



**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 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 to include other O&P devices would be extraordinarily detrimental to patient care because it would deny Medicare beneficiaries with limb loss and 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 past six months: (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, and; (4) sought comments on its direction for competitive bidding (AOPA responded on March 28, 2014).

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.
2. 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).
3. Prosthetics and more complex orthotics were not included in competitive bidding because these items are customized to fit an individual and need more specialized tailoring to the individual’s body and needs.
4. Prosthetics and orthotics are not part of Durable Medical Equipment and have a separate Medicare fee schedule.

(Over)

5. Unlike many products in competitive bidding, a prescription is needed for prosthetics and more complex orthotics. The IRS found that most prosthetics and their component parts are exempt from the Affordable Care Act's 2.3% medical device excise tax because they fit the retail sales exemption as do eye glasses and hearing aids which were specifically exempted by statute and because like prosthetics/orthotics, they are sold at retail for individual use and require a prescription.
6. Competitive Bidding works best when applied to products and services that cost very little and require little if any expertise on the part of the provider. Most prosthetics and orthotics are made to fit a specific individual and therefore are not comparable or produced on a scale needed to make competitive bidding work.
7. 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.
8. 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 has only created more questions, considering CMS has not issued any clear guidance on the proper use of the new "split codes".

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.

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