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

September 16, 2013

**Sent Via Email**

Laurence Wilson
Joel Kaiser
Chronic Care Policy Group
Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD

RE: **Off-the-Shelf (OTS) Orthotics and Medicare Competitive Bidding**

Dear Laurence and Joel:

On behalf of the Orthotic & Prosthetic Alliance (the O&P Alliance), a coalition of the five major national orthotic and prosthetic organizations representing over 10,000 O&P professionals and 3,000 accredited O&P facilities, we write to thank you for meeting with us on August 26th to discuss our continued concerns with CMS' "Analysis of and Responses to Public Comments" related to Off-The-Shelf (OTS) Orthotics, dated August 2013. This letter summarizes our key concerns and responds further to some of the dialogue we had during our meeting.

## Background

In response to CMS' original proposal in March of 2012 to identify 66 HCPCS codes as satisfying the definition of "off-the-shelf" orthotics, the O&P Alliance organizations—comprising the key national organizations most engaged in the full-time practice of comprehensive orthotic and prosthetic care—conducted a detailed analysis of the codes at issue, submitted a lengthy written document detailing our findings,[1] and met with you to discuss our perspective. In that July 2012 meeting, we identified 22 HCPCS codes that we felt met the statutory definition of OTS orthotics referenced in Section 302 of the Medicare Modernization Act of 2003. According to the statute, OTS orthotics are orthoses 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] A separate, comprehensive document was submitted by the American Orthotic and Prosthetic Association which was consistent with the O&P Alliance's position.

At that same meeting, we highlighted nine HCPCS codes and exhibited real examples of such orthoses to demonstrate why we felt the orthoses described by these HCPCS codes were not OTS. These orthoses were illustrative of our broader point; that two thirds of the HCPCS codes identified by CMS as OTS did not meet the statutory OTS definition, required varying degrees of clinical expertise to appropriately fit to the patient, and would cause extensive complications and confusion if subjected to competitive bidding.

In its response to comments on this OTS proposal, CMS acknowledges that many of the existing HCPCS codes contain a wide variety of orthoses that require clinical expertise, but states its intention to "explode" these HCPCS codes into those orthoses within each code that can be described as OTS and those that require greater clinical expertise. The rationale for this decision appears to be that the MMA Section 302 requires CMS to competitively bid OTS orthotics and to the extent that existing HCPCS codes contain even a small percentage of orthoses that could arguably fit the definition of OTS, these codes must be bifurcated. Presumably, every brand name orthotic device that uses these codes will have to be assessed by CMS to determine whether it fits the OTS code or the code that requires greater clinical expertise (i.e., a prefabricated orthoses requiring custom fitting); an admittedly daunting task for CMS. What is also missing in CMS's analysis is how differing clinical situations and diagnoses will be taken into consideration when determining which orthoses require more clinical involvement and which do not.

Finally, CMS cites the OIG report "Medicare Supplier Acquisition Costs for L0631 Back Orthoses" (OEI-03-11-00600) to establish a principle that it applies widely in its responses to public comments on its OTS orthotics list of codes. The OIG report found in its analysis of the L0631 spinal orthosis code that some percentage of the orthoses examined were provided without significant clinical involvement in the fitting and modifying of the device to the patient. When pressed by AOPA, OIG stated that it "estimated" that in its sample, approximately one third of the orthoses billed under this code did not include a significant clinical service and, therefore, in its view, the code could be competitively bid. This means that—if the OIG analysis is accurate—two thirds of the orthoses provided under this code *did* involve clinical expertise in fitting and adjustment and, therefore, competitive bidding of these orthoses would violate the statutory OTS definition.

At our meeting, an argument was made that bifurcating the HCPCS codes would allow CMS to collect data as to which orthoses are truly provided with or without clinical expertise. This data would help build the case that Congress should grant CMS the authority to competitively bid all orthoses other than custom fabricated orthoses. This, of course, would extend competitive bidding into an area of clinical care, not just devices and products that are easily comparable and, therefore, more appropriate for competitive acquisition.

The reason Congress explicitly exempted custom orthotics and all prosthetics (prosthetic limbs) from competitive acquisition was because of the clinical, service-oriented, and customized nature of most orthoses. Congress recognized that the quality of care would be materially impacted if competitive bidding applied to such a clinically oriented and customized service. Easy comparisons of like "products" are not possible with custom O&P care. Therefore, the Alliance believes that competitive acquisition of custom orthotics would compromise quality, potentially compromise patient safety, and should not be authorized by Congress or adopted by the Medicare program.

The MMA Section 302 does not, in fact, mandate that CMS competitively bid every individual orthosis that could arguably be described as OTS. To be specific, the statute does mandate the establishment of a competitive bidding program for certain identified DMEPOS items. It also authorizes specific items to be competitively bid, including OTS orthotics which is specifically defined (see above definition). However, in addition to the inherent discretion the HHS Secretary possesses to effectively run the Medicare program, the statute allows CMS to vary the items that are competitively bid in different areas of the country. It also permits the Secretary the authority to exempt rural areas or exempt items that are not likely to result in significant savings. Indeed, the history of the competitive bidding program is replete with examples where CMS has chosen to exempt certain products and items based on its discretion to effectively run the competitive bidding program.

**O&P Alliance's Continuing Concerns**

The O&P Alliance summarizes below our concerns with respect to CMS' responses to the public comments to the OTS orthotics list, as well as our conversation during our meeting:

1. "Exploding" the Codes: We continue to object to and oppose CMS' intention to "explode" the HCPCS orthotic code set. Only codes that describe truly OTS orthoses that can be used safely by the patient with minimal self-adjustment should be identified as OTS codes for purposes of competitive bidding. We believe CMS' current interpretation of OTS orthotics violates the statutory definition of OTS orthotics.

2. Operational/Clinical Consequences: We are disappointed that CMS essentially ignored the clinical expertise of the O&P profession. CMS agreed to remove only one code (i.e., a pediatric "Pavlik" orthosis) out of the nine codes we demonstrated to illustrate the concept that 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 will be bifurcated, 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 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 treatment plans have progressed as the patient has undergone orthotic assessment and treatment and for some reason, the physician's notes do not reflect this.

i. For instance, suppose a general practitioner (M.D.) prescribes an orthoses to a Medicare beneficiary and suggests several certified orthotists. The patient is seen by a certified orthotist whose company does not have a competitively bid contract with Medicare for OTS orthotics. The certified 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 to 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 orthotist? The certified 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?

These are some of the complexities that will inevitably arise if CMS proceeds to "explode" the orthotic code set and impose competitive bidding on a much wider range of orthoses than Congress ever intended.

3. OIG Report on L-0631: During the course of our meeting, the O&P Alliance was asked whether in response to the OIG report on L-0631, we had requested the OIG to further study whether clinical care was being provided with the provision of additional orthotic codes. We responded that we, as the key organizations representing the O&P profession, had no interest in having the Medicare program pay for clinical services the beneficiary is not receiving. In fact, we responded to the OIG that L-0631 is a code which includes the provision of clinical care. Failure to provide such clinical care diminishes the quality of care provided to the patient and is an inappropriate allocation of Medicare resources. In addition, we criticized the OIG for not conducting an analysis of the qualifications of the orthotic providers identified in their report, consistent with the still-unimplemented federally mandated requirements of Section 427 of the Benefits Improvement and Protection Act of 2000 (BIPA, Section 427).

4. 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.

   One of the reasons cited during our meeting by CMS for not implementing this section of the law was the diversity of opinion CMS heard during the course of the Negotiated Rulemaking held in 2002. We acknowledge this diversity of opinion, but do not think this is a valid reason for failing to implement and enforce federal law 13 years after it was enacted. Examples of regulations that have been finalized by CMS despite a wide diversity of opinion are too numerous to cite. We also believe that the policy positions and opinions of O&P professionals engaged full-time in the practice of O&P care, and who have devoted their careers to orthotic and prosthetic patient care, should not be valued equally with every organization or entity that cares to take a position on these issues. When CMS publishes the inpatient PPS proposed rule, we suspect it pays greater attention to the comments of the American Hospital Association than it does to the comments received by a sole physician or a fringe medical organization. The fact is that all providers have potential conflicts of interest in advising CMS, but this does not make their positions and recommendations irrelevant and unworthy of consideration by CMS.

5. Bifurcation of HCPCS Codes: It was not clear during our meeting whether CMS intends to bifurcate each orthotic HCPCS code identified in its written response by dividing all of the brand name products under each code into an OTS code and a prefabricated code or if each orthosis would be subject to treatment as an OTS device (and therefore subject to competitive bidding) based on how the orthosis is being applied to a patient with a particular diagnosis. In other words,

it was not clear whether the same orthosis will be treated as an OTS device for one patient and a prefabricated device for another, based on the needs and circumstances of the individual patient. Unfortunately, both approaches are fraught with complexity and confusion.

6. Unrealistic Workload for CMS: As an example of the daunting task that awaits CMS if it moves forward with exploding the orthotic code set, the OIG Report on L-0631 included a list of almost three full pages of brand name orthotic products that were considered reimbursable under the L-0631 HCPCS code. Exploding this and many other orthotic codes into an OTS version and a more customized "prefabricated" version, assessing each brand name product to determine the level of clinical care needed in its application to the patient, and then determining which code should apply to each product is a massive undertaking. CMS has yet to explain how this process will be conducted, on what timeline it would be pursued, what burdens would be imposed on orthotic manufacturers and suppliers, and how the process would be sufficiently transparent to enable genuine disagreements to be resolved in a timely manner.

7. Process and Timing: The last sentence of CMS' "Analysis and Response to Public Comments for Off-the-Shelf Orthotics List" states that "HCPCS codes finalized on this list will be considered OTS effective January 1, 2014." Since CMS' response is clearly the framework for how it intends to eventually implement competitive bidding for OTS orthotics, this statement is truly alarming. We seek greater clarification from CMS as to the meaning of this statement, the process CMS intends to use going forward, and the timing of this major undertaking.

8. OTS As Reimbursable Medicare Benefits: On at least three occasions during the course of our meeting, CMS questioned whether the Medicare program should be covering and reimbursing off-the-shelf orthotics at all. The statement seemed to be linked to CMS' desire to collect data to assess how much clinical care is being provided in connection with a wide variety of orthoses. There seemed to be a suggestion that if little or no clinical care is being provided with OTS orthoses, there is a question as to whether Medicare should consider them reimbursable Medicare benefits.

   The O&P Alliance believes that all providers and suppliers furnishing custom orthoses should be providing the associated clinical care necessary to treat the patient and providers who do not provide this clinical care should be subject to overpayment liability. However, we do not believe it follows that OTS orthoses that require only minimal self-adjustment are not worthy of Medicare reimbursement. The fact that some orthoses require only minimal self-adjustment does not mean that patients do not benefit from them. And it does not mean that these orthoses do not fit within the statutory and regulatory definitions of covered Medicare benefits. In fact, this potential change in policy would only shift greater cost burdens onto Medicare beneficiaries in need of orthotic treatment, regardless of whether the specific treatment is characterized as off-the-shelf.

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

Timothy E. Miller, CPO
President
American Board for Certification in
Orthotics, Prosthetics and Pedorthics, Inc.

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

Thomas F. Kirk, PhD
President
American Orthotic & Prosthetic Association

John P. Kenney, MURP, BOCO
BOC Chairman
Board of Certification/Accreditation, International

cc: Jonathan Blum
Deputy Director, CMS
Director for the Center on Medicare