

114TH CONGRESS
1ST SESSION

H. R. 1530

To amend title XVIII of the Social Security Act to refine how Medicare pays for orthotics and prosthetics, to improve beneficiary experience and outcomes with orthotic and prosthetic care, and to streamline the Medicare administrative appeals process, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MARCH 23, 2015

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 refine how Medicare pays for orthotics and prosthetics, to improve beneficiary experience and outcomes with orthotic and prosthetic care, and to streamline the Medicare administrative appeals process, 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,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) SHORT TITLE.—This Act may be cited as the
3 “Medicare Orthotics and Prosthetics Improvement Act of
4 2015”.

5 (b) TABLE OF CONTENTS.—The table of contents for
6 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Eligibility for Medicare payment for health professionals based on qualifications.
- Sec. 3. Modification of requirements applicable under Medicare to the designation of accreditation organizations for suppliers of orthotics and prosthetics.
- Sec. 4. Application of existing accreditation and licensure requirements to certain prosthetics and custom-fabricated or custom-fitted orthotics.
- Sec. 5. Eligibility for Medicare payment for orthotics and prosthetics based on supplier qualifications and complexity of care.
- Sec. 6. Orthotist’s and prosthetist’s clinical notes as part of the patient’s medical record.
- Sec. 7. Distinguishing orthotists and prosthetists from suppliers of durable medical equipment and supplies.
- Sec. 8. Greater accountability and transparency of recovery audit contractors.
- Sec. 9. Maintaining due process and satisfying the ninety-day statutory period for administrative law judge decisions.
- Sec. 10. Clarification about minimal self-adjustment for off-the-shelf orthotics.
- Sec. 11. Regulations.

7 **SEC. 2. ELIGIBILITY FOR MEDICARE PAYMENT FOR**
8 **HEALTH PROFESSIONALS BASED ON QUALI-**
9 **FICATIONS.**

10 (a) IN GENERAL.—Title XVIII of the Social Security
11 Act is amended by inserting after section 1863 (42 U.S.C.
12 1395z) the following new section:

13 “ELIGIBILITY FOR MEDICARE PAYMENT FOR SUPPLIERS
14 BASED ON QUALIFICATIONS

15 “SEC. 1863A. No payment may be made under this
16 part for an item or service that is furnished (i) in a State

1 that requires a provider or supplier to be licensed in order
2 to furnish such item or service, unless the provider or sup-
3 plier furnishing such item or service possesses all applica-
4 ble licensure from the State, or (ii) in a State that does
5 not require a provider or supplier to be licensed in order
6 to furnish such item or service, unless the provider or sup-
7 plier meets all applicable qualifications, as established by
8 the Secretary. Applicable qualifications means all applica-
9 ble accreditations, certifications, and credentials required
10 under this part for providers and suppliers, including the
11 requirements established under section 427 of the Medi-
12 care, Medicaid, and SCHIP Benefits Improvement and
13 Protections Act of 2000, as enacted into law by section
14 1(a)(6) of Public Law 106–554, with these requirements
15 to be applicable immediately in accordance with that stat-
16 utory language even in advance of the Secretary issuing
17 applicable regulations under this provision, as well as any
18 and all applicable regulations as established by the Sec-
19 retary, this being noted inasmuch as issuance of these reg-
20 ulations are approximately fourteen years beyond the stat-
21 utory requirement for their being issued in final form by
22 the Secretary, which it is anticipated the Secretary will
23 remedy expeditiously.”.

24 (b) EFFECTIVE DATE.—This section shall take effect
25 on the date of enactment of this Act.

1 **SEC. 3. MODIFICATION OF REQUIREMENTS APPLICABLE**
 2 **UNDER MEDICARE TO THE DESIGNATION OF**
 3 **ACCREDITATION ORGANIZATIONS FOR SUP-**
 4 **PLIERS OF ORTHOTICS AND PROSTHETICS.**

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

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

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

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

14 “(ii) SPECIAL REQUIREMENTS FOR
 15 ACCREDITATION OF SUPPLIERS OF
 16 ORTHOTICS AND PROSTHETICS.—For pur-
 17 poses of applying quality standards under
 18 subparagraph (A) for suppliers (other than
 19 suppliers described in clause (iii)) of items
 20 and services described in subparagraph
 21 (D)(ii), the Secretary shall designate and
 22 approve independent accreditation organi-
 23 zations under clause (i) only if such orga-
 24 nizations are Boards or programs de-
 25 scribed in subsection (h)(1)(F)(iv). Not
 26 later than January 1, 2016, the Secretary

1 shall ensure that at least one, and ideally
2 multiple, independent accreditation organi-
3 zations are designated and approved in ac-
4 cordance with this clause.

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

13 (b) EFFECTIVE DATE.—The designated and ap-
14 proved organizations must satisfy the requirement of sec-
15 tion 1834(a)(20)(B)(ii), as added by subsection (a)(2), not
16 later than January 1, 2016, regardless of whether such
17 organizations are designated or approved as an inde-
18 pendent accreditation organization before, on, or after the
19 date of the enactment of this Act.

1 **SEC. 4. 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, 2016, that is included in a com-
10 petitive acquisition area under such sec-
11 tion.”.

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, 2016.

15 **SEC. 5. 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 the provision of orthotics and prosthetics
25 furnished on or after January 1, 2016, and subject

1 to paragraph (5)(A), satisfies all applicable criteria
 2 of the provider qualification designation for such
 3 category described in the respective clause, and
 4 who”;

5 (2) in paragraph (1)(F)(iv), by inserting before
 6 the period the following: “and, with respect to the
 7 provision of orthotics and prosthetics furnished on
 8 or after January 1, 2016, and subject to paragraph
 9 (5)(A), satisfies all applicable criteria of the provider
 10 qualification designation for such orthotic or pros-
 11 thetic”; 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, 2016, 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) INDIVIDUALS AND ENTITIES EX-
7 EMPTED FROM SUPPLIER QUALIFICATION
8 CRITERIA.—With respect to the provision
9 of orthotics or prosthetics, any criteria for
10 supplier qualifications shall not apply to
11 physicians, occupational therapists, or
12 physical therapists who are licensed or oth-
13 erwise regulated by the State in which they
14 are practicing and who receive payment
15 under this title, including regulations pro-
16 mulgated pursuant to this subsection, for
17 the provision of orthotics and prosthetics.

18 “(iii) SUPPLIERS MEDICARE-ELIGIBLE
19 PRIOR TO JANUARY 1, 2016 EXEMPTED.—
20 In the case of a qualified supplier who is
21 eligible to receive payment under this title
22 before January 1, 2016, with respect to
23 the provision of orthotics and prosthetics,
24 any new criteria for provider qualifications
25 established after such date shall not apply

1 to such supplier, for the furnishing or fab-
2 rication of such an item.

3 “(iv) MODIFICATIONS.—The Secretary
4 shall, in consultation with the Boards and
5 programs described in paragraph
6 (1)(F)(iv), periodically review the criteria
7 for supplier qualifications and may imple-
8 ment by regulation any modifications to
9 such criteria, as determined appropriate in
10 accordance with such consultation. Any
11 such modifications shall take effect no ear-
12 lier than January 1, 2016.

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

1 supplier qualification designation for each
2 HCPCS code as stated in such document. In
3 the case that Transmittal 656 is updated, re-
4 issued, or replaced by a subsequent document,
5 the previous sentence shall be applied with re-
6 spect to the most recent update, reissuance, or
7 replacement of such document.”.

8 **SEC. 6. ORTHOTIST’S AND PROSTHETIST’S CLINICAL NOTES**

9 **AS PART OF THE PATIENT’S MEDICAL**
10 **RECORD.**

11 Section 1834(h) of the Social Security Act (42 U.S.C.
12 1395m(h)), as amended by section 5, is amended by add-
13 ing at the end the following new paragraph:

14 “(6) DOCUMENTATION CREATED BY
15 ORTHOTISTS AND PROSTHETISTS.—With respect to
16 claims filed after August 11, 2011, for purposes of
17 determining the reasonableness, medical necessity,
18 and functional level (applicable to prosthetics) of
19 prosthetic devices and orthotics and prosthetics, doc-
20 umentation created by an orthotist or prosthetist
21 shall be considered part of the patient’s medical
22 record and, consistent with the treatment of orthotic
23 and prosthetic patient care delivery stated in the
24 health care professional exception provided in clause
25 (ii) of subsection (a)(20)(F), shall be given the same

1 consideration as documentation created by other
 2 health professionals, including physicians, nurse
 3 practitioners, occupational therapists, and physical
 4 therapists. For claims filed before date of enactment
 5 of this Act, this paragraph shall not apply to those
 6 appeals of claim denials that have been waived, de-
 7 nied at the last level of appeal, or otherwise set-
 8 tled.”.

9 **SEC. 7. DISTINGUISHING ORTHOTISTS AND PROSTHETISTS**
 10 **FROM SUPPLIERS OF DURABLE MEDICAL**
 11 **EQUIPMENT AND SUPPLIES.**

12 (a) REQUIREMENTS FOR SUPPLIERS OF MEDICAL
 13 EQUIPMENT AND SUPPLIES.—Section 1834(j)(5) of the
 14 Social Security Act (42 U.S.C. 1395m(j)(5)) is amended
 15 by striking subparagraph (C).

16 (b) REQUIREMENTS FOR ORTHOTISTS AND
 17 PROSTHETISTS.—Section 1834 of the Social Security Act
 18 (42 U.S.C. 1395m) is amended by adding at the end the
 19 following new subsection:

20 “(r) REQUIREMENTS FOR ORTHOTISTS AND
 21 PROSTHETISTS.—

22 “(1) ISSUANCE AND RENEWAL OF SUPPLIER
 23 NUMBER.—

24 “(A) PAYMENT.—

1 “(i) IN GENERAL.—No payment may
2 be made under this part to an orthotic or
3 prosthetic supplier unless such orthotic or
4 prosthetic supplier obtains (and renews at
5 such intervals as the Secretary may re-
6 quire) a supplier number; provided, how-
7 ever, that providers otherwise permitted to
8 receive payment for orthotics and pros-
9 thetics under Part A may continue to re-
10 ceive such payment without interruption.

11 “(B) STANDARDS FOR POSSESSING A SUP-
12 PLIER NUMBER.—An orthotic and/or prosthetic
13 supplier may not obtain a supplier number un-
14 less the supplier meets standards prescribed by
15 the Secretary that include requirements that
16 the orthotic/prosthetic supplier (and, where ap-
17 plicable, the orthotist or prosthetist)—

18 “(i) comply with all applicable State
19 and Federal licensure and regulatory re-
20 quirements;

21 “(ii) acquire accreditation from the
22 American Board for Certification in
23 Orthotics, Prosthetics and Pedorthics, Inc.
24 (ABC) or the Board of Certification/Ac-
25 creditation, International (BOC), or other

1 accreditation entity deemed by the HHS
2 Secretary to have standards that are essen-
3 tially equivalent to such boards;

4 “(iii) maintain a physical facility on
5 an appropriate site;

6 “(iv) have proof of appropriate liabil-
7 ity insurance; and

8 “(v) meet such other requirements as
9 the Secretary shall specify.

10 “(C) PROHIBITION AGAINST MULTIPLE
11 SUPPLIER NUMBERS.—The Secretary may not
12 issue more than one supplier number to any
13 orthotic and/or prosthetic supplier unless the
14 Secretary finds that the issuance of more than
15 one number is appropriate to identify other en-
16 tities under the orthotic or prosthetic supplier’s
17 ownership or control.

18 “(2) ORDER FOR ORTHOTICS OR PROS-
19 THETICS.—

20 “(A) INFORMATION PROVIDED BY
21 ORTHOTISTS AND PROSTHETISTS ON DETAILED
22 ORDERS FOR ORTHOTICS AND PROSTHETICS.—
23 An orthotist or prosthetist may distribute to
24 physicians, or to an individual entitled to bene-
25 fits under this part, a detailed written order for

1 orthotics or prosthetics (as defined in para-
2 graph (4)) for commercial purposes that con-
3 tains the following information:

4 “(i) An identification of the orthotic
5 or prosthetic supplier and the beneficiary
6 to whom such orthotics or prosthetics are
7 furnished.

8 “(ii) An identification of the treating
9 physician, including the name, Medicare
10 provider number, address, and telephone
11 number.

12 “(iii) Signature of the physician iden-
13 tified in (ii).

14 “(iv) A description of such orthotics
15 or prosthetics.

16 “(v) Any billing code identifying such
17 orthotics or prosthetics.

18 “(vi) Diagnosis codes, a description of
19 the beneficiary’s medical and functional
20 condition, and information about the need
21 for the orthotics or prosthetics.

22 “(vii) Any other administrative infor-
23 mation identified by the Secretary.

24 “(B) INFORMATION ON CODING AND
25 DESCRIPTORS OF COMPONENTS PROVIDED.—If

an orthotist or prosthetist distributes a detailed written order for orthotics or prosthetics, the orthotist or prosthetist also shall list on the order the HCPCS codes and summary descriptors of the items and services being recommended prior to distribution of such order to the treating physician.

“(C) WRITTEN PHYSICIAN ORDER.—A detailed written order for orthotics or prosthetics must be signed by the treating physician identified in (a)(ii) of this subsection, and be included in the orthotist or prosthetist’s order.

“(3) LIMITATION ON PATIENT LIABILITY.—If an orthotist or prosthetist—

“(A) furnishes an orthotic or prosthetic to a beneficiary for which no payment may be made under this part; or

“(B) subject to section 1879, furnishes an orthosis or prosthesis to a beneficiary for which payment is denied under section 1862(a)(1) of this title,

any expenses incurred for such orthotics or prosthetics furnished to an individual by the orthotist or prosthetist not on an assigned basis shall be the responsibility of such orthotist or prosthetist. The in-

1 dividual shall have no financial responsibility for
2 such expenses and the orthotist or prosthetist shall
3 refund on a timely basis to the individual (and shall
4 be liable to the individual for) any amounts collected
5 from the individual for such items and services. The
6 provisions of subsection (a)(18) of this section shall
7 apply to refunds required under the previous sen-
8 tence in the same manner as such provisions apply
9 to refunds under such subsection.

10 “(4) PATIENT LIABILITY.—If an orthotist or
11 prosthetist furnishes an orthotic or prosthetic to a
12 beneficiary for which payment is denied in advance
13 under subsection (a)(15) of this section, expenses in-
14 curred for such orthotic or prosthetic furnished to
15 the beneficiary by the orthotist or prosthetist shall
16 be the responsibility of the beneficiary.

17 “(5) DEFINITIONS.—For purposes of this para-
18 graph—

19 “(A) ‘Orthotist or prosthetist’ shall mean
20 an individual who is specifically trained and
21 educated in the provision of, and patient care
22 management related to, prosthetics and custom-
23 fabricated or custom-fit orthotics, and—

24 “(i) in the case of a State that pro-
25 vides for the licensing of orthotists and

1 prosthetists, is licensed by the State in
2 which the orthotics or prosthetics were
3 supplied; or

4 “(ii) in the case of a State that does
5 not provide for the licensing of orthotists
6 and prosthetists, is certified by the Amer-
7 ican Board of Certification in Orthotics,
8 Prosthetics and Pedorthics, Inc. or by the
9 Board of Certification/Accreditation, Inter-
10 national, or certified and approved by a
11 program that the Secretary determines has
12 certification and approval standards that
13 are essentially equivalent to those of such
14 Boards listed in this subsection.

15 “(B) ‘Orthotics and prosthetics’ shall have
16 the meaning given such term in 1834(h)(4)(C).

17 “(C) ‘Detailed Written Order for orthotics
18 or prosthetics’ shall mean a form or other docu-
19 ment prepared by an orthotist or prosthetist
20 and signed by the physician (as defined by sec-
21 tion 1861(r) of the Social Security Act) that
22 contains information required by the Secretary
23 to be submitted to show that an orthotic or
24 prosthetic is reasonable and necessary for the

1 treatment of an illness or injury or to improve
 2 the functioning of a malformed body member.”.

3 (c) EFFECTIVE DATE.—The amendments made by
 4 this section shall take effect on the date of enactment of
 5 this Act, and apply to items and services furnished on or
 6 after such date.

7 **SEC. 8. GREATER ACCOUNTABILITY AND TRANSPARENCY**
 8 **OF RECOVERY AUDIT CONTRACTORS.**

9 (a) IN GENERAL.—Section 1893(h) of the Social Se-
 10 curity Act (42 U.S.C. 1395ddd(h)) is amended by adding
 11 at the end the following:

12 “(9) PUBLIC REPORTING OF RECOVERY AUDIT
 13 CONTRACTOR PERFORMANCE.—

14 “(A) IN GENERAL.—With respect to each
 15 recovery audit contractor with a contract under
 16 this section for a contract year the Secretary
 17 shall publish on the Internet website of the
 18 Centers for Medicare & Medicaid Services the
 19 following information with respect to the per-
 20 formance of each such recovery audit con-
 21 tractor:

22 “(i) Audit rates.

23 “(ii) Appeals outcomes rates at each
 24 stage of the appeals process under section
 25 1869.

1 “(B) SEPARATE CATEGORIES OF PRO-
2 VIDERS OF SERVICES AND SUPPLIERS FOR IN-
3 FORMATION REPORTED.—When compiling and
4 publicly reporting the information described in
5 subparagraph (A), the Secretary shall create
6 separate categories of providers and suppliers,
7 including a separate category for orthotics and
8 prosthetics instead of aggregating orthotics and
9 prosthetics with durable medical equipment and
10 supplies.”.

11 (b) EFFECTIVE DATE.—The amendment made by
12 subsection (a) shall apply not later than contract years
13 beginning on or after the date of enactment of this Act.

14 **SEC. 9. MAINTAINING DUE PROCESS AND SATISFYING THE**
15 **NINETY-DAY STATUTORY PERIOD FOR AD-**
16 **MINISTRATIVE LAW JUDGE DECISIONS.**

17 (a) TIMELY DECISIONS.—Subject to subsection (b),
18 the Secretary shall not recoup more than 50 percent of
19 any overpayments for qualified providers and hospitals in
20 response to an audit carried out by a recovery audit con-
21 tractor under this section until an administrative law
22 judge has rendered a decision, until such time as the Sec-
23 retary certifies that, in the majority of requests for hear-
24 ing filed by providers and suppliers under section 1869(d)
25 of the Social Security Act (42 U.S.C. 1395ff(d)), an ad-

1 administrative law judge has rendered a decision within the
2 90-day period beginning on the date a request for hearing
3 has been timely filed.

4 (1) For purposes of this subsection, a quali-
5 fying provider is one that—

6 (A) meets the requirements as a Medicare
7 provider or supplier;

8 (B) has maintained a Medicare provider
9 number for a minimum of six years;

10 (C) is in good standing with applicable
11 Federal and State laws and regulations;

12 (D) has a good record of proper payments
13 under Medicare, as determined by the Sec-
14 retary; and

15 (E) the beneficiary was treated in person.

16 (2) This subsection shall be voluntary for pro-
17 viders and shall not prohibit providers from choosing
18 a different course of action.

19 (b) EXCEPTION FOR AUDITS RELATED TO FRAUDU-
20 LENT ACTIVITY.—Notwithstanding subsection (a), the
21 Secretary may recoup overpayments related to or resulting
22 from fraudulent activity on the part of a Medicare pro-
23 vider or supplier.

24 (c) EFFECTIVE DATE.—This section shall take effect
25 on the date of enactment of this Act.

1 **SEC. 10. CLARIFICATION ABOUT MINIMAL SELF-ADJUST-**
2 **MENT FOR OFF-THE-SHELF ORTHOTICS.**

3 (a) IN GENERAL.—Section 1847(a)(2)(C) of the So-
4 cial Security Act (42 U.S.C. 1395w–3(a)(2)(C)) is amend-
5 ed—

6 (1) by inserting “furnished to a patient” after
7 “section 1861(s)(9) of this title”;

8 (2) by inserting “by that patient (and not by
9 any other person)” after “minimal self-adjustment”;
10 and

11 (3) by striking “to fit to the individual” and in-
12 serting “to fit to that patient”.

13 (b) INCLUSION IN MEDICAL AND OTHER HEALTH
14 SERVICES.—Section 1861(s)(9) of the Social Security Act
15 (42 U.S.C. 1395) is amended—

16 (1) by striking “leg, arm” and inserting “(A)
17 leg, arm”;

18 (2) in subparagraph (A), as added by para-
19 graph (1), by striking the semicolon and inserting “;
20 and”; and

21 (3) by adding the following new subparagraph:

22 “(B) off-the-shelf orthotics (as defined in
23 section 1847(a)(2)(C)).”.

24 (c) EFFECTIVE DATE.—The amendments made by
25 this section shall take effect on April 1, 2007, and apply
26 to items and services furnished on or after such date.

1 **SEC. 11. REGULATIONS.**

2 No later than 120 days after enactment of this Act,
3 the Secretary shall promulgate regulations to implement—

4 (1) the provisions of, and amendments made
5 by, this Act; and

6 (2) the provisions of, and amendments made
7 by, section 427 of the Medicare, Medicaid and
8 SCHIP Benefits Improvement and Protections Act
9 of 2000, as enacted into law by section 1(a)(6) of
10 Public Law 106–554.

○