

112TH CONGRESS
2D SESSION

S. 2125

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.

IN THE SENATE OF THE UNITED STATES

FEBRUARY 17, 2012

Mr. WYDEN (for himself, Ms. SNOWE, and 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 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.

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 Improvement Act of 2012”.

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

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

11 (1) by striking “ORGANIZATIONS.—Not later
12 than” and inserting “ORGANIZATIONS.—

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

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

17 “(ii) SPECIAL REQUIREMENTS FOR
18 ACCREDITATION OF SUPPLIERS OF
19 ORTHOTICS AND PROSTHETICS.—For pur-
20 poses of applying quality standards under
21 subparagraph (A) for suppliers (other than
22 suppliers described in clause (iii)) of items
23 and services described in subparagraph
24 (D)(ii), the Secretary shall designate and
25 approve an independent accreditation orga-
26 nization under clause (i) only if such orga-

1 nization is a Board or program described
2 in subsection (h)(1)(F)(iv). Not later than
3 January 1, 2013, the Secretary shall en-
4 sure that at least one independent accredi-
5 tation organization is designated and ap-
6 proved in accordance with this clause.

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

15 (b) EFFECTIVE DATE.—An organization must satisfy
16 the requirement of section 1834(a)(20)(B)(ii), as added
17 by subsection (a)(2), not later than January 1, 2013, re-
18 gardless of whether such organization is designated or ap-
19 proved as an independent accreditation organization be-
20 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, 2013, 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, 2013.

15 **SEC. 4. ELIGIBILITY FOR MEDICARE PAYMENT FOR**
16 **ORTHOTICS AND PROSTHETICS BASED ON**
17 **PRACTITIONER 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-

graph (5)(C) furnished on or after January 1, 2013,
and subject to paragraph (5)(A), satisfies all appli-
cable criteria of the provider qualification designa-
tion for such category described in the respective
clause, and who”;

(2) in paragraph (1)(F)(iv), by inserting before
the period the following: “and, with respect to a cat-
egory of orthotics and prosthetics care described in
clause (i), (ii), (iii), (iv), or (v) of paragraph (5)(C)
furnished on or after January 1, 2013, and subject
to paragraph (5)(A), satisfies all applicable criteria
of the provider qualification designation for such
category described in the respective clause”; and

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

“(5) ELIGIBILITY FOR PAYMENT BASED ON
PRACTITIONER 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-
ment may be made under this subsection
for orthotics and prosthetics furnished on

1 or after January 1, 2013, 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 PROVIDER 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 pro-
14 vider 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) PRACTITIONERS MEDICARE-ELI-
25 GIBLE PRIOR TO JANUARY 1, 2013 EXEMPT-

1 ED.—In the case of a qualified practitioner
2 or qualified supplier who is eligible to re-
3 ceive payment under this title before Janu-
4 ary 1, 2013—

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

15 “(II) with respect to an item of
16 orthotics or prosthetics described in
17 clause (ii), (iii), or (iv) of subpara-
18 graph (C), any criteria for the pro-
19 vider qualification designations under
20 the respective clause (or a subsequent
21 clause of such subparagraph), includ-
22 ing application of subparagraph (D),
23 shall not apply to such practitioner or
24 supplier, respectively, for the fur-
25 nishing or fabrication of such an item

described in such respective (or such subsequent) clause.

“(iv) DELAYED APPLICATION OF CERTAIN PROVIDER QUALIFICATION DESIGNATION CRITERIA.—The provider qualification designations under clauses (i), (ii), and (iii) of subparagraph (C), including the application of subparagraph (D) to such clauses, shall not be taken into account with respect to payment made under this subsection for orthotics and prosthetics furnished before January 1, 2014.

“(v) MODIFICATIONS.—The Secretary shall, in consultation with the Boards and programs described in paragraph (1)(F)(iv), periodically review the criteria for the provider qualification designation under subparagraph (C)(i)(III) and may implement by regulation any modifications to such criteria, as determined appropriate in accordance with such consultation. Any such modification shall take effect no earlier than January 1, 2015.

“(B) ASSIGNMENT OF BILLING CODES.—

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 and the 2008 Orthotics and Prosthetics Tri-
10 partite Document, a multi-organization com-
11 pilation of HCPCS codes. Transmittal 656 shall
12 be the controlling source of category, product,
13 and code assignments for the orthotics and
14 prosthetics care described in each of clauses (i)
15 through (v) of subparagraph (C) using the pro-
16 vider qualification designation for each HCPCS
17 code as stated in such document and, in cases
18 in which Transmittal 656 does not include a
19 particular item of orthotics or prosthetics or a
20 related code or in cases in which Transmittal
21 656 is revoked or abridged, the 2008 Orthotics
22 and Prosthetics Tripartite Document shall be
23 the secondary source for such category, prod-
24 uct, and code assignments. In the case that ei-
25 ther of the documents described in the previous

1 sentence is updated or reissued, the previous
2 sentence shall be applied with respect to the
3 most recent update or reissuance of such docu-
4 ment.

5 “(C) CATEGORIES OF ORTHOTIC AND
6 PROSTHETIC CARE DESCRIBED.—

7 “(i) CUSTOM FABRICATED LIMB PROS-
8 THETICS CATEGORY.—The category of
9 orthotic and prosthetic care described in
10 this clause is a category for artificial legs
11 and arms, including replacements (as de-
12 scribed in section 1861(s)(9)) that are
13 made from detailed measurements, images,
14 or models in accordance with a prescrip-
15 tion and that can only be utilized by a spe-
16 cific intended patient and for which pay-
17 ment is made under this part. The pro-
18 vider qualification designation for the cat-
19 egory shall reflect each of the following, in
20 accordance with subparagraph (D):

21 “(I) The category of care involves
22 the highest level of complexity with
23 substantial clinical risk.

24 “(II) The category of care re-
25 quires a practitioner who satisfies any

1 of the education requirements de-
2 scribed in subclause (III), has com-
3 pleted a prosthetic residency accred-
4 ited by the National Commission on
5 Orthotic and Prosthetic Education
6 (‘NCOPE’), and is certified or li-
7 censed in prosthetics to ensure the
8 comprehensive provision of prosthetic
9 care.

10 “(III) The category of care re-
11 quires a practitioner who has com-
12 pleted any of the following education
13 requirements:

14 “(aa) A bachelor’s degree or
15 master’s degree in prosthetics as
16 offered by educational institu-
17 tions accredited by the Commis-
18 sion on Accreditation of Allied
19 Health Education Programs.

20 “(bb) A bachelor’s degree,
21 plus a certificate in prosthetics as
22 offered by educational institu-
23 tions accredited by the Commis-
24 sion on Accreditation of Allied
25 Health Education Programs.

1 “(cc) A foreign degree deter-
 2 mined by the World Education
 3 Service to be equivalent to an
 4 educational program in pros-
 5 thetics accredited by the Com-
 6 mission on Accreditation of Allied
 7 Health Education Programs.

8 “(ii) CUSTOM FABRICATED
 9 ORTHOTICS CATEGORY.—The category of
 10 orthotics and prosthetics care described in
 11 this clause is a category for custom-fab-
 12 ricated orthotics that are made from de-
 13 tailed measurements, images, or models in
 14 accordance with a prescription and that
 15 can only be utilized by a specific intended
 16 patient. The provider qualification designa-
 17 tion for the category shall reflect the fol-
 18 lowing, in accordance with subparagraph
 19 (D):

20 “(I) The category of care involves
 21 the highest level of complexity with
 22 substantial clinical risk.

23 “(II) The category of care re-
 24 quires a practitioner who satisfies any
 25 of the education requirements de-

1 scribed in clause (i)(III) (except that
2 for purposes of this subclause such
3 clause shall be applied by substituting
4 the term ‘orthotics’ each place the
5 term ‘prosthetics’ is used), has com-
6 pleted an orthotic residency accredited
7 by the National Commission on
8 Orthotic and Prosthetic Education,
9 and is certified or licensed in orthotics
10 to ensure the appropriate provision of
11 orthotic care.

12 “(iii) CUSTOM FITTED HIGH
13 ORTHOTICS CATEGORY.—The category of
14 orthotic care described in this clause is a
15 category for prefabricated orthotics that
16 are manufactured with no specific patient
17 in mind, but that are appropriately sized,
18 adapted, modified, and configured (with
19 the required tools and equipment) to a spe-
20 cific patient in accordance with a prescrip-
21 tion. The provider qualification designation
22 for the category shall reflect the following,
23 in accordance with subparagraph (D):

1 “(I) The category of care involves
 2 moderate to high complexity with sub-
 3 stantial clinical risk.

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

6 “(aa) satisfies any of the
 7 education requirements described
 8 in clause (i)(III), except that for
 9 purposes of this subclause such
 10 clause shall be applied by sub-
 11 stituting the term ‘orthotics’ each
 12 place the term ‘prosthetics’ is
 13 used; or

14 “(bb) is certified or licensed
 15 in orthotics to ensure the appro-
 16 priate provision of orthotic care
 17 within the practitioner’s normal
 18 scope of practice.

19 “(iv) CUSTOM FITTED LOW
 20 ORTHOTICS CATEGORY.—The category of
 21 orthotics and prosthetics care described in
 22 this clause is a category for prefabricated
 23 orthotics that are manufactured with no
 24 specific patient in mind, but that are ap-
 25 propriately sized and adjusted to a specific

1 patient in accordance with a prescription.
2 The provider qualification designation for
3 the category shall reflect the following:

4 “(I) The category of care involves
5 a low level of complexity and low clin-
6 ical risk.

7 “(II) The category of care re-
8 quires a supplier that is certified or li-
9 censed within a limited scope of prac-
10 tice to ensure appropriate provision of
11 orthotic care. The supplier’s education
12 and training shall ensure that basic
13 clinical knowledge and technical ex-
14 pertise is available to confirm success-
15 ful fit and device compliance with the
16 prescription.

17 “(v) OFF-THE-SHELF.—The category
18 of orthotic care described in this clause is
19 described in section 1847(a)(2)(C). The
20 provider qualification designation for the
21 category shall reflect that no formal
22 credentialing, clinical education, or tech-
23 nical training is required to dispense such
24 items.

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

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

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

SEC. 5. CONSULTATION.

In implementing the provisions of, and amendments
made by, this Act, the Secretary of Health and Human
Services shall consult with appropriate experts in orthotics
and prosthetics, including practitioners that furnish items
within the categories of orthotic and prosthetic care de-

1 scribed in section 1834(h)(5)(C) of the Social Security
 2 Act, as added by section 4.

3 **SEC. 6. REPORTS.**

4 (a) REPORT ON ENFORCING NEW LICENSING AND
 5 ACCREDITATION REQUIREMENTS.—Not later than 18
 6 months after the date of the enactment of this Act, the
 7 Secretary of Health and Human Services shall submit to
 8 Congress a report on the steps taken by the Department
 9 of Health and Human Services to ensure that the State
 10 licensure and accreditation requirements under section
 11 1834(h)(1)(F) of the Social Security Act, as amended by
 12 section 3, are enforced. Such report shall include a deter-
 13 mination of the extent to which payments for orthotics and
 14 prosthetics under the Medicare program under title XVIII
 15 of such Act are made only to those providers of services
 16 and suppliers that meet the relevant accreditation and li-
 17 censure requirements under such section and a determina-
 18 tion of whether additional steps are needed.

19 (b) REPORT ON FRAUD AND ABUSE.—Not later than
 20 30 months after the date of the enactment of this Act,
 21 the Secretary of Health and Human Services shall submit
 22 to Congress a report on the effect of the requirements
 23 under subsection (a)(20)(B)(ii) of section 1834 of the So-
 24 cial Security Act (42 U.S.C. 1395m), as added by section
 25 2, and subsection (h)(1)(F) of such section, as amended

1 by section 3, on the occurrence of fraud and abuse under
 2 the Medicare program under title XVIII of such Act, with
 3 respect to orthotics and prosthetics for which payment is
 4 made under such program.

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

6 (a) PROJECTION OF CUMULATIVE EFFECT ON
 7 SPENDING.—Not later than December 31, 2013, the Sec-
 8 retary of Health and Human Services (in this section re-
 9 ferred to as the “Secretary”), acting through the Chief
 10 Actuary of the Centers for Medicare & Medicaid Services
 11 (in this section referred to as the “Chief Actuary”), shall
 12 submit to Congress, and have published in the Federal
 13 Register, a projection of the effect on cumulative Federal
 14 spending under part B of title XVIII of the Social Security
 15 Act for the period of years 2013 through 2017 as a result
 16 of the implementation of the provisions of, and amend-
 17 ments made by, this Act.

18 (b) STRENGTHENING STANDARDS APPLICABLE IF
 19 SAVINGS NOT ACHIEVED.—

20 (1) IN GENERAL.—Subject to paragraph (2), if
 21 the Chief Actuary projects under subsection (a) that
 22 the implementation of the provisions of, and amend-
 23 ments made by, this Act will not result in a cumu-
 24 lative reduction in spending under such part of at
 25 least \$250,000,000 for the period of years 2013

1 through 2017 (using a 2012 baseline), the Secretary
 2 shall, in accordance with the Chief Actuary's projec-
 3 tion, issue an interim final regulation (to take effect
 4 for 2014 and subsequent years) with a period for
 5 public comment on such regulation after the date of
 6 publication to strengthen the licensure, accredita-
 7 tion, and quality standards applicable to suppliers of
 8 orthotics and prosthetics under title XVIII of the
 9 Social Security Act, including such standards de-
 10 scribed in subsections (a)(20) and (h)(1)(F) of sec-
 11 tion 1834 of such Act (42 U.S.C. 1395m), as
 12 amended by this Act, in order to produce such cu-
 13 mulative reduction by December 31, 2017.

14 (2) EXCEPTION.—The interim final regulation
 15 issued under paragraph (1) shall not apply to a
 16 qualified physical therapist or qualified occupational
 17 therapist (as described in section 1834(h)(1)(F)(iii)
 18 of the Social Security Act (42 U.S.C.
 19 1395m(h)(1)(F)(iii))).

20 **SEC. 8. NO EFFECT ON PAYMENT BASIS FOR ORTHOTICS**
 21 **AND PROSTHETICS OR COMPETITIVE BID-**
 22 **DING PROGRAMS.**

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

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

4 (2) the implementation of competitive acquisi-
5 tion programs under section 1847 of such Act (42
6 U.S.C. 1395w-3), including such implementation
7 with respect to off-the-shelf orthotics described in
8 subsection (a)(2)(C) of that section, that are in-
9 cluded in a competitive acquisition program in a
10 competitive acquisition area under that section.

○