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(Original Signature of Member)

113TH CONGRESS
1ST SESSION

H. R. _____

To amend title XVIII of the Social Security Act to modify the designation of accreditation organizations for orthotics and prosthetics, to apply accreditation and licensure requirements to suppliers of such devices and items for purposes of payment under the Medicare program, and to modify the payment rules for such devices and items under such program to account for practitioner qualifications and complexity of care, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. THOMPSON of Pennsylvania introduced the following bill; which was referred to the Committee on _____

A BILL

To amend title XVIII of the Social Security Act to modify the designation of accreditation organizations for orthotics and prosthetics, to apply accreditation and licensure requirements to suppliers of such devices and items for purposes of payment under the Medicare program, and to modify the payment rules for such devices and items under such program to account for practitioner qualifications and complexity of 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.**

4 This Act may be cited as the “Medicare Orthotics and
5 Prosthetics Improvement Act of 2013”.

6 **SEC. 2. MODIFICATION OF REQUIREMENTS APPLICABLE**
7 **UNDER MEDICARE TO DESIGNATION OF AC-**
8 **CREDITATION ORGANIZATIONS FOR SUP-**
9 **PLIERS OF ORTHOTICS AND PROSTHETICS.**

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

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

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

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

19 “(ii) SPECIAL REQUIREMENTS FOR
20 ACCREDITATION OF SUPPLIERS OF
21 ORTHOTICS AND PROSTHETICS.—For pur-
22 poses of applying quality standards under
23 subparagraph (A) for suppliers (other than
24 suppliers described in clause (iii)) of items
25 and services described in subparagraph

1 (D)(ii), the Secretary shall designate and
2 approve an independent accreditation orga-
3 nization under clause (i) only if such orga-
4 nization is a Board or program described
5 in subsection (h)(1)(F)(iv). Not later than
6 January 1, 2014, the Secretary shall en-
7 sure that at least one independent accredi-
8 tation organization is designated and ap-
9 proved in accordance with this clause.

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

18 (b) EFFECTIVE DATE.—An organization must satisfy
19 the requirement of section 1834(a)(20)(B)(ii), as added
20 by subsection (a)(2), not later than January 1, 2014, re-
21 gardless of whether such organization is designated or ap-
22 proved as an independent accreditation organization be-
23 fore, on, or after the date of the enactment of this Act.

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

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

8 (1) in the heading, by inserting “**OR CUSTOM-**
9 **FITTED**” after “**CUSTOM-FABRICATED**”;

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

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

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

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

3 “(v) EXEMPTION OF OFF-THE-SHELF ORTHOTICS
4 INCLUDED IN A COMPETITIVE ACQUISITION PROGRAM.—
5 This subparagraph shall not apply to an item of orthotics
6 described in paragraph (2)(C) of section 1847(a) fur-
7 nished on or after January 1, 2014, that is included in
8 a competitive acquisition program in a competitive acquisi-
9 tion area under such section.”.

10 (b) EFFECTIVE DATE.—The amendments made by
11 subsection (a) shall apply to orthotics and prosthetics fur-
12 nished on or after January 1, 2014.

13 **SEC. 4. ELIGIBILITY FOR MEDICARE PAYMENT FOR**
14 **ORTHOTICS AND PROSTHETICS BASED ON**
15 **SUPPLIER QUALIFICATIONS AND COM-**
16 **PLEXITY OF CARE.**

17 Section 1834(h) of the Social Security Act (42 U.S.C.
18 1395m(h)) is amended—

19 (1) in paragraph (1)(F)(iii), in the matter pre-
20 ceding subclause (I), by striking “other individual
21 who” and inserting “other individual who, with re-
22 spect to a category of orthotics and prosthetics care
23 described in clause (i), (ii), (iii), (iv), or (v) of para-
24 graph (5)(C) furnished on or after January 1, 2014,
25 and subject to paragraph (5)(A), satisfies all appli-

1 cable criteria of the supplier qualification designa-
2 tion for such category described in the respective
3 clause, and who”;

4 (2) in paragraph (1)(F)(iv), by inserting before
5 the period the following: “and, with respect to a cat-
6 egory of orthotics and prosthetics care described in
7 clause (i), (ii), (iii), (iv), or (v) of paragraph (5)(C)
8 furnished on or after January 1, 2014, and subject
9 to paragraph (5)(A), satisfies all applicable criteria
10 of the provider qualification designation for such
11 category described in the respective clause”; and

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

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

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

19 “(i) IN GENERAL.—In applying
20 clauses (iii) and (iv) of paragraph (1)(F)
21 for purposes of determining whether pay-
22 ment may be made under this subsection
23 for orthotics and prosthetics furnished on
24 or after January 1, 2014, the Secretary
25 shall take into account the complexity of

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

6 “(ii) INDIVIDUAL AND ENTITIES EX-
7 EMPTED FROM SUPPLIER QUALIFICATION
8 DESIGNATION CRITERIA.—With respect to
9 an item of orthotics or prosthetics de-
10 scribed in clause (ii), (iii), (iv) or (v) of
11 subparagraph (C), any criteria for the sup-
12 plier qualification designations under such
13 respective clause, including application of
14 subparagraph (D), shall not apply to phy-
15 sicians, occupational therapists, or physical
16 therapists who are licensed or otherwise
17 regulated by the State in which they are
18 practicing and who receive payment under
19 this title, including regulations promul-
20 gated pursuant to this subsection, for the
21 provision of orthotics and prosthetics.

22 “(iii) SUPPLIERS MEDICARE-ELIGIBLE
23 PRIOR TO JANUARY 1, 2014 EXEMPTED.—
24 In the case of a qualified supplier who is

1 eligible to receive payment under this title
2 before January 1, 2014—

3 “(I) with respect to an item of
4 orthotics or prosthetics described in
5 clause (i) of subparagraph (C), any
6 criteria for the provider qualification
7 designations under such clause, in-
8 cluding application of subparagraph
9 (D), shall not apply to such supplier,
10 respectively, for the furnishing or fab-
11 rication of such an item so described;
12 and

13 “(II) with respect to an item of
14 orthotics or prosthetics described in
15 clause (ii), (iii), or (iv) of subpara-
16 graph (C), any criteria for the sup-
17 plier qualification designations under
18 the respective clause (or a subsequent
19 clause of such subparagraph), includ-
20 ing application of subparagraph (D),
21 shall not apply to such supplier, re-
22 spectively, for the furnishing or fab-
23 rication of such an item described in
24 such respective (or such subsequent)
25 clause.

1 “(iv) DELAYED APPLICATION OF CER-
2 TAIN SUPPLIER QUALIFICATION DESIGNA-
3 TION CRITERIA.—The supplier qualifica-
4 tion designations under clauses (i), (ii),
5 and (iii) of subparagraph (C), including
6 the application of subparagraph (D) to
7 such clauses, shall not be taken into ac-
8 count with respect to payment made under
9 this subsection for orthotics and pros-
10 thetics furnished before January 1, 2015.

11 “(v) MODIFICATIONS.—The Secretary
12 shall, in consultation with the Boards and
13 programs described in paragraph
14 (1)(F)(iv), periodically review the criteria
15 for the supplier qualification designation
16 under subparagraph (C)(i)(III) and may
17 implement by regulation any modifications
18 to such criteria, as determined appropriate
19 in accordance with such consultation. Any
20 such modification shall take effect no ear-
21 lier than January 1, 2016.

22 “(B) ASSIGNMENT OF BILLING CODES.—
23 For purposes of subparagraph (A), the Sec-
24 retary, in consultation with representatives of
25 the fields of occupational therapy, physical ther-

1 apy, orthotics, and prosthetics shall utilize and
2 incorporate the set of L-codes listed, as of the
3 date of the enactment of this paragraph, in the
4 Centers for Medicare & Medicaid Services docu-
5 ment entitled Transmittal 656 (CMS Pub. 100–
6 04, Change Request 3959, August 19, 2005).
7 Transmittal 656 shall be the controlling source
8 of category, product, and code assignments for
9 the orthotics and prosthetics care described in
10 each of clauses (i) through (v) of subparagraph
11 (C) using the supplier qualification designation
12 for each HCPCS code as stated in such docu-
13 ment. In the case that Transmittal 656 is up-
14 dated, reissued, or replaced by a subsequent
15 document, the previous sentence shall be ap-
16 plied with respect to the most recent update,
17 reissuance, or replacement of such document.

18 “(C) CATEGORIES OF ORTHOTIC AND
19 PROSTHETIC CARE DESCRIBED.—

20 “(i) CUSTOM FABRICATED LIMB PROS-
21 THETICS CATEGORY.—The category of
22 orthotic and prosthetic care described in
23 this clause is a category for artificial legs
24 and arms, including replacements (as de-
25 scribed in section 1861(s)(9)) that are

1 made from detailed measurements, images,
2 or models in accordance with a prescrip-
3 tion and that can only be utilized by a spe-
4 cific intended patient and for which pay-
5 ment is made under this part. The supplier
6 qualification designation for the category
7 shall reflect each of the following, in ac-
8 cordance with subparagraph (D):

9 “(I) The category of care involves
10 the highest level of complexity with
11 substantial clinical risk.

12 “(II) The category of care re-
13 quires a supplier who satisfies any of
14 the education requirements described
15 in subclause (III), has completed a
16 prosthetic residency accredited by the
17 National Commission on Orthotic and
18 Prosthetic Education (‘NCOPE’), and
19 is certified or licensed in prosthetics
20 to ensure the comprehensive provision
21 of prosthetic care.

22 “(III) The category of care re-
23 quires a supplier who has completed
24 any of the following education require-
25 ments:

1 “(aa) A bachelor’s degree or
2 master’s degree in prosthetics as
3 offered by educational institu-
4 tions accredited by the Commis-
5 sion on Accreditation of Allied
6 Health Education Programs.

7 “(bb) A bachelor’s degree,
8 plus a certificate in prosthetics as
9 offered by educational institu-
10 tions accredited by the Commis-
11 sion on Accreditation of Allied
12 Health Education Programs.

13 “(cc) A foreign degree deter-
14 mined by the World Education
15 Service to be equivalent to an
16 educational program in pros-
17 thetics accredited by the Com-
18 mission on Accreditation of Allied
19 Health Education Programs.

20 “(ii) CUSTOM FABRICATED
21 ORTHOTICS CATEGORY.—The category of
22 orthotics and prosthetics care described in
23 this clause is a category for custom-fab-
24 ricated orthotics that are made from de-
25 tailed measurements, images, or models in

1 accordance with a prescription and that
2 can only be utilized by a specific intended
3 patient. The supplier qualification designa-
4 tion for the category shall reflect the fol-
5 lowing, in accordance with subparagraph
6 (D):

7 “(I) The category of care involves
8 the highest level of complexity with
9 substantial clinical risk.

10 “(II) The category of care re-
11 quires a supplier who satisfies any of
12 the education requirements described
13 in clause (i)(III) (except that for pur-
14 poses of this subclause such clause
15 shall be applied by substituting the
16 term ‘orthotics’ each place the term
17 “prosthetics’ is used), has completed
18 an orthotic residency accredited by
19 the National Commission on Orthotic
20 and Prosthetic Education, and is cer-
21 tified or licensed in orthotics to ensure
22 the appropriate provision of orthotic
23 care.

24 “(iii) CUSTOM FITTED HIGH
25 ORTHOTICS CATEGORY.—The category of

1 orthotic care described in this clause is a
2 category for prefabricated orthotics that
3 are manufactured with no specific patient
4 in mind, but that are appropriately sized,
5 adapted, modified, and configured (with
6 the required tools and equipment) to a spe-
7 cific patient in accordance with a prescrip-
8 tion. The supplier qualification designation
9 for the category shall reflect the following,
10 in accordance with subparagraph (D):

11 “(I) The category of care involves
12 moderate to high complexity with sub-
13 stantial clinical risk.

14 “(II) The category of care re-
15 quires a practitioner who either—

16 “(aa) satisfies any of the
17 education requirements described
18 in clause (i)(III), except that for
19 purposes of this subclause such
20 clause shall be applied by sub-
21 stituting the term ‘orthotics’ each
22 place the term ‘prosthetics’ is
23 used; or

24 “(bb) is certified or licensed
25 in orthotics to ensure the appro-

1 priate provision of orthotic care
2 within the practitioner's normal
3 scope of practice.

4 “(iv) CUSTOM FITTED LOW
5 ORTHOTICS CATEGORY.—The category of
6 orthotics and prosthetics care described in
7 this clause is a category for prefabricated
8 orthotics that are manufactured with no
9 specific patient in mind, but that are ap-
10 propriately sized and adjusted to a specific
11 patient in accordance with a prescription.
12 The supplier qualification designation for
13 the category shall reflect the following:

14 “(I) The category of care involves
15 a low level of complexity and low clin-
16 ical risk.

17 “(II) The category of care re-
18 quires a supplier that is certified or li-
19 censed within a limited scope of prac-
20 tice to ensure appropriate provision of
21 orthotic care. The supplier's education
22 and training shall ensure that basic
23 clinical knowledge and technical ex-
24 pertise is available to confirm success-

1 ful fit and device compliance with the
2 prescription.

3 “(v) OFF-THE-SHELF.—The category
4 of orthotic care described in this clause is
5 described in section 1847(a)(2)(C). The
6 supplier qualification designation for the
7 category shall reflect that no formal
8 credentialing, clinical education, or tech-
9 nical training is required to dispense such
10 items.

11 “(D) CARE BASED ON SOUND CLINICAL
12 JUDGMENT AND TECHNICAL EXPERTISE.—Care
13 described in clauses (i), (ii), and (iii) of sub-
14 paragraph (C) shall be based on sound clinical
15 judgment and technical expertise based on the
16 supplier’s education and clinical training, in
17 order to allow the practitioner to determine—

18 “(i) with respect to care described in
19 clause (i) or (ii) of subparagraph (C), the
20 device parameters and design, fabrication
21 process, and functional purpose specific to
22 the needs of the patient to maximize opti-
23 mal clinical outcomes; and

24 “(ii) with respect to care described in
25 clause (iii) of such subparagraph, the ap-

1 appropriate device relative to the diagnosis
2 and specific to the needs of the patient to
3 maximize optimal clinical outcomes.”.

4 **SEC. 5. CONSULTATION.**

5 In implementing the provisions of, and amendments
6 made by, this Act, the Secretary of Health and Human
7 Services shall consult with appropriate experts in orthotics
8 and prosthetics, including suppliers that furnish items
9 within the categories of orthotic and prosthetic care de-
10 scribed in paragraph (5)(C) of section 1834(h) of the So-
11 cial Security Act (42 U.S.C. 1395m(h)), as added by sec-
12 tion 4.

13 **SEC. 6. REPORTS.**

14 (a) REPORT ON ENFORCING NEW LICENSING AND
15 ACCREDITATION REQUIREMENTS.—Not later than 18
16 months after the date of the enactment of this Act, the
17 Secretary of Health and Human Services shall submit to
18 Congress a report on the steps taken by the Department
19 of Health and Human Services to ensure that the State
20 licensure and accreditation requirements under section
21 1834(h)(1)(F) of the Social Security Act (42 U.S.C.
22 1395m(h)(1)(F)), as amended by section 3, are enforced.
23 Such report shall include a determination of the extent
24 to which payments for orthotics and prosthetics under the
25 Medicare program under title XVIII of such Act are made

1 only to those suppliers that meet the relevant accreditation
2 and licensure requirements under such section and a de-
3 termination of whether additional steps are needed.

4 (b) REPORT ON FRAUD AND ABUSE.—Not later than
5 30 months after the date of the enactment of this Act,
6 the Secretary of Health and Human Services shall submit
7 to Congress a report on the effect of the requirements
8 under subsection (a)(20)(B)(ii) of section 1834 of the So-
9 cial Security Act (42 U.S.C. 1395m), as added by section
10 2, and subsection (h)(1)(F) of such section, as amended
11 by section 3, on the occurrence of fraud and abuse under
12 the Medicare program under title XVIII of such Act, with
13 respect to orthotics and prosthetics for which payment is
14 made under such program.

15 **SEC. 7. REDUCTION IN MEDICARE SPENDING.**

16 (a) PROJECTION OF CUMULATIVE EFFECT ON
17 SPENDING.—Not later than December 31, 2014, the Sec-
18 retary of Health and Human Services (in this section re-
19 ferred to as the “Secretary”), acting through the Chief
20 Actuary of the Centers for Medicare & Medicaid Services
21 (in this section referred to as the “Chief Actuary”), shall
22 submit to Congress, and have published in the Federal
23 Register, a projection of the effect on cumulative Federal
24 spending under part B of title XVIII of the Social Security
25 Act for the period of years 2014 through 2018 as a result

1 of the implementation of the provisions of, and amend-
2 ments made by, this Act.

3 (b) STRENGTHENING STANDARDS APPLICABLE IF
4 SAVINGS NOT ACHIEVED.—

5 (1) IN GENERAL.—Subject to paragraph (2), if
6 the Chief Actuary projects under subsection (a) that
7 the implementation of the provisions of, and amend-
8 ments made by, this Act will not result in a cumu-
9 lative reduction in spending under such part of at
10 least \$250,000,000 for the period of years 2014
11 through 2018 (using a 2013 baseline), the Secretary
12 shall, in accordance with the Chief Actuary's projec-
13 tion, issue an interim final regulation (to take effect
14 for 2015 and subsequent years) with a period for
15 public comment on such regulation after the date of
16 publication to strengthen the licensure, accredita-
17 tion, and quality standards applicable to suppliers of
18 orthotics and prosthetics under title XVIII of the
19 Social Security Act, including such standards de-
20 scribed in subsections (a)(20) and (h)(1)(F) of sec-
21 tion 1834 of such Act (42 U.S.C. 1395m), as
22 amended by this Act, in order to produce such cu-
23 mulative reduction by December 31, 2018.

24 (2) EXCEPTION.—The interim final regulation
25 issued under paragraph (1) shall not apply to a

1 qualified physical therapist or qualified occupational
2 therapist (as described in section 1834(h)(1)(F)(iii)
3 of the Social Security Act (42 U.S.C.
4 1395m(h)(1)(F)(iii))).

5 **SEC. 8. NO EFFECT ON PAYMENT BASIS FOR ORTHOTICS**
6 **AND PROSTHETICS OR COMPETITIVE BID-**
7 **DING PROGRAMS.**

8 Nothing in the provisions of, or amendments made
9 by, this Act shall have any effect on—

10 (1) the determination of the payment basis for
11 orthotics and prosthetics under section 1834(h) of
12 the Social Security Act (42 U.S.C. 1395m(h)); or

13 (2) the implementation of competitive acquisi-
14 tion programs under section 1847 of such Act (42
15 U.S.C. 1395w-3), including such implementation
16 with respect to off-the-shelf orthotics described in
17 subsection (a)(2)(C) of that section, that are in-
18 eluded in a competitive acquisition program in a
19 competitive acquisition area under that section.