



**American Orthotic &
Prosthetic Association**

Orthotics & Prosthetics and Competitive Bidding

Background

Some have suggested that Medicare savings could be achieved by including all orthotics and prosthetics in the competitive bidding program; this is an attractive, albeit false and dangerous notion. The concept of why orthotics and prosthetics should be included in competitive bidding could be tied to the fact that Medicare payment for orthotics and prosthetics has been made on the basis of the device, or treated like a commodity. However, orthotics and prosthetics are not commodities or a one size fits all item, but rather custom-fabricated/fitted devices which require a great deal of fitting to meet the unique anatomical challenges of each patient. The complexity of custom-fabricated/fitted prosthetics and orthotics, combined with the patient's possible need for regular, ongoing training, and interaction with a provider they trust underscores the risk and detriment to existing patient care that would be perpetrated if the competitive bidding program were expanded to include all orthotics and prosthetics.

AOPA and the Amputee Coalition, the largest advocacy group for amputees, believe and have communicated, on several occasions, to Congressional offices, Health and Human Services (HHS) officials, and Center for Medicare and Medicaid Services (CMS) officials that any misdirected effort to expand competitive bidding beyond what was enacted with the Medicare Modernization Act (MMA) would be extraordinarily detrimental to patients. The expansion would deny patients access to the clinical care (the cost of which is included in the Medicare fee for all orthotic & prosthetic devices); and it would separate those patients from health care professionals—who understand and have earned the patients' trust over decades of specialized treatment and care.

AOPA believes that the current law, which includes only true "off-the-shelf orthotics," that is, those devices that can be safely used by the patient with only "minimal **self** adjustment" (emphasis added) remains the proper delineation of those orthotic devices simple enough and appropriate for inclusion in the competitive bidding program, thereby providing the appropriate balance of cost savings without the possible additional harm to patients.

OTS & Competitive Bidding Summary

1. When Competitive Bidding was authorized, "off the shelf" orthoses were designated as appropriate for possible inclusion in competitive bidding. The statutory definition, contained in section 1847(a) (2) (C) of the Social Security Act, defines off the shelf orthoses as those: which can be used safely by the patient with only minimal self-

- adjustment and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.
2. April 2007: CMS expanded the definition of the term “minimal self adjustment” in C.F.R. 414.402 as follows: minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board of Certification/Accreditation) or an individual who has specialized training.
 3. December 2013: CMS created a new subset of prefabricated items/services/procedures, 55 in total, which they deemed to be off-the-shelf (OTS) orthoses, including 23 devices (so-called exploded codes or split codes) which can either be off-the-shelf or custom fitted depending on the patient and physician prescription.
 4. March 2014: The four DME MAC contractors further expanded the statutory and regulatory definition of the term “minimal self adjustment” beyond the intent of the original statute when it indicated that in order for an orthosis to be classified as custom fitted, “**substantial modification**” to the orthosis to achieve proper fit and function must occur. [The DME MACs appear to have been seeking to create new policy without any clear statutory authority and without following the required rulemaking process of notice, comment, and stakeholder input.]
 5. August 2014 CMS’ HCPCS Coding Workgroup increased the number of split codes from 23 to 25, with the release of two “K” codes to describe the off-the-shelf versions of products described by L1843 and L1845. In less than 12 months CMS has made a complete reversal. In the August 2013 response to public comments regarding the proposed list of OTS orthotic codes, CMS stated that L1843 and L1845 were being removed from the proposed OTS list “as these orthoses require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual and do not meet the definition of an OTS orthosis. [The creation of these two “K” codes took place without the appropriate notice and comment process or stakeholder input.]
 6. June 2014: An update to Appendix C of the Medicare DMEPOS Quality Standards, adopts several provisions of the proposed rule on End-Stage Renal Disease (ERSD) Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies; a proposed rule which had not even been published as of June 2014. [The incorporation of this information from the proposed rule into the DMEPOS Quality Standards document prior to completion of the notice and rulemaking process is entirely inappropriate].
 7. July 2014: CMS released its proposed rule on ERSD Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies. The proposed rule updated the definition of minimal self-adjustment to make it clear that minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or a physician as defined in section 1861(r) of the Act, a treating practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, an occupational therapist as defined in 42 CFR §484.4, or physical therapist as defined in 42 CFR §484.4 in compliance with all applicable Federal and State licensure and regulatory requirements.
 8. October 2014: CMS published the final ESRD rule, which included the following statement : “*C. Summary of the Proposed Provisions and Responses to Comments on the Definition of Minimal Self-Adjustment of Orthotics Under Competitive Bidding*”

At this time, we have decided not to finalize any changes to the definition of minimal self-adjustment in § 414.402 to recognize as an individual with specialized training. We may address this provision in future rulemaking.”

9. February 2015: CMS Frequently-Asked-Questions about Competitive Bidding included the following question and answer:

“1Q. CMS proposed a revision to the definition of “minimal self-adjustment” at 42 CFR 414.402 of the Federal regulations, specifically to expand on the part of the definition related to individuals who have specialized training that enables them to furnish orthotics beyond those that require minimal self-adjustment (e.g., custom fitted orthotics). This proposed revision was not finalized. Does this mean that the guidance regarding which individuals have specialized training that enables them to furnish custom fitted orthotics is not valid?

1A. No. The guidance regarding which individuals have specialized training that enables them to furnish custom fitted orthotics remains in effect. Although the regulation was not updated to reflect this guidance, it remains in effect under the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) articles discussing when orthotics can be considered custom fitted and coded using HCPCS codes specific to custom fitted orthotics. The DME MACs have discretion to define what constitutes custom fitting for accurate coding and payment of claims. It also remains in effect under Appendix C of the DMEPOS Quality Standards related to specialized training necessary for furnishing custom fitted orthotics.”

Recommendation

Congress was very clear, and recognized the distinction between commodities and customized orthotic & prosthetic care, in specifying that only those “off-the-shelf orthoses” that can be used by the patient with “minimal self adjustment” by the individual user should be considered for the competitive bidding program when they enacted the MMA. AOPA believes that the expanded regulatory definition of minimal self adjustment (created by CMS) goes beyond both the intent and the language of the statute, and the use of this expanded regulatory definition (which is inconsistent with the statutory definition) has resulted in the classification of many orthotic items and services as off the shelf; which in reality requires a level of professional care to avoid potential harm to Medicare beneficiaries.

We ask for your support as we seek regulatory refinements to ensure that the term "off-the shelf orthoses" is appropriately defined, and that only those items which meet the statutory definition of off-the-shelf are considered eligible to be included in possible future rounds of the competitive bidding program. Specifically, in enacting the Medicare O&P Improvements Act of 2017, Section 1847(a)(2)(C) of the Social Security Act (42 U.S.C. 1395w-3(a)(2)(C)) would be clarified via amendment by inserting “by that patient (and not by any other person)” after “minimal self-adjustment,” thereby reinforcing the long-standing statutory language and intent.

We also ask that you ensure that any future policy or regulatory changes, either by Medicare or its contractors, be subject to proper stakeholder comments and that Medicare’s contractors must adhere to Medicare’s decisions on prior rulemakings regarding those stakeholder’s comments.

For more information contact the American Orthotic & Prosthetic Association (AOPA) at (571) 431-0876 or www.AOPAnet.org.