



**American Orthotic &
Prosthetic Association**

Serious Adverse Impact on Amputee Care Would Ensnue If Recent Proposal in Obama Budget Were Adopted, and Competitive Bidding Were Applied to Acquisition of All Medicare Prosthetic & Orthotic Devices.

Background

Some have suggested that vast Medicare savings could be achieved by including all orthotics and prosthetics in the competitive bidding program. This attractive, albeit false and dangerous, notion was reinforced with the release of President Obama's FY 2017 budget, which included a distinct proposal to expand competitive bidding to include all prosthetics and orthotics; Page 72 of the budget under the heading "Provide Authority to Expand Competitive Bidding for Certain Durable Medical Equipment" contains the text "This proposal expands the competitive bidding program to additional categories, including: inhalation drugs, all prosthetics and orthotics, and ostomy, tracheostomy, and urological supplies."

The concept of why all orthotics and prosthetics should be included in competitive bidding could be tied to the fact that, for whatever historical reasons, Medicare payment for orthotics and prosthetics has been made on the basis of the device, like the other items listed on page 72 of the budget proposal. However, orthotics and prosthetics are different from those items, as they are not commodities or a one size fits all item, but rather custom-fabricated devices which require a great deal of fitting to meet the unique anatomical challenges of each patient. Also, the provision of custom fabricated or custom fitted orthoses/prostheses may require numerous direct encounters with a health care provider (orthotist or prosthetist), who the patient trusts and who understands the patient's needs.

The complexity of custom-fabricated or 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 this one aspect of the President's proposed budget were acted upon. AOPA and the Amputee Coalition, the largest advocacy group for amputees, believe and have communicated to all Congressional offices that any misdirected effort to expand competitive bidding beyond off-the-shelf orthotics would be extraordinarily detrimental to patients because it would deny them 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 trusted health care professionals—who understand and have earned the patients' trust over decades of specialized treatment and care.

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 Medicare Modernization Act (MMA). So, implementing the Obama budget proposal would require a reversal of sound statutory standards found in the MMA—and doing that would comprise “legislating malpractice”. Custom-fabricated and custom-fitted orthotic and prosthetic devices are clearly NOT commodities which can be bought nationally and shipped directly to the patient. It would misunderstand the multi-specialty teamwork of O&P care, and prove detrimental to Medicare patients (as published in “Suggested Guidelines for the Prescription of Orthotic Services, Device Delivery, Education, and Follow-up care: A Multidisciplinary White Paper,” Fisk, et al., Military Medicine, Vol 181, February Supplement 2016, pp 11-17).

AOPA believes that the current law, which includes only orthotics that need “minimal **self** adjustment” (emphasis added) to be used by an individual, provides the appropriate balance of cost savings without the possible additional harm to patients.

Facts about Orthotics, Prosthetics and Competitive Bidding

1. When Competitive Bidding was authorized only “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.
2. October 2012 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 published a list of off-the-shelf 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; and established new codes for these off-the-shelf devices,
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 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’ 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?
 - A. 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.
10. February 2016 the President’s budget for FY 2017 included a proposal to expand competitive bidding beyond those devices defined as “off-the-shelf” orthoses which require minimal self-adjustment, by the patient, for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. The proposed expansion would include all prosthetics and orthotics.

Recommendation

We ask for your support in not advancing, or be attracted to the promise of unrealistic savings, of the President's budget proposal for expanding the competitive bidding program to include all orthotics and prosthetics; and limit competitive bidding to only those orthotic items which require minimal self adjustment, as specifically provided by Congress previously under the MMA.

In addition to the harm expanding the competitive bidding program could have on patients, AOPA also believes that the expanded regulatory definition of minimal self adjustment (created by CMS) goes beyond the intent of the statute, and the use of this expanded definition has resulted in the erroneous, unauthorized classification of many orthotic items and services as off-the-shelf; which in reality require 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 supporting the following pieces of legislation that are appropriately defining "minimal self adjustment":

- The Medicare O&P Improvements Act of 2015 (H.R. 1530, S. 829)
- The Medicare Audit Improvement Act of 2015 (H.R. 1526)
- The Protecting Access through Competitive-pricing Transition (PACT) Act of 2015 (H.R. 4185)

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 else CMS can withdraw a policy but the contractors would 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.