



August 27, 2014

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1614-P
P.O. Box 8010
Baltimore, MD 21244-8010

Submitted electronically via www.regulations.gov (CMS-1614-P)

Re: CMS-1614-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Dear Sir/Madam:

We are writing to provide comments on the proposed rule CMS-1614-P entitled, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies". This proposed rule was published in the July 11, 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.

AOPA's comments will be limited to the provisions of the proposed rule that address the definition of the term "minimal self adjustment", currently codified at 42 CFR 414.402, and related topics bearing on the provision of off the shelf (OTS) orthoses to Medicare beneficiaries.

AOPA Comments Regarding the Progressive Expansion of the Definition of “Minimal Self Adjustment” Through Regulation and Policy Statements

As AOPA has stated numerous times before, CMS’s decision to expand the definition of “minimal self adjustment” has led to significant confusion and inconsistency in the overall approach to billing certain kinds of orthoses. The *Social Security Act*¹ defines OTS 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. (Emphasis added)*

This definition clearly describes what qualifies as an OTS orthosis: an item that is self-adjustable – by the patient – and that doesn’t require any expertise in order to fit it.

Nevertheless, CMS unilaterally redefined “minimal self adjustment,” expanding its scope while simultaneously making it inconsistent with the statute:

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.²

AOPA has raised its concerns about this issue multiple times, including its comments submitted in the 2006-07 rulemaking, multiple pieces of correspondence with CMS officials, the CMS Administrator, the Secretary of Health and Human Services, and most recently, as part of its comments on the March, 2014 Advanced Notice of Proposed Rulemaking titled, “*Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies*” (CMS-1460-ANPRM). The continued regulatory expansion of the definition of “minimal self adjustment” blatantly goes beyond the statute’s intent in defining OTS orthoses subject to competitive bidding as if CMS had authority to selectively modify the words of the statute to obliterate the word “self” from section 1847(a)(2)(C) of the Social Security Act.

The result has been a confusing and counterintuitive classification of many orthotic HCPCS codes as OTS that simultaneously require some level of professional care, treatment and fitting. Specifically, CMS took 23 of the 55 “OTS” HCPCS codes and created parallel “custom fit” codes describing *exactly the same items*. With CMS’s self-described “explosion” of these 23 codes into either OTS or custom fit pairs, suppliers must now choose between codes depending on a variety of factors far beyond those described or contemplated in the original Social Security Act definition. This has only created more questions and confusion regarding documentation requirements for claim payment, to the detriment of the quality of care Medicare beneficiaries receive

¹ Section 1847(a)(2)(C)

² C.F.R. 414.402

In addition to its concern about CMS' continued regulatory expansion of the term "minimal self adjustment" to regulate who may provide OTS orthoses, AOPA believes that the proposed rule also uses this definition to improperly regulate who may provide non-OTS orthoses. Section 427 of The Benefit Improvement Act of 2000 (BIPA) states that only qualified practitioners or qualified suppliers may furnish custom fabricated orthoses to Medicare beneficiaries. BIPA 427 defined the term "qualified practitioner" as a physician, a qualified physical or occupational therapist, a state-licensed orthotist or prosthetist, or an appropriately certified orthotist or prosthetist (in states without O&P licensing), and the term "qualified supplier" as an entity that holds appropriate accreditation from a CMS deemed accrediting body such as the American Board for Certification in Orthotics, Prosthetics and Pedorthics (ABC), the Board of Certification/Accreditation (BOC), or another authority that is "essentially equivalent." Only these entities are permitted to furnish custom-fabricated orthoses to Medicare beneficiaries. The statute makes no reference to "an individual who has specialized training" as someone who is able to provide custom fabricated orthoses to Medicare beneficiaries. The proposed rule, which claims to only address OTS orthoses, effectively regulates all orthoses as it goes beyond what an OTS orthosis is and also defines what it is not, therefore impacting most of the orthoses provided to Medicare beneficiaries while disregarding the statutory language contained in section 427 of BIPA, which clearly defines who may provide custom-fabricated orthotics and prosthetics. AOPA believes that CMS is exceeding its authority in this proposed rule by issuing regulations that are in direct conflict with statutory language included in section 427 of BIPA.

Concurrent with the release of this CMS proposed rule, AOPA learned that CMS's HCPCS Coding Workgroup is unilaterally increasing the number of dual codes from 23 to 25. It has done so by end-running the appropriate notice and comment process and has afforded no opportunity for stakeholder input. As a result, two new "K" codes have suddenly materialized effective October 1, 2014, according to a report in the most recent HCPCS quarterly update:

K0901	Ko single upright pre ots	Knee orthosis (KO), single upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf	Add
K0902	Ko double upright pre ots	Knee orthosis (KO), double upright, thigh and calf, with adjustable flexion and extension joint (unicentric or polycentric), medial-lateral and rotation control, with or without varus/valgus adjustment, prefabricated, off-the-shelf	Add

These represent OTS versions of existing codes L1843 and L1845, respectively. Products described by these codes are specifically designed to “unload” the knee compartment and relieve pain in patients with osteoarthritis through the application of force/counterforce applied through the combination of specialized joints and straps. The release of these two new “K” codes to describe off the shelf versions of products described by L1843 and L1845 appear to be a complete reversal, within less than 12 months, of CMS’ previous position on these very same orthoses. 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. This orthosis must be provided as a custom fitted device and therefore must be modified by an individual with expertise in order to meet the requirements to meet this HCPCS code.” By releasing these two new “K” codes, CMS appears to be acting in direct conflict with its previous acknowledgement that products described by L1843 and L1845 should never be provided in an OTS environment.

These are knee orthoses that virtually any legitimate caregiver—including physicians, therapists or certified/licensed orthotists—would maintain should **never** be delivered in an OTS environment. They must be **fit and adjusted to precise specifications by a trained individual in order to achieve the desired clinical effect**. What Medicare patient could really be expected to have the clinical knowledge required to determine how much force must be applied through the combined alignment of the knee joints and adjustment of the specially designed strapping system to properly realign the spatial relationship of the tibia, patella, and femur so as to safely prevent direct contact with each other while maintaining an anatomically stable and functional knee joint?

Delivery of these knee orthoses in an OTS form will result in the potential for further injury and joint deterioration for Medicare beneficiaries who are already compromised as a result of osteoarthritis. No science and no process that has any transparency whatsoever appears to have been offered to support these actions [the non-transparency issues for the alphanumeric process have been top concerns, including a promise from Jonathan Blum to examine and evaluate (sadly, not completed) in a meeting with the O&P Alliance two years or so ago], and yet Medicare beneficiaries are worse off. This also constitutes a prime example on the list of devices where the instructions incorporated into the FDA approved labeling is indecipherable to the typical Medicare beneficiaries—these two new ‘split’ codes do not come anywhere near the statutory minimal self-adjustment definition/threshold.

For these two code additions, AOPA believes CMS is violating the Administrative Procedures Act and the process CMS itself used for the introduction of the initial 23 OTS split/exploded codes, where CMS provided some opportunity for input, albeit a website-based outreach far short of a notice-and-comment rulemaking. If CMS wishes to expand the list of split codes, it needs to initiate a full-notice and comment rulemaking to provide stakeholders the proper opportunity for input as to both the initial 23 split

codes, as well as the even more egregious situation of the ‘surprise’ addition of two additional split/exploded codes.

We urge CMS to correct the serious deficiencies and excesses of its regulatory definition of “minimal self adjustment” and to conform it to the clear and unambiguous words and intent of the statute. CMS must revise this definition to incorporate the plain meaning of the statute, so that minimal self-adjustment references only those orthoses that are actually safely and appropriately adjustable by the user himself or herself.

AOPA Comments Regarding the March 27, 2014 DME MAC Policy Bulletin Regarding OTS orthoses

On March 27, 2014, the four DME MAC contractors published a joint policy bulletin entitled, “Correct Coding - Definitions Used for Off-the-Shelf versus Custom Fitted Prefabricated Orthotics (Braces) - Revised Joint DME MAC Publication.” This policy bulletin 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 bulletin further defined the term substantial modification as, “changes made to achieve an individualized fit of the item that requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements.”

The joint policy bulletin introduced the term “substantial modification” into the definition of OTS orthoses without any opportunity for stakeholder or public input. While AOPA acknowledges that the DME MACs may provide clarification on existing regulation and policy without following the notice and rulemaking process required by the Administrative Procedures Act, this bulletin went far beyond simple clarification. Rather, 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.

Moreover, while the DME MACs published this policy bulletin on March 27, 2014, they retroactively applied its terms to claims with a date of service on or after January 1, 2014, almost 3 months prior to publication. AOPA believes that enforcement of this policy bulletin for dates of service prior to its publication and with no opportunity for stakeholder and public input deprives Medicare suppliers of basic due process rights to which they are entitled and may severely compromise the quality of care Medicare beneficiaries receive.

AOPA Comments Regarding the Recent Update to Appendix C of the DMEPOS Quality Standards

A recent update to Appendix C of the Medicare DMEPOS Quality Standards, dated June 2014, effectively adopts several of the provisions of the proposed rule, which had not even been published as of the June, 2014 release date of the update to the Quality Standards, including the list of specific individuals who are considered to have specialized training necessary to provide custom fitting services for patients with a medical need for orthotics. AOPA believes that 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 because it treats as a foregone conclusion that the notice and comment period will simply “rubber stamp” the CMS draft proposal. AOPA requests that CMS immediately remove this information until such time as it has collected and formally responded to public comment regarding the proposed rule and has issued a final rule as required by the Administrative Procedures Act.

AOPA Comments Regarding the Lack of Scientific Support for Its List of Off The Shelf Orthoses

The process used in developing the OTS list did not meet the requirements of the Administrative Procedures Act (APA), establishing split codes with identical reimbursement that did not recognize the added value of the work of the certified orthotist.

Since the initial CMS release of the list of proposed HCPCS codes that represented off the shelf orthoses, AOPA has repeatedly requested citations from clinical literature that supported the classification of the identified HCPCS codes as appropriate to be delivered in an OTS environment. In AOPA's February 2012 response to the initial list of codes under consideration for classification as OTS, it provided 479 pages of comments, the vast majority of which consisted of clinical literature that supported the need for proper fitting of the products represented by the codes by qualified individuals with proper training in the custom fitting of these devices, and which identified potential risks and harm to patients that would result from failure to attain proper fitting, in accordance with FDA-approved device labeling.

Part of the CMS response to comments on the February, 2012 initial list was the creation of 23 “split” codes that would represent both OTS and custom fit versions of identical products respectively. What CMS failed to do in its response was to comment on or even acknowledge the vast amount of clinical literature that AOPA had provided as part of its comments. CMS offered no clinical reasoning for the creation of the split codes and did not reference a single piece of clinical literature, or scientific support for its decision to justify the OTS delivery of any of the 55 HCPCS codes that were re-classified as part of its final list of OTS orthoses.

AOPA believes that in order to properly implement a regulation that will have significant impact on Medicare beneficiaries, there must be support within the clinical literature before devices represented by specific HCPCS codes can be classified as safe and effective for delivery in an OTS environment. In this case, the clinical literature clearly rebuts CMS' action, demonstrating that providing these devices OTS, with no assurance of proper fitting and adjustment by the trained health professional is detrimental to the health and safety of the very Medicare beneficiaries CMS purports to serve.

Therefore, CMS should recognize that the list of purported OTS devices published by CMS in 2013 (and the related HCPCS coding revisions) is severely misguided, and its potential impact on patient care, were it to advance any farther, would be devastating.

AOPA Comments Regarding the Use of Auxiliary Professionals in the Provision of Custom Fitted Orthoses

AOPA agrees with CMS' position in the proposed rule to include certified orthotists along with physicians among those identified as persons with the expertise needed to provide custom fitted orthoses, but the proposed rule fails to address the role of appropriate auxiliary personnel in delivery of orthoses. More specifically, the rule significantly understates the role of certified orthotic fitters.

AOPA believes that the proposed rule should be modified to recognize some auxiliary personnel – namely those who have been licensed and/or certified to regularly engage and/or assist in the care and treatment of patients with conditions requiring orthotic treatment. AOPA believes that these individuals may provide some components of those services and treatment provided they do so under the supervision of one of the recognized persons with expertise. This would ensure that a certified orthotic fitter, as well as an orthotic assistant could assist in treating patients under the supervision of the certified orthotist, and that a licensed nurse could assist in treating patients under the supervision of the treating physician. Other persons not meeting the definition of a licensed or certified health professional, or not operating under supervision, so defined, would not be authorized to participate in any aspect of patient care other than the provision of off-the-shelf orthotic devices.

Specific to the role of the certified orthotic fitter, section 427 of BIPA established both the American Board for Certification in Orthotics, Prosthetics, and Pedorthics (ABC) and the Board of Certification/Accreditation (BOC) as deemed agencies in the accreditation of orthotic and prosthetic facilities. While, as a result of the provisions of section 427 of BIPA, CMS has also deemed several other organizations as deemed accrediting bodies for purposes of ensuring compliance with DMEPOS quality standards, both of these organizations offer the credential of certified orthotic fitter including detailed scope of practice documents that clearly indicate that certified orthotic fitters, who are properly supervised, possess the educational and clinical knowledge to provide custom fitted orthoses. These scope of practice documents clearly delineate differences between custom fitted orthoses (OR02) and OTS orthoses (OR03) as well as the appropriate level of certification that must be maintained through required training, education, and

professional testing prior to credentialing and mandatory continuing education requirements once the credential is awarded.

The statement in the proposed rule that indicates that certified orthotic fitters do not possess the specialized training for the purpose of providing custom fitted orthoses and therefore orthoses adjusted by these individuals would still be considered OTS appears to be in direct conflict with the ABC and BOC scope of practice documents for certified orthotic fitters and therefore violates the regulatory provisions contained in section 427 of BIPA. BIPA 427 recognized that accrediting bodies set the standard for practice. CMS is now, contrary to that statute, abrogating to itself that authority to set standards as to fitters, trumping both the accrediting organizations and state licensure authority. These regulations therefore violate BIPA Section 427. Limiting the role of certified orthotic fitters to only the provision of OTS orthoses effectively restricts an entire category of certified professionals to the provision of devices that, by statute, require no fitting at all other than adjustments that can be made by the beneficiary themselves.

AOPA believes that certified orthotic fitters who are operating under the specific supervision requirements of CMS deemed accrediting agencies should be allowed to provide services that are clearly included within their established scope of practice. Limiting certified orthotic fitters to the provision of OTS orthoses only eliminates their effectiveness as a certified health care provider since, by statutory definition, OTS orthoses only require minimal self adjustment.

While the proposed rule discusses the fact that not all of the 17 states that currently require licensure in O&P either recognize and/or license orthotic fitters, the failure of CMS to comply with existing statutes in states that do offer licensure as an orthotic fitter is a violation of the Constitution as well as existing federal preemption statutes and case law.

In summary, AOPA strongly supports the following clear criteria for both personnel and conditions that may (or may not) appropriately participate in provision of custom fitted orthoses to Medicare beneficiaries, as stated in the following excerpt of the comments on this proposed rulemaking by the Orthotic & Prosthetic Alliance.

“As noted above, CMS’s proposed rule precludes most unlicensed/non-certified personnel on the office staff in physician practices, therapy offices or orthotic facilities from fitting and adjusting prefabricated/custom-fitted orthoses for Medicare beneficiaries. The O&P Alliance agrees that the unlicensed/non-certified, non-clinical staff and persons who are in the health professional’s practice should not be permitted to provide such services.

Unless the state’s licensure statute provides otherwise, those licensed or certified healthcare professionals who regularly engage and/or assist in the care and treatment of patients with conditions requiring orthotic treatment (including certified orthotic fitters) that truly act under the supervision of a physician (or other individual who has specialized training*) should be

permitted to continue providing such services with respect to custom-fitted orthoses.”

* Defined as a physician, treating practitioner, occupational therapist, physical therapist, or certified orthotist operating in compliance with all applicable federal and state licensure and regulatory requirements.

AOPA Comments Regarding the Cost Effectiveness of Providing OTS Orthoses When the Patient Requires a Custom Fitted or Custom Fabricated Orthosis

AOPA fully supports the need to protect the Medicare funds and maintain cost effectiveness through proper orthotic care, including the provision of an OTS device when it meets the medical needs of the Medicare beneficiary. Recent data analysis by Dobson DaVanzo & Associates, LLC, summarized in the table below, provides very useful information regarding Medicare beneficiaries that initially receive an orthosis classified as OTS who ultimately require either a custom fitted or custom fabricated orthosis to meet their complex medical needs.

Distribution of OTS Patients who Subsequently Received Custom Fabricated or Fitted Orthotics (2008)

Type	Total Patients	Received OTS as First Orthotic Device		Subsequently Received Custom Fitted/Fabricated Device	
		Patients	Percent of Total Patients	Patients	Percent of OTS Patients
TLSOs	20,408	1,519	7.4%	163	10.7%
LSOs	197,906	19,917	10.1%	3,372	16.9%
AFOs	268,232	56,959	21.2%	11,359	19.9%
Total	486,546	78,395	16.1%	14,894	19.0%

Source: Dobson-DaVanzo analysis of custom cohort Standard Analytic Files (2007-2010) for Medicare beneficiaries who received O&P services from January 1, 2008 through December 31, 2008.

Medicare’s own data shows that frequently patients who receive a Medicare-reimbursed OTS device subsequently also receive a Medicare-reimbursed custom-fitted or custom-fabricated orthotic device. Medicare’s own data on Medicare patients who received various off-the-shelf orthotics shows that roughly 19% of these patients, after receiving a Medicare-reimbursed OTS device subsequently also receive a Medicare-reimbursed custom-fitted or custom-fabricated orthosis. Clearly, some modest portion of these data reflect instances in which OTS devices are fitted out of necessity in the acute or emergency setting and occasionally with the knowledge that a custom device will be required further down the road. There are also instances with progressive disorders where an OTS device may be sufficient for a period of time before their condition warrants a custom device. Clinical experience indicates that such instances could account for a relatively small portion of the 19%. But it also appears likely that there is a very significant percentage of cases where OTS devices do not fully or appropriately meet the patients’ needs. These data reflect historical experience in 2008, and now,

with CMS' efforts to expand the statutory definition of "Off-the-Shelf/Minimal Self-Adjustment" we would intuitively anticipate that the segment where these patients subsequently need a Medicare-reimbursed custom-fitted or custom-fabricated device would increase even higher, resulting in added government cost and poorer beneficiary patient care. It appears that delivering substantial numbers of OTS devices without any accompanying adjustment and clinical care may **not** result in patients getting better, but results, at least in a substantial number of instances, in wasted Medicare funds on that OTS device AND a delay in the patient receiving any improvement in their symptoms/health. Additionally, providers may be less likely to face the reimbursement challenges of providing a custom fitted or fabricated orthosis rather than an OTS orthosis even if they do not believe an OTS orthosis will properly address the patient's medical needs. In this unfortunate reality, both the patient and the Medicare program will be negatively impacted as a result of increased patient co-payments and additional expenses to the Medicare program, and a disregard for patient health for Medicare beneficiaries as a result of CMS mandating that devices be provided to patients without professional adjustment and fitting, contrary to the premises for FDA-approved labeling..

Summary of AOPA Comments

AOPA believes that significant changes to the provisions of the proposed rule that address the definition of minimal self adjustment as it relates to the provision of OTS and custom fitted orthoses must occur, in order to remain consistent with maintaining high quality orthotic care, and to avoid CMS introducing new, potentially very substantial risks of health impairment to Medicare beneficiaries. While we commend CMS for those aspects dealing with recognition of certified orthotists as providers with expertise authorized for customized orthotic care, and its recognition of accreditation under Section 427 of BIPA 2000, if this proposed rule were to advance in its current form, it would essentially harm all stakeholders—including orthotists, other care providers, and most importantly, Medicare beneficiaries.

Thank you for the opportunity to provide AOPA's comments.

Sincerely,



Thomas F. Fise
Executive Director