federal licensure and regu-
15 latory requirements; and

16 “(II) acquires accreditation from
17 the American Board for Certification
18 in Orthotics, Prosthetics and
19 Pedorthics, Inc. or the Board of Cer-
20 tification/Accreditation, International,
21 or other accreditation entity that the
22 Secretary determines has standards
23 that are equivalent to the standards of
24 such Boards;

1 “(ii) maintains a physical facility on
2 an appropriate site;

3 “(iii) has proof of appropriate liability
4 insurance; and

5 “(iv) meets such other requirements
6 as the Secretary shall specify.

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

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

17 “(A) INFORMATION PROVIDED BY
18 ORTHOTISTS AND PROSTHETISTS ON DETAILED
19 WRITTEN ORDERS FOR ORTHOTICS AND PROS-
20 THETICS.—An orthotist or prosthetist may dis-
21 tribute to physicians, physician assistants,
22 nurse practitioners, clinical nurse specialists, or
23 individuals entitled to benefits under this part,
24 a detailed written order for orthotics or pros-
25 thetics (as defined in paragraph (5)) for com-

1 mercial purposes that contains the following in-
2 formation:

3 “(i) The identification of—

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

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

8 “(ii) The identification of the treating
9 physician, physician assistant, nurse prac-
10 titioner, or clinical nurse specialist.

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

13 “(iv) The date of the order described
14 in this subparagraph.

15 “(B) INFORMATION ON CODING AND
16 DESCRIPTORS OF COMPONENTS PROVIDED.—If
17 an orthotist or prosthetist distributes a detailed
18 written order for orthotics or prosthetics de-
19 scribed in subparagraph (A), the orthotist or
20 prosthetist shall also list on the order the sum-
21 mary descriptors of the items and services being
22 recommended prior to submission of the order
23 to the treating physician for approval.

24 “(C) SIGNATURE BY TREATING PHYSI-
25 CIAN.—A detailed written order for orthotics or

1 prosthetics described in subparagraph (A) shall
2 be signed by the treating physician.

3 “(3) LIMITATION ON PATIENT LIABILITY.—Ex-
4 cept as provided in paragraph (4), if an orthotist or
5 prosthetist—

6 “(A) furnishes an orthosis or prosthesis to
7 a beneficiary for which no payment may be
8 made under this part; or

9 “(B) subject to section 1879, furnishes an
10 orthosis or prosthesis to a beneficiary for which
11 payment is denied under section 1862(a)(1),
12 any expenses incurred for the orthosis or prosthesis
13 furnished to an individual by the orthotist or pros-
14 thetist not on an assigned basis shall be the respon-
15 sibility of such orthotist or prosthetist. The indi-
16 vidual shall have no financial responsibility for such
17 expenses and the orthotist or prosthetist shall refund
18 on a timely basis to the individual (and shall be lia-
19 ble to the individual for) any amounts collected from
20 the individual for such items and services. The pro-
21 visions of subsection (a)(18) shall apply to refunds
22 required under the previous sentence in the same
23 manner as such provisions apply to refunds under
24 such subsection.

1 “(4) PATIENT LIABILITY.—If an orthotist or
2 prosthetist furnishes an orthosis or prosthesis to a
3 patient for which payment is denied in advance
4 under subsection (a)(15), expenses incurred for such
5 orthosis or prosthesis furnished to the individual by
6 the orthotist or prosthetist shall be the responsibility
7 of the individual.

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

9 “(A) DETAILED WRITTEN ORDER FOR
10 ORTHOTICS OR PROSTHETICS.—

11 “(i) IN GENERAL.—The term ‘detailed
12 written order for orthotics or prosthetics’
13 means a form or other document prepared
14 by an orthotist or prosthetist and signed
15 by the physician (as defined by section
16 1861(r)) that contains information re-
17 quired by the Secretary to show that an
18 orthosis or prosthesis is reasonable and
19 necessary for the treatment of an illness or
20 injury or to improve the functioning of a
21 malformed body member.

22 “(ii) CLARIFICATION.—The detailed
23 written order for orthotics or prosthetics
24 shall not be considered alone for purposes
25 of determining the reasonableness, medical

1 necessity, and functional level (applicable
2 to prosthetics) of orthotics and prosthetics.

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

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

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

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

1 are essentially equivalent to the certifi-
2 cation and approval standards of such
3 Boards.”.

4 (b) PROHIBITING PAYMENT FOR CERTAIN
5 ORTHOTICS AND PROSTHETICS.—Section 1834(h)(1) of
6 the Social Security Act (42 U.S.C. 1395m(h)(1)) is
7 amended by adding at the end the following new subpara-
8 graph:

9 “(I) SPECIAL PAYMENT RULES FOR
10 ORTHOTICS OR PROSTHETICS.—

11 “(i) IN GENERAL.—No payment shall
12 be made under this subsection for—

13 “(I) a prosthesis (excluding pros-
14 thetic supplies) that is delivered by
15 drop shipment;

16 “(II) a custom-fabricated or cus-
17 tom-fitted orthosis (excluding orthotic
18 supplies) described in subparagraph
19 (F)(ii) that is delivered by drop ship-
20 ment; and

21 “(III) an orthotic item that is
22 not otherwise competitively bid that is
23 delivered by drop shipment.

24 “(ii) DROP SHIPMENT DEFINED.—In
25 this subparagraph, the term ‘drop ship-

1 ment’ means the shipping of an orthosis or
2 prosthesis to a beneficiary without receiv-
3 ing from a trained, educated, and certified
4 or licensed health care practitioner,
5 orthotist, or prosthetist direct patient care
6 with respect to assessing, adjusting, and
7 training in the care and use of the orthosis
8 or prosthesis.”.

9 (c) STANDARDIZING THE DEFINITIONS OF
10 ORTHOTICS AND PROSTHETICS.—Section 1834(h)(4) of
11 the Social Security Act (42 U.S.C. 1395m(h)(4)) is
12 amended—

13 (1) in subparagraph (B), by striking at the end
14 “and”;

15 (2) in subparagraph (C)—

16 (A) by striking “the term ‘orthotics and
17 prosthetics’ has the meaning given such term”
18 and inserting “the terms ‘orthotics and pros-
19 thetics’ and ‘orthoses and prostheses’ have the
20 meaning given such terms”; and

21 (B) by striking the period at the end and
22 inserting “; and”; and

23 (3) by inserting after subparagraph (C), as
24 amended by paragraph (2), the following new sub-
25 paragraph:

1 “(D) the terms ‘prosthetics’ and ‘pros-
2 theses’ refer to a device (including the clinical
3 services associated with such device) that re-
4 places all or part of a limb.”.

5 (d) LIMITATION OF COMPETITIVE ACQUISITION FOR
6 OFF-THE-SHELF ORTHOTICS.—Section 1847(a) of the
7 Social Security Act (42 U.S.C. 1395w–3(a)) is amended—

8 (1) in paragraph (2)(C), by inserting “by the
9 patient (and not by another person)” after “minimal
10 self-adjustment”; and

11 (2) in paragraph (7)(A)(i)—

12 (A) by inserting “, orthotist or prosthetist
13 (as defined in section 1834(x)(5)(C)),” after
14 “by a physician”;

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

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

19 (e) REGULATIONS.—Not later than 1 year after the
20 date of the enactment of this Act, the Secretary of Health
21 and Human Services shall promulgate final regulations to
22 implement the provisions of, and amendments made by,
23 this Act.

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