I

110TH CONGRESS
2D SESSION

H. R. 6878

To amend title XVIII of the Social Security Act to modify the designation of accreditation organizations for prosthetic devices and orthotics and prosthetics, to apply accreditation and licensure requirements to such devices and items for purposes of payment under the Medicare program, and to modify the payment methodology for such devices and items under such program to account for practitioner qualifications and complexity of care.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 11, 2008

Ms. BERKLEY (for herself and Mr. DAVIS of Alabama) 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 prosthetic devices and orthotics and prosthetics, to apply accreditation and licensure requirements to such devices and items for purposes of payment under the Medicare program, and to modify the payment methodology for such devices and items under such program to account for practitioner qualifications and complexity of care.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Orthotics and Prosthetics Improvement Act of 2008''.

SEC. 2. MODIFICATION OF REQUIREMENTS APPLICABLE UNDER MEDICARE TO DESIGNATION OF ACCREDITATION ORGANIZATIONS FOR SUPPLIERS OF PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1834(a)(20)(B) of the Social Security Act (42 U.S.C. 1395m(a)(20)(B)) is amended—

(1) by striking ''Not later than'' and inserting ''(i) IN GENERAL.—Subject to clause (ii), not later than'' with the same indentation as the clause added by paragraph (2); and

(2) by adding at the end the following new clause:

''(ii) SPECIAL REQUIREMENTS FOR ACCREDITATION OF PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—For purposes of applying quality standards under subparagraph (A) for suppliers of items and services described in subpara-

graph (D)(ii), the Secretary shall designate and approve an independent accreditation organization under clause (i) only if such organization is a Board or program described in subsection (h)(1)(F)(iv). Not later than January 1, 2009, the Secretary shall ensure that at least one independent accreditation organization is designated and approved in accordance with this clause.''.

(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, 2009, 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.

SEC. 3. APPLICATION OF EXISTING ACCREDITATION AND LICENSURE REQUIREMENTS FOR CERTAIN PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS TO PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1834(h)(1)(F) of the Social Security Act (42 U.S.C. 1395m(h)(1)(F)) is amended—

(1) in the heading, by striking ''SPECIAL PAYMENT RULES FOR CERTAIN PROSTHETICS AND CUSTOM-FABRICATED ORTHOTICS'' and inserting ''PAYMENT RULES'';

(2) in clause (i), by striking ''an item of custom-fabricated orthotics described in clause (ii) or for an item of prosthetics unless such item is'' and inserting ''a prosthetic device or an item of orthotics or prosthetics, including an item of custom-fabricated orthotics described in clause (ii), unless such device or item, respectively, is'';

(3) in clause (ii)(II), by striking ''a list of items to which this subparagraph applies'' and inserting ''a list of items for purposes of clause (i)''; and

(4) in clause (iii)(III), by striking ''to provide or manage the provision of prosthetics and custom-designed or -fabricated orthotics'' and inserting ''to provide or manage the provision of prosthetics and orthotics (and custom-designed or -fabricated orthotics, in the case of an item described in clause (iii))''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to devices and items furnished on or after January 1, 2009.

SEC. 4. REPORTS.

(a) REPORT ON ENFORCING NEW LICENSING AND ACCREDITATION REQUIREMENTS.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the steps taken by the Department of Health and Human Services to ensure that the State licensure and accreditation requirements under section 1834(h)(1)(I) of the Social Security Act, as added by section 3, are enforced. Such report shall include a determination of the extent to which payments for prosthetic devices and orthotics and prosthetics under the Medicare program under title XVIII of such Act are made only to those providers of services and suppliers that meet the relevant accreditation and licensure requirements under such section, as well as a determination of whether additional steps are needed.

(b) REPORT ON FRAUD AND ABUSE.—Not later than 30 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report on the effect of the requirements under subsection (a)(20)(B)(ii) of section 1834 of the Social Security Act (42 U.S.C. 1395m), as added by section 2, and subsection (h)(1)(I) of such section, as added by section 3, on the occurrence of fraud and abuse under the Medicare program under title XVIII of such Act, with re-

spect to prosthetic devices and orthotics and prosthetics for which payment is made under such program.

SEC. 5. MODIFICATION OF MEDICARE PAYMENT METHODOLOGY FOR PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.

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

(1) in paragraph (1)(B), by striking ''and (H)(i)'' and inserting ''(H)(i), and paragraph (5)''; and

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

''(5) MODIFICATION OF PAYMENT METHODOLOGY TO ACCOUNT FOR PRACTITIONER QUALIFICATIONS AND COMPLEXITY OF CARE.—

''(A) IN GENERAL.—The Secretary shall modify the payment basis under paragraph (1)(B) for prosthetic devices and orthotics and prosthetics in a manner that links the complexity of the respective item and the qualifications of the individual or entity furnishing and fabricating such respective item in determining the payment basis for such item. Such modifications shall be implemented in a manner that provides for the application of such modifica-

tions to items furnished on or after January 1, 2009. Such modifications shall be designed to result in the same aggregate amount of expenditures for prosthetic devices and orthotics and prosthetics under this section for a year as would be made if this subparagraph did not apply, as estimated by the Secretary.

''(B) ASSIGNMENT OF BILLING CODES.—For purposes of subparagraph (A), in modifying the payment basis under paragraph (1)(B), the Secretary shall utilize and incorporate the '2008 Orthotics and Prosthetics Tripartite Document' a multi-organization compilation of HCPCS codes to assign specific billing codes to the category of orthotics and prosthetics care described in each of clauses (i) through (iv) of subparagraph (C) using the provider qualification designation for each HCPCS code as stated in such document.

''(C) CATEGORIES OF ORTHOTICS AND PROSTHETICS CARE DESCRIBED.—

''(i) CUSTOM-FABRICATED CATEGORY.—The category of orthotics and prosthetics care described in this clause is a category for custom-fabricated devices

that are made from detailed measurements, images, or models in accordance with a prescription and that can only be utilized by a specific intended patient. The provider qualification designation for the category shall reflect the following:

''(I) The category of care involves the highest level of complexity with substantial clinical risk.

''(II) The category of care requires a practitioner who is credentialed, certified, or licensed in orthotics or prosthetics, respectively, to insure the comprehensive provision of orthotic care or prosthetic care, respectively. Such care shall be based on sound clinical judgment and technical expertise based on the practitioner's education and clinical training, in order to allow the practitioner to determine the device parameters and design, fabrication process, and functional purpose specific to the needs of the patient to maximize optimal clinical outcomes.

''(ii) CUSTOM-FITTED HIGH.—The category of orthotics and prosthetics care described in this clause is a category for prefabricated devices that are manufactured with no specific patient in mind, but that are appropriately sized, adapted, modified, and configured (with the required tools and equipment) to a specific patient in accordance with a prescription. The provider qualification designation for the category shall reflect the following:

''(I) The category of care involves moderate to high complexity with substantial clinical risk.

''(II) The category of care requires a practitioner who is credentialed, certified, or licensed in orthotics or prosthetics or a related field in which orthotics or prosthetics is the primary focus of the course of study, to insure the appropriate provision of orthotic care or prosthetic care, respectively. Such care shall be based on sound clinical judgment and technical expertise based on the practitioner's

education and clinical training, in order to allow the practitioner to determine the appropriate device relative to the diagnosis and specific to the needs of the patient to maximize optimal clinical outcomes.

''(iii) CUSTOM-FITTED LOW.—The category of orthotics and prosthetics care described in this clause is a category for prefabricated devices that are manufactured with no specific patient in mind, but that are appropriately sized and adjusted to a specific patient in accordance with a prescription. The provider qualification designation for the category shall reflect the following:

''(I) The category of care involves a low level of complexity and low clinical risk.

''(II) The category of care requires a supplier that is credentialed, certified, or licensed within a limited scope of practice to insure appropriate provision of orthotic care. The supplier's education and training shall in-

sure that basic clinical knowledge and technical expertise is available to confirm successful fit and device compliance with the prescription.

''(iv) OFF-THE-SHELF.—The category of orthotics and prosthetics care described in this clause is a category for prefabricated devices that require minimal self adjustment for appropriate use. The provider qualification designation for the category shall reflect that such devices do not require expertise in trimming, bending, molding, assembling, or customizing to fit the patient and that no formal credentialing, clinical education, or technical training is required to dispense such devices.

''(D) CONSULTATION.—In modifying the payment basis, the Secretary shall consult with appropriate experts in orthotics and prosthetics, including practitioners that furnish devices and items within the categories of prosthetics and orthotics care described in subparagraph (C).''.

○