

113TH CONGRESS
1ST SESSION

H. R. 3112

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

SEPTEMBER 17, 2013

Mr. THOMPSON of Pennsylvania (for himself and Mr. THOMPSON of California) 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 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
4 ORTHOTICS INCLUDED IN A COMPETITIVE
5 ACQUISITION PROGRAM.—This subpara-
6 graph shall not apply to an item of
7 orthotics described in paragraph (2)(C) of
8 section 1847(a) furnished on or after Jan-
9 uary 1, 2014, that is included in a com-
10 petitive acquisition program in a competi-
11 tive acquisition area under such section.”.

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

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

19 Section 1834(h) of the Social Security Act (42 U.S.C.
20 1395m(h)) is amended—

21 (1) in paragraph (1)(F)(iii), in the matter pre-
22 ceding subclause (I), by striking “other individual
23 who” and inserting “other individual who, with re-
24 spect to a category of orthotics and prosthetics care
25 described in clause (i), (ii), (iii), (iv), or (v) of para-

1 graph (5)(C) furnished on or after January 1, 2014,
2 and subject to paragraph (5)(A), satisfies all appli-
3 cable criteria of the supplier qualification designa-
4 tion for such category described in the respective
5 clause, and who”;

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

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

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

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

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

1 or after January 1, 2014, the Secretary
2 shall take into account the complexity of
3 the respective item and, subject to clauses
4 (ii), (iii), and (iv), the qualifications of the
5 individual or entity furnishing and fabri-
6 cating such respective item in accordance
7 with this paragraph.

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

24 “(iii) SUPPLIERS MEDICARE-ELIGIBLE
25 PRIOR TO JANUARY 1, 2014, EXEMPTED.—

1 In the case of a qualified supplier who is
2 eligible to receive payment under this title
3 before January 1, 2014—

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

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

1 such respective (or such subsequent)
2 clause.

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

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

24 “(B) ASSIGNMENT OF BILLING CODES.—

25 For purposes of subparagraph (A), the Sec-

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

20 “(C) CATEGORIES OF ORTHOTIC AND
21 PROSTHETIC CARE DESCRIBED.—

22 “(i) CUSTOM-FABRICATED LIMB PROS-
23 THETICS CATEGORY.—The category of
24 orthotic and prosthetic care described in
25 this clause is a category for artificial legs

1 and arms, including replacements (as de-
2 scribed in section 1861(s)(9)) that are
3 made from detailed measurements, images,
4 or models in accordance with a prescrip-
5 tion and that can only be utilized by a spe-
6 cific intended patient and for which pay-
7 ment is made under this part. The supplier
8 qualification designation for the category
9 shall reflect each of the following, in ac-
10 cordance with subparagraph (D):

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

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

24 “(III) The category of care re-
25 quires a supplier who has completed

1 any of the following education require-
2 ments:

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

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

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

22 “(ii) CUSTOM-FABRICATED
23 ORTHOTICS CATEGORY.—The category of
24 orthotics and prosthetics care described in
25 this clause is a category for custom-fab-

1 ricated orthotics that are made from de-
2 tailed measurements, images, or models in
3 accordance with a prescription and that
4 can only be utilized by a specific intended
5 patient. The supplier qualification designa-
6 tion for the category shall reflect the fol-
7 lowing, in accordance with subparagraph
8 (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 clause (i)(III) (except that for pur-
16 poses of this subclause such clause
17 shall be applied by substituting the
18 term ‘orthotics’ each place the term
19 ‘prosthetics’ is used), has completed
20 an orthotic residency accredited by
21 the National Commission on Orthotic
22 and Prosthetic Education, and is cer-
23 tified or licensed in orthotics to ensure
24 the appropriate provision of orthotic
25 care.

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

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

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

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

1 “(bb) is certified or licensed
2 in orthotics to ensure the appro-
3 priate provision of orthotic care
4 within the practitioner’s normal
5 scope of practice.

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

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

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

1 pertise is available to confirm success-
2 ful fit and device compliance with the
3 prescription.

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

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

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

1 “(ii) with respect to care described in
2 clause (iii) of such subparagraph, the ap-
3 propriate device relative to the diagnosis
4 and specific to the needs of the patient to
5 maximize optimal clinical outcomes.”.

6 **SEC. 5. CONSULTATION.**

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

15 **SEC. 6. REPORTS.**

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

1 to which payments for orthotics and prosthetics under the
2 Medicare program under title XVIII of such Act are made
3 only to those suppliers that meet the relevant accreditation
4 and licensure requirements under such section and a de-
5 termination of whether additional steps are needed.

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

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

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

1 spending under part B of title XVIII of the Social Security
2 Act for the period of years 2014 through 2018 as a result
3 of the implementation of the provisions of, and amend-
4 ments made by, this Act.

5 (b) STRENGTHENING STANDARDS APPLICABLE IF
6 SAVINGS NOT ACHIEVED.—

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

1 (2) EXCEPTION.—The interim final regulation
2 issued under paragraph (1) shall not apply to a
3 qualified physical therapist or qualified occupational
4 therapist (as described in section 1834(h)(1)(F)(iii)
5 of the Social Security Act (42 U.S.C.
6 1395m(h)(1)(F)(iii))).

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

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

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

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

○