THE ORTHOTIC AND
PROSTHETIC ALLIANCE

1501 M Street, NW, 7th Floor
Washington, DC 20005
Phone: 202-466-6550
Fax: 202-785-1756
Email: opalliance@gmail.com

March 28, 2014

Submitted electronically via: www.regulations.gov

Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1460-ANPRM
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Using Information From Competitive Bidding Programs [CMS-1460-ANPRM]

Dear Administrator Tavenner,

On behalf of the Orthotic & Prosthetic Alliance (the O&P Alliance), a coalition of the five major national orthotic and prosthetic organizations representing over 13,000 O&P professionals and 3,575 accredited O&P facilities, we write to provide comments on the above-referenced advance notice of proposed rulemaking (ANPRM). This letter summarizes our key concerns regarding the competitive bidding program and any potential application of such program to the methodology for setting payment amounts for "off-the-shelf" (OTS) orthotics, in particular.

We are gratified that CMS has not included OTS competitive bidding in this ANPRM and continue to believe that CMS' decisions to date in defining and coding OTS orthotics are seriously flawed. Notwithstanding the other important issues raised in the ANPRM, we wish to take this opportunity to reiterate our concerns with CMS' treatment to date of OTS orthotics in case CMS decides to include this issue in the Notice of Proposed Rulemaking.

Background

When Congress authorized competitive bidding in 2003, it exempted all prosthetic limbs and orthotic braces except OTS orthotics. Congress defined OTS orthotics as devices that require "minimal self-adjustment" for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual.[1] This statutory definition limited competitive bidding under Medicare to the types of orthoses generally available in pharmacies or durable medical equipment (DME) supply businesses.

[1] 42 U.S.C. § 1395w-3(a)(2)(C).

However, when CMS regulated this provision, it significantly expanded the definition of OTS orthotics. The regulatory definition of "minimal self-adjustment" in CMS regulations is "an adjustment that the *beneficiary, caretaker for the beneficiary, or supplier* of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training."[2] This is a far more expansive definition of OTS orthotics than set forth in the statute and defies the notion of OTS orthotics requiring only "minimal *self*-adjustment."

In August 2013, CMS published a list of HCPCS codes that it believed met the regulatory definition of OTS orthotics. This expansive list included 32 codes that CMS deemed as always describing OTS orthoses. The list also addressed 23 existing orthotic codes that CMS believed sometimes described OTS codes and sometimes described orthoses that required expertise in fitting or customizing. CMS proposed to "explode" these 23 codes into two versions, a new code for OTS applications and the existing code for orthoses that required a greater degree of custom fitting by "an individual with expertise."[3] The O&P Alliance met with CMS to explain our reasons for opposing this proposal. The Alliance believes that approximately 22 HCPCS codes qualify as OTS codes for purposes of competitive bidding. The Alliance opposed the "explosion" of the other orthotic codes as an unauthorized overreach by CMS to expand its statutory authority on competitive bidding.

Following the expansion of the definition of OTS orthotics, CMS published on November 29, 2013, a final list of HCPCS codes that it believes meets the regulatory definition of OTS orthotics. This list includes 23 OTS "split codes," separated into a code for OTS orthotics and a code for custom fit orthotics that fit within the same overall description, and 32 OTS-only codes, for a total of 55 possible OTS codes subject to competitive bidding. This represents a wide swath of orthoses routinely provided by physicians, therapists, orthotists, orthotic fitters and orthotic manufacturers and suppliers. Most experts agree that many of these orthoses that are now deemed OTS in fact require clinical expertise and, in many instances, custom fitting to appropriately fit the patient.

CMS indicated that publication of this list did not signify that competitive bidding of these codes is necessarily forthcoming. Yet, if and when competitive bidding is implemented for OTS orthotics by CMS, this will presumably be the list that is used as a starting point. Given the publication of the recent ANPRM, the O&P Alliance would like to address its continuing concerns with the application of competitive bidding to OTS orthotics and the process of defining specific orthotic devices as OTS.

O&P Alliance's Continuing Concerns

1. "Exploding" the Codes: We continue to object to and oppose CMS' "exploding" of the HCPCS orthotic code set. Only codes that describe truly OTS orthoses that can be used safely by the patient with minimal self-adjustment in all instances should be identified as OTS codes for

[2] 42 C.F.R. §414.402.
[3] http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2014-Alpha-Numeric-HCPCS.html?DLPage=1&DLSort=0&DLSortDir=descending

purposes of competitive bidding. We believe CMS' current interpretation of OTS orthotics violates the statutory definition of OTS orthotics.

2. Operational/Clinical Consequences: HCPCS codes that do not meet the statutory definition of OTS orthoses should be removed from the OTS list for purposes of competitive bidding.

   a. If CMS proceeds to competitively bid the orthoses described under the HCPCS codes that have been "exploded," there will be a whole host of clinical, documentation, and administrative consequences as this decision is operationalized. We would expect widespread confusion in the physician and provider communities as a result of mixing the application of competitive bidding to both OTS and prefabricated orthoses requiring more customized care and clinical expertise.

   b. In most instances, the decision whether to use an OTS orthosis or resort to a prefabricated orthosis is determined once the orthotist or orthotic fitter examines the patient. Most physicians are not intimately familiar with the wide range of orthotic options and will often write a prescription for a type of orthotic treatment (e.g., "KAFO" (a knee-ankle-foot orthosis)). The specific orthosis is often recommended by an orthotist or other provider after assessment of the patient. This situation would quickly lead to a variety of situations where the patient is sent from one provider to another to obtain the appropriate orthosis, all the while not having access to the prescribed device that is supposed to support a malformed or weakened portion of the leg, arm, back or neck. This could further compromise patient care. It could also have the unfortunate effect of creating a whole new wave of Medicare audits that examine the physician's records and deny claims where the physician's notes do not adequately reflect the specific treatment plan the patient has undergone.

      i. For instance, suppose a general practice physician prescribes an orthosis for a Medicare beneficiary and suggests several certified/licensed orthotists. The patient is seen by a certified/licensed orthotist whose company does not have a competitively bid contract with Medicare for OTS orthotics. The certified/licensed orthotist determines that an OTS orthosis will be sufficient and a custom orthosis is not necessary and, therefore, will not be covered by Medicare. What happens? Will the patient be required to leave the orthotist's office without the required orthotic treatment? Will the patient have to return to the physician for guidance, contact a contracted supplier, and then potentially provide measurements and await a drop-shipped device in the mail?

      ii. Suppose a physician prescribes an OTS orthosis for a Medicare beneficiary and offers that patient a list of suppliers with OTS orthotic contracts. The non-certified supplier determines—even with limited orthotic education and training—that the patient is more complex clinically than assumed and requires a greater degree of clinical care. Does the supplier do the best it can by providing the OTS orthosis

and risk patient harm, refer the patient back to the physician for another prescription for a prefabricated orthosis, or refer the patient directly to a certified/licensed orthotist? The certified/licensed orthotist will be subject to a denial of any care provided unless the physician is ultimately contacted and convinced to write a new prescription for a more customized orthosis. Meanwhile, the beneficiary waits for the appropriate orthotic treatment, risking potential harm.

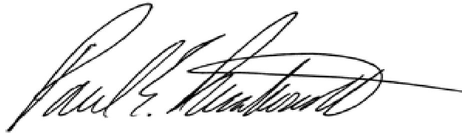
iii. Finally, suppose a physician prescribes an orthosis for a Medicare beneficiary and offers the patient a list of orthotic suppliers with competitively bid contracts. The supplier fits the patient with an OTS orthosis. The complexity of the patient's condition outstrips the ability of the OTS orthosis to address the patient's clinical needs and a misaligned and ill-fitting OTS orthosis leads to an exacerbation of the underlying condition and a skin breakdown. The patient returns to the physician, who, after additional and unnecessary expense to treat the skin breakdown, prescribes a more customized orthosis. Will Medicare cover the second prefabricated or custom fabricated orthosis to treat the same condition that should have been addressed the first time around? Will beneficiaries be forced to pay an additional 20% of the fee schedule amount for the subsequent orthosis?

c. These are some of the complexities that will inevitably arise under the "exploded" orthotic code set. If CMS does not amend its interpretation of OTS orthotics and decides to press forward with competitive bidding, we urge CMS to confine competitive bidding to a subset of HCPCS codes that it describes as OTS orthoses. Competitive bidding should be restricted to only those codes that are truly OTS under the statutory definition, i.e., those orthoses that truly only require minimal self-adjustment. In addition, because of the complexity of competitively bidding OTS from an operational standpoint, described immediately above, if CMS proceeds with OTS competitive bidding, it should limit OTS competitive bidding to a small number of MSAs, so as to assess the impact of this policy on patient care before it is implemented nationwide.

3. BIPA Section 427: We continue to believe that CMS' refusal to implement BIPA Section 427 has contributed to and exacerbated the problems that now exist with the Medicare O&P benefit. Linking the ability to receive Medicare payment for custom orthoses and prostheses to the qualifications of the practitioner or supplier providing the O&P care would significantly advance accountability and quality in this area, while reducing fraud and abuse. We, therefore, once again, reiterate our request to CMS to implement this important section of the Medicare law.

We appreciate your time and attention on this important matter. If you have any questions or would like to discuss our concerns and observations, please contact our Washington Counsel, Peter Thomas, at 202-466-6550.

Sincerely,



Paul E. Prusakowski, CPO, FAAOP
President
National Association for the
Advancement of Orthotics and Prosthetics

Curt A. Bertram, CO, FAAOP
President
American Board for Certification in
Orthotics, Prosthetics and Pedorthics, Inc.

Michelle J. Hall, CPO, FAAOP
President
American Academy of Orthotists and
Prosthetists

Anita Liberman-Lampear, MA
President
American Orthotic & Prosthetic Association

James L. Hewlett, BOCO
BOC Chairman
Board of Certification/Accreditation, International