

117TH CONGRESS
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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 HOUSE OF REPRESENTATIVES

MARCH 17, 2021

Mr. THOMPSON of California (for himself, Mr. GUTHRIE, Mr. THOMPSON of Pennsylvania, and Mr. BUTTERFIELD) 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 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medicare Orthotics and
3 Prosthetics Patient-Centered Care Act”.

4 **SEC. 2. INCREASING PROTECTIONS FOR BENEFICIARIES**
5 **RECEIVING ORTHOTIC AND PROSTHETIC**
6 **CARE UNDER THE MEDICARE PROGRAM.**

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

11 (1) in subsection (j)(5), by striking subpara-
12 graph (C) and redesignating the subsequent sub-
13 paragraphs accordingly; and

14 (2) by adding at the end the following new sub-
15 section:

16 “(x) REQUIREMENTS FOR ORTHOTISTS AND
17 PROSTHETISTS.—

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

20 “(A) PAYMENT.—

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

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

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

15 “(i) licensure and accreditation—

16 “(I) complies with all applicable
17 State and Federal licensure and regu-
18 latory requirements; and

19 “(II) acquires accreditation from
20 the American Board for Certification
21 in Orthotics, Prosthetics and Pedorth-
22 ics, Inc. or the Board of Certification/
23 Accreditation, International, or other
24 accreditation entity that the Secretary
25 determines has standards that are

1 equivalent to the standards of such
2 Boards;

3 “(ii) maintains a physical facility on
4 an appropriate site;

5 “(iii) has proof of appropriate liability
6 insurance; and

7 “(iv) meets such other requirements
8 as the Secretary shall specify.

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

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

19 “(A) INFORMATION PROVIDED BY
20 ORTHOTISTS AND PROSTHETISTS ON DETAILED
21 WRITTEN ORDERS FOR ORTHOTICS AND PROS-
22 THETICS.—An orthotist or prosthetist may dis-
23 tribute to physicians, physician assistants,
24 nurse practitioners, clinical nurse specialists, or
25 individuals entitled to benefits under this part,

1 a detailed written order for orthotics or pros-
2 thetics (as defined in paragraph (5)) for com-
3 mercial purposes that contains the following in-
4 formation:

5 “(i) The identification of—

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

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

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

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

15 “(iv) The date of the order described
16 in this subparagraph.

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

1 “(C) SIGNATURE BY TREATING PHYSI-
2 CIAN.—A detailed written order for orthotics or
3 prosthetics described in subparagraph (A) shall
4 be signed by the treating physician.

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

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

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

1 manner as such provisions apply to refunds under
2 such subsection.

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

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

11 “(A) DETAILED WRITTEN ORDER FOR
12 ORTHOTICS OR PROSTHETICS.—

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

24 “(ii) CLARIFICATION.—The detailed
25 written order for orthotics or prosthetics

1 shall not be considered alone for purposes
2 of determining the reasonableness, medical
3 necessity, and functional level (applicable
4 to prosthetics) of orthotics and prosthetics.

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

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

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

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

1 entity that the Secretary determines has
2 certification and approval standards that
3 are essentially equivalent to the certifi-
4 cation and approval standards of such
5 Boards.”.

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

11 “(I) SPECIAL PAYMENT RULES FOR
12 ORTHOTICS OR PROSTHETICS.—

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

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

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

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

1 “(ii) DROP SHIPMENT DEFINED.—In
2 this subparagraph, the term ‘drop ship-
3 ment’ means the shipping of an orthosis or
4 prosthesis to a beneficiary without receiv-
5 ing from a trained, educated, and certified
6 or licensed health care practitioner,
7 orthotist, or prosthetist direct patient care
8 with respect to assessing, adjusting, and
9 training in the care and use of the orthosis
10 or prosthesis.”.

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

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

17 (2) in subparagraph (C)—

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

23 (B) by striking the period at the end and
24 inserting “; and”; and

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

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

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

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

14 (2) in paragraph (7)(A)(i)—

15 (A) by inserting “, orthotist or prosthetist
16 (as defined in section 1834(x)(5)(C)),” after
17 “by a physician”;

18 (B) by inserting “, orthotist’s or prosthet-
19 ist’s,” after “to the physician’s”; and

20 (C) by inserting “, orthotist’s or prosthet-
21 ist’s,” after “of the physician’s”.

22 (e) REGULATIONS.—Not later than 1 year after the
23 date of the enactment of this Act, the Secretary of Health
24 and Human Services shall promulgate final regulations to

1 implement the provisions of, and amendments made by,
2 this Act.

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