

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.

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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

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## 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.”.

(b) EFFECTIVE DATE.—An organization must satisfy the requirement of section 1834(a)(20)(B)(ii), as added by subsection (a)(2), not later than January 1, 2013, regardless of whether such organization is designated or approved as an independent accreditation organization before, 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 subparagraph  
6                             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-

1 graph (5)(C) furnished on or after January 1, 2013,  
2 and subject to paragraph (5)(A), satisfies all appli-  
3 cable criteria of the provider 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, 2013, 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 PRACTITIONER QUALIFICATIONS AND COMPLEXITY  
18 OF 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, 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 ear-  
lier than January 1, 2015.

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           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-

scribed in clause (i)(III) (except that for purposes of this subclause such clause shall be applied by substituting the term ‘orthotics’ each place the term ‘prosthetics’ is used), has completed an orthotic residency accredited by the National Commission on Orthotic and Prosthetic Education, and is certified or licensed in orthotics to ensure the appropriate provision of orthotic care.

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

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

“(II) The category of care requires a supplier that is certified or licensed within a limited scope of practice to ensure appropriate provision of orthotic care. The supplier’s education and training shall ensure that basic clinical knowledge and technical expertise is available to confirm successful fit and device compliance with the 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.

1                 “(D) CARE BASED ON SOUND CLINICAL  
2                 JUDGMENT AND TECHNICAL EXPERTISE.—Care  
3                 described in clauses (i), (ii), and (iii) of sub-  
4                 paragraph (C) shall be based on sound clinical  
5                 judgment and technical expertise based on the  
6                 practitioner’s education and clinical training, in  
7                 order to allow the practitioner to determine—  
8                         “(i) with respect to care described in  
9                 clause (i) or (ii) of subparagraph (C), the  
10                 device parameters and design, fabrication  
11                 process, and functional purpose specific to  
12                 the needs of the patient to maximize optim-  
13                 al clinical outcomes; and  
14                         “(ii) with respect to care described in  
15                 clause (iii) of such subparagraph, the ap-  
16                 propriate device relative to the diagnosis  
17                 and specific to the needs of the patient to  
18                 maximize optimal clinical outcomes.”.

19 **SEC. 5. CONSULTATION.**

20                 In implementing the provisions of, and amendments  
21                 made by, this Act, the Secretary of Health and Human  
22                 Services shall consult with appropriate experts in orthotics  
23                 and prosthetics, including practitioners that furnish items  
24                 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.

○