

112TH CONGRESS
1ST SESSION

H. R. 1958

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 HOUSE OF REPRESENTATIVES

MAY 24, 2011

Ms. BERKLEY (for herself, Mr. THOMPSON of Pennsylvania, Mr. RUPPERSBERGER, Mr. GUTHRIE, and Mr. NEAL) 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.

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 2011”.

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 “Not later than” and inserting
14 “(i) IN GENERAL.—Subject to clause (ii), not later
15 than” with the same indentation as the clauses
16 added by paragraph (2); and

17 (2) by adding at the end the following new
18 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, 2012, 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, 2012, 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))”.

1 (b) EFFECTIVE DATE.—The amendments made by
2 subsection (a) shall apply to orthotics and prosthetics fur-
3 nished on or after January 1, 2012.

4 **SEC. 4. MEDICARE PAYMENT RULES FOR ORTHOTICS AND**
5 **PROSTHETICS TO ACCOUNT FOR PRACTI-**
6 **TIONER QUALIFICATIONS AND COMPLEXITY**
7 **OF CARE.**

8 Section 1834(h) of the Social Security Act (42 U.S.C.
9 1395m(h)) is amended—

10 (1) in paragraph (1)(F)(iii), by striking “other
11 individual who” and inserting “other individual who,
12 with respect to a category of orthotics and pros-
13 thetics care described in clause (i), (ii), (iii), (iv), or
14 (v) of paragraph (5)(C) furnished on or after Janu-
15 ary 1, 2012, and subject to paragraph (5)(A), satis-
16 fies all applicable criteria of the provider qualifica-
17 tion designation for such category described in the
18 respective clause, and who”;

19 (2) in paragraph (1)(F)(iv), by inserting before
20 the period the following: “and, with respect to a cat-
21 egory of orthotics and prosthetics care described in
22 clause (i), (ii), (iii), (iv), or (v) of paragraph (5)(C)
23 furnished on or after January 1, 2012, and subject
24 to paragraph (5)(A), satisfies all applicable criteria

1 of the provider qualification designation for such
2 category described in the respective clause”; and

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

5 “(5) PAYMENT RULES TO ACCOUNT FOR PRAC-
6 TITIONER QUALIFICATIONS AND COMPLEXITY OF
7 CARE.—

8 “(A) CONSIDERATIONS FOR PAYMENTS.—

9 “(i) IN GENERAL.—In applying
10 clauses (iii) and (iv) of paragraph (1)(F)
11 for purposes of determining whether pay-
12 ment may be made under this subsection
13 for orthotics and prosthetics furnished on
14 or after January 1, 2012, the Secretary
15 shall take into account the complexity of
16 the respective item and, subject to clauses
17 (ii), (iii), and (iv), the qualifications of the
18 individual or entity furnishing and fabri-
19 cating such respective item in accordance
20 with this paragraph.

21 “(ii) INDIVIDUAL AND ENTITIES EX-
22 EMPTED FROM PROVIDER QUALIFICATION
23 DESIGNATION CRITERIA.—With respect to
24 an item of orthotics or prosthetics de-
25 scribed in clause (ii), (iii), (iv) or (v) of

1 subparagraph (C), any criteria for the pro-
2 vider qualification designations under such
3 respective clause, including application of
4 subparagraph (D), shall not apply to phy-
5 sicians, occupational therapists, or physical
6 therapists who are licensed or otherwise
7 regulated by the State in which they are
8 practicing and who receive payment under
9 this title, including regulations promul-
10 gated pursuant to this subsection, for the
11 provision of orthotics and prosthetics.

12 “(iii) PRACTITIONERS MEDICARE-ELI-
13 GIBLE PRIOR TO JANUARY 1, 2013 EXEMPT-
14 ED.—In the case of a qualified practitioner
15 or qualified supplier who is eligible to re-
16 ceive payment under this title before Janu-
17 ary 1, 2013—

18 “(I) with respect to an item of
19 orthotics or prosthetics described in
20 clause (i) of subparagraph (C), any
21 criteria for the provider qualification
22 designations under such clause, in-
23 cluding application of subparagraph
24 (D), shall not apply to such practi-
25 tioner or supplier, respectively, for the

1 furnishing or fabrication of such an
2 item so described; and

3 “(II) with respect to an item of
4 orthotics or prosthetics described in
5 clause (ii), (iii), or (iv) of subpara-
6 graph (C), any criteria for the pro-
7 vider qualification designations under
8 the respective clause (or a subsequent
9 clause of such subparagraph), includ-
10 ing application of subparagraph (D),
11 shall not apply to such practitioner or
12 supplier, respectively, for the fur-
13 nishing or fabrication of such an item
14 described in such respective (or such
15 subsequent) clause.

16 “(iv) DELAYED APPLICATION OF CER-
17 TAIN PROVIDER QUALIFICATION DESIGNA-
18 TION CRITERIA.—The provider qualifica-
19 tion designations under clauses (i), (ii),
20 and (iii) of subparagraph (C), including
21 the application of subparagraph (D) to
22 such clauses, shall not be taken into ac-
23 count with respect to payment made under
24 this subsection for orthotics and pros-
25 thetics furnished before January 1, 2013.

1 “(v) MODIFICATIONS.—The Secretary
2 shall, in consultation with the boards and
3 programs described in paragraph
4 (1)(F)(iv), periodically review the criteria
5 for the provider qualification designation
6 under subparagraph (C)(i)(III) and may
7 implement by regulation any modifications
8 to such criteria, as determined appropriate
9 in accordance with such consultation. Any
10 such modification shall take effect no ear-
11 lier than January 1, 2014.

12 “(B) ASSIGNMENT OF BILLING CODES.—
13 For purposes of subparagraph (A), the Sec-
14 retary, in consultation with representatives of
15 the fields of occupational therapy, physical ther-
16 apy, orthotics, and prosthetics shall utilize and
17 incorporate the set of L-codes listed, as of the
18 date of the enactment of this paragraph, in the
19 Centers for Medicare & Medicaid Services docu-
20 ment entitled Transmittal 656 (CMS Pub. 100–
21 04, Change Request 3959, August 19, 2005)
22 and the 2008 Orthotics and Prosthetics Tri-
23 partite Document, a multi-organization com-
24 pilation of HCPCS codes. Transmittal 656 shall
25 be the controlling source of category, product,

1 and code assignments for the orthotics and
2 prosthetics care described in each of clauses (i)
3 through (v) of subparagraph (C) using the pro-
4 vider qualification designation for each HCPCS
5 code as stated in such document and, in cases
6 in which Transmittal 656 does not include a
7 particular item of orthotics or prosthetics or a
8 related code or in cases in which Transmittal
9 656 is revoked or abridged, the 2008 Orthotics
10 and Prosthetics Tripartite Document shall be
11 the secondary source for such category, prod-
12 uct, and code assignments. In the case that ei-
13 ther of the documents described in the previous
14 sentence is updated or reissued, the previous
15 sentence shall be applied with respect to the
16 most recent update or reissuance of such docu-
17 ment.

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 pro-
6 vider qualification designation for the cat-
7 egory shall reflect each of the following, in
8 accordance 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 practitioner who satisfies any
14 of the education requirements de-
15 scribed in subclause (III), has com-
16 pleted a prosthetic residency accred-
17 ited by the National Commission on
18 Orthotic and Prosthetic Education
19 (‘NCOPE’), and is certified or li-
20 censed in prosthetics to ensure the
21 comprehensive provision of prosthetic
22 care.

23 “(III) The category of care re-
24 quires a practitioner who has com-

1 pleted any of the following education
2 requirements:

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 provider 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 practitioner who satisfies any
14 of the education requirements de-
15 scribed in clause (i)(III) (except that
16 for purposes of this subclause such
17 clause shall be applied by substituting
18 the term ‘orthotics’ each place the
19 term ‘prosthetics’ is used), has com-
20 pleted an orthotic residency accredited
21 by the National Commission on
22 Orthotic and Prosthetic Education,
23 and is certified or licensed in orthotics
24 to ensure the appropriate provision of
25 orthotic 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 provider 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 provider 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 a category for prefabricated orthotics that
7 require minimal self adjustment for appro-
8 priate use. The provider qualification des-
9 ignation for the category shall reflect that
10 such orthotics do not require expertise in
11 trimming, bending, molding, assembling, or
12 customizing to fit the patient and that no
13 formal credentialing, clinical education, or
14 technical training is required to dispense
15 such items.

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

23 “(i) with respect to care described in
24 clause (i) and (ii) of subparagraph (C), the
25 device parameters and design, fabrication

1 process, and functional purpose specific to
2 the needs of the patient to maximize opti-
3 mal clinical outcomes; and

4 “(ii) with respect to care described in
5 subparagraph (C)(iii), the appropriate de-
6 vice relative to the diagnosis and specific to
7 the needs of the patient to maximize opti-
8 mal clinical outcomes.

9 “(E) CONSULTATION.—In modifying the
10 payment basis, the Secretary shall consult with
11 appropriate experts in orthotics and prosthetics,
12 including practitioners that furnish items within
13 the categories of prosthetics and orthotics care
14 described in subparagraph (C).”.

15 **SEC. 5. 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, as amended by
24 section 3, are enforced. Such report shall include a deter-
25 mination of the extent to which payments for orthotics and

1 prosthetics under the Medicare program under title XVIII
2 of such Act are made only to those providers of services
3 and suppliers that meet the relevant accreditation and li-
4 censure requirements under such section, as well as 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. 6. REDUCTION IN MEDICARE SPENDING.**

18 Not later than December 31, 2012, the Secretary of
19 Health and Human Services, acting through the Chief Ac-
20 tuary of the Centers for Medicare & Medicaid Services,
21 shall submit to Congress, and have published in the Fed-
22 eral Register, a projection of the effect on cumulative Fed-
23 eral spending under part B of title XVIII of the Social
24 Security Act for the period of years 2012 through 2016
25 that will result from the implementation of this Act, in-

1 cluding the amendments made by this Act. If the Chief
2 Actuary projects that the implementation of the amend-
3 ments made by this Act will not result in a cumulative
4 reduction in spending under such part of at least
5 \$250,000,000 for the period of years 2012 through 2016
6 (using a 2011 baseline), the Secretary shall, in accordance
7 with the Actuary's projection, issue an interim final regu-
8 lation (to take effect for 2014 and subsequent years) with
9 comment period to strengthen the licensure, accreditation,
10 and quality standards applicable to suppliers of orthotics
11 and prosthetics, as described in this Act (and amendments
12 made by this Act), in order to produce such cumulative
13 reduction by the end of 2016, except that such regulation
14 shall not apply to a qualified physical therapist or qualified
15 occupational therapist (as described in section
16 1834(h)(1)(F)(iii) of the Social Security Act (42 U.S.C.
17 1395m(h)(1)(F)(iii)).

○