



**American Orthotic &
Prosthetic Association**

Facts about Orthotics and Prosthetics and Competitive Bidding

Background

Some have suggested that Medicare savings could be achieved by including orthotics and prosthetics in competitive bidding. AOPA believes that current law, which includes only orthotics that need “minimal **self** adjustment” (emphasis added) to be used by an individual, provides the appropriate balance and inclusion of products that are similar enough to be included in competitive bidding. AOPA has communicated to all Congressional offices that any misdirected effort to expand competitive bidding beyond off-the-shelf orthotics to include other O&P devices would be extraordinarily detrimental to patient care because it would deny Medicare beneficiaries with limb impairment access to the clinical care, the cost of which is now included in the fee Medicare pays for most O&P devices.

A great deal has happened in the last year and a half: (1) CMS has published a list of OTS devices, including 23 devices (so-called exploded codes) which can either be Off-the-Shelf or custom fitted depending on the patient and physician prescription; (2) established codes for these OTS devices; (3) remarkably for these 23 exploded codes, CMS determined to pay the identical reimbursement for the OTS version with NO orthotic services, and the same reimbursement for the same device as custom fitted with clinical support of bending, molding fitting, trimming and training from the certified/licensed orthotist, (4) Medicare’s contractors expand the definition of minimal-self-adjustment; separate from CMS, (5) CMS decided to introduce two new OTS codes; bringing the total number of OTS split/exploded codes to 25 (6) CMS released a proposed rule for expanding the definition of minimal-self-adjustment; and eventually decided not to expand the definition, (7) The DME MAC’s adopted the new expanded definition of minimal-self-adjustment

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 require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. CMS has not yet included in competitive bidding these ‘off-the-shelf’ orthoses, those for which minimal self adjustment by the individual patient (and this is, and should remain the only contingent of O&P devices eligible for possible competitive bidding).
2. 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. As noted above, CMS created a new subset of prefabricated items/services/procedures, 55 in total, which they deemed to be off-the-shelf (OTS) orthoses. They also created a series of 23 "split codes" or orthoses that can be provided either off the shelf or customized to fit a specific patient by an individual with expertise. The introduction of 23 "split codes" that represent items that are sometimes delivered OTS and sometimes delivered with proper fitting and training by a certified/ trained individual.
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 joint policy bulletin introduced the term "substantial modification" without any opportunity for stakeholder or public input. The DME MACs are creating new policy without any clear statutory authority and without following the required rulemaking process of notice, comment, and stakeholder input.
5. August 2014 CMS's HCPCS Coding Workgroup is unilaterally increased the number of dual codes from 23 to 25. It did so by end-running the appropriate notice and comment process and has afforded no opportunity for stakeholder input. As a result, two new "K" codes suddenly materialized with an effective date of October 1, 2014. The release of these two new "K" codes to describe off the shelf versions of products described by L1843 and L1845 appear to be a complete reversal, within less than 12 months, of CMS' previous position on these very same orthoses. 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.
6. July 2014 CMS released its proposed rule on End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics and Supplies, which included a substantial rulemaking relating to OTS Orthotic Devices. The proposed rule updated the definition of minimal self-adjustment to make 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.
7. An update to Appendix C of the Medicare DMEPOS Quality Standards, dated June 2014, effectively adopts several of the provisions of the July 2014 proposed rule, which had not even been published as of the June, 2014 release date of the update to the Quality Standards. 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.
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 specific in specifying that only those off-the-shelf orthoses that can be used by the patient with “minimal self adjustment” by the individual user could be considered for the competitive bidding program. AOPA believes that the expanded regulatory definition of minimal self adjustment goes beyond the intent of the statute, and the use of this expanded 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 future rounds of the competitive bidding program; by signing onto the joint, bipartisan congressional letter to Secretary Burwell and acting CMS Administrator Slavitt and join in the support the Medicare O&P Improvements Act of 2015.

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; or what is the purpose of having stakeholders comment if those comments are going to ultimately be completely ignored when CMS withdraws a policy but the contractors have the ability to implement the policy unilaterally?

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