Competive Bidding and/or Other Directions for Off-the-Shelf Orthotics

American Orthotic & Prosthetic Association

March 28, 2014

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

Submitted electronically via www.regulations.gov (CMS-1460-ANPRM)

Dear Sir/Madam:

We are writing to provide comments on CMS-1460-ANPRM *titled Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*. This advanced notice of proposed rulemaking (ANPRM) was published in the February 26, 2014 *Federal Register*. The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a national membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

The ANPRM "solicits public comment on different methodologies we may consider using with regard to applying information from the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) competitive bidding programs to adjust Medicare fee schedule payment amounts or other Medicare payment amounts for DMEPOS items and services furnished in areas that are not included in these competitive bidding programs." AOPA is pleased to submit the following comments in response to the ANPRM.

I. AOPA is concerned about the potential adjustment of off the shelf (OTS) orthosis fee schedules based on competitive bidding of unrelated Durable Medical Equipment (DME).

One of AOPA's primary concerns regarding the ANPRM is that payment information established through competitive bidding of DME included in rounds 1 and 2 of competitive bidding as well as the round 1 re-compete will be used as a basis for adjustments to the fee schedule for OTS orthoses. Section 1834 (h)(1)(H)(ii) of the Social Security Act states the following:

(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2011, subject to subparagraph (G)(1)(A), that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such competitive acquisition program; and

(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

According to the statute, the Secretary may use information obtained through a competitive acquisition program involving OTS orthoses to adjust payment amounts for an area that is not a competitive acquisition area. To date, OTS orthoses have not been included as a product category in any competitive acquisition program. Without the establishment of a competitive acquisition program for OTS orthoses, AOPA believes there is no statutory authority for the Secretary to adjust payment amounts for OTS orthoses either in metropolitan statistical areas (MSAs) currently included in competitive bidding programs or those MSAs not currently included in competitive bidding. There is certainly no information relevant to OTS orthotics payment amounts because there has to date been NO competitive bidding program for those products.

Any attempt to use payment information obtained through product categories subject to competitive bidding, but unrelated to OTS orthoses would be in direct violation of the statute as outlined at 1834 (h)(1)(H)(ii).

II. AOPA Remains Concerned About the Expanded Definition of the term "Minimal Self Adjustment" Used to Define Off the Shelf Orthoses

AOPA, once again, would like to express its continued concern regarding the use of the expanded regulatory definition of the term "minimal self adjustment" as the basis for the inclusion of a total of 55 HCPCS codes in the category of off the shelf orthoses. The statutory definition of an off the shelf orthosis 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 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 for Orthotist/Prosthetist Certification) or an individual who has specialized training.

AOPA has repeatedly voiced its concern regarding the expanded regulatory definition of the term "minimal self adjustment" and the subsequent use of the regulatory definition to classify 55 HCPCS codes as OTS, 23 of which represent HCPCS codes that were "exploded" into custom fitted and OTS codes used to describe the same device, differentiated by the process used in ensuring a proper fit for the patient. Efforts to date have included multiple pieces of correspondence with CMS officials, the CMS Administrator, as well as the Secretary of Health and Human Services.

AOPA believes that the expanded regulatory definition of minimal self adjustment goes beyond the intent of the statute in defining OTS orthoses subject to competitive bidding. The use of this expanded definition has resulted in the classification of many orthotic HCPCS codes as off the shelf items that in reality require some level of professional care to avoid potential harm to Medicare beneficiaries. The subsequent explosion of 23 HCPCS codes that represent items that are sometimes delivered OTS and sometimes delivered with proper fitting and training by a certified or trained individual has only created more questions and confusion regarding documentation requirements for claim payment.

This confusion has been further escalated by the February 28, 2014 joint release and subsequent March 7, 2014 retraction of a policy bulletin on OTS orthoses by the four DME MAC contractors. While only published for a short time before its retraction, several statements in the policy bulletin reinforced AOPA's concern regarding the correct use of both off the shelf orthosis and custom fitted orthosis codes when submitting claims to Medicare contractors. For example, the bulletin articulated the position that the decision whether a prefabricated OTS orthosis should be utilized vs. a custom-fit or custom-fabricated orthosis that included clinical care would be made by the physician. The fact is that these decisions will generally be made by the physician in consultation with, or with guidance from the orthotist. The physician typically does not have access to the device, its labeling or other information; moreover, the majority of physicians prescribing an orthotic device do not have substantial experience with either the devices or those therapeutic indications which necessitate the clinical services of the orthotist. So, any statement or implication that this decision will be made by the physician alone, without appropriate acknowledgement of collaboration with the orthotist assumes circumstances which are not compatible with either the clinical setting or the realities of patient care. Another example of ambiguity, this one relating back to the chasm between the statutory and regulatory definition of OTS, is contained in the discussion regarding the definition of custom fitted orthoses. The policy bulletin included a statement that custom fitted orthoses require **substantial modification** for fitting at the time of delivery. This is a term that is found nowhere in the statutory definition, and appears to be something created de novo without benefit of either scientific justification or any stakeholder input via notice and comment rulemaking, e.g., as CMS appears to have attempted in the 2007 rule. The bulletin further defines substantial modification as "changes made to achieve an individualized fit of the item that requires the expertise of a qualified practitioner i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self adjustment." While the bulletin attempts to clearly define the term substantial modification, it actually creates confusion among the supplier community when trying to decide if modifications they have made to assure a proper fit of the orthosis would meet the threshold of this new "substantial" modification terminology. This will lead to increased exposure to audit activity and may contribute to unnecessary claim denials due to different interpretations of the term substantial. CMS would be much wiser, and beneficiaries much better served, if CMS stuck to the statutory definition (without the expansion of CMS' rulemaking), which is remarkably clear. The

policy bulletin also indicates that providers must provide the product that is specified by the ordering physician, i.e. type of orthosis and method of fitting and/or fabrication (OTS, custom fitted or custom fabricated). AOPA believes that in most cases, the ordering physician is relying on the specific expertise of the orthotist to determine, through direct evaluation, if the patient requires an OTS or custom fitted orthosis and therefore cannot pre-determine the exact method of fabrication and fitting that will be required.

CMS must also further clarify the limits of the qualified provider status of the physician both regarding personnel in that physician's practice, and possibly also in terms of the ancillary services exception. It is clear that the physician is a qualified provider—that is as it should be and is beyond challenge. But will an otherwise unqualified employee in the physician's office (be that an R.N. who has not training/credentialing in orthotics, or the receptionist/billing clerk who removes a device from a consignment closet and hands it to the patient) be permitted to circumvent the qualified provider provisions and by purporting to operate "under the supervision of the physician" be considered by CMS as sufficient to support billing for custom-fitting/clinical services? What about an unaccredited manufacturer sales rep who happens to be in the physician' office—does he/she become a de facto qualified provider just because the encounter occurs within the four walls of a physician's office, even though the physician takes no role in the fitting, adjustment and/or other clinical services? In both cases, AOPA suggests the answer must be "no." Within the physician office setting, quality of beneficiary care would be compromised if any orthotic care/adjustment were considered legitimately provided in any circumstance where the patient does NOT receive that fitting/adjusmtent /clinical care directly from the physician, but instead it is provided by a person who does not meet the criteria of a qualified provider. While the policy bulletin was retracted on March 7, 2014, AOPA expects a revised version of the bulletin to be published in the near future and remains concerned, hoping that CMS/DME MAC attempts at clarification will not continue to try to stake out entirely new ground without any foundation or basis in the statute itself. Obviously, that would both violate the law and may actually lead to detriment for patients/beneficiaries as well as additional confusion among suppliers.

AOPA strongly believes that competitive bidding authority, as designated by the statute, should be limited to only those OTS orthoses that may be provided with the need for minimal self adjustment, specifically provided by the patient, i.e., "self-adjustment.".

In conclusion, AOPA reiterates its concern regarding the potential adjustment to established fee schedule payment amounts for off the shelf orthoses based on the fact that OTS orthoses have never been included in any competitive acquisition program. In addition, AOPA appreciates the opportunity to reaffirm its long time concern regarding the use of the expanded regulatory definition of the term "minimal self adjustment" in establishing new and revised HCPCS codes for OTS orthoses subject to competitive bidding authority.

Sincerely,

Thomas F. Fise, JD
Executive Director