

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.

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## 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

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## 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

1 an orthotist or prosthetist distributes a detailed  
2 written order for orthotics or prosthetics, the  
3 orthotist or prosthetist also shall list on the  
4 order the HCPCS codes and summary  
5 descriptors of the items and services being rec-  
6 ommended prior to distribution of such order to  
7 the treating physician.

8 “(C) WRITTEN PHYSICIAN ORDER.—A de-  
9 tailed written order for orthotics or prosthetics  
10 must be signed by the treating physician identi-  
11 fied in (a)(ii) of this subsection, and be included  
12 in the orthotist or prosthetist’s order.

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

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

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

22 any expenses incurred for such orthotics or pros-  
23 thetics furnished to an individual by the orthotist or  
24 prosthetist not on an assigned basis shall be the re-  
25 sponsibility 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.

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