December 17, 2018

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Public Comments on New Product Categories to be Phased-In for the Next Round of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program

Submitted Electronically at DMEPOS@cms.hhs.gov.

Dear Administrator Verma,

On behalf of the 1,500 members of the American Alliance of Orthopaedic Executives (AAOE), the 15,000 physicians they serve, the 70,000 people they employ, and the state and associated societies that have agreed to sign on to this letter, we are pleased to provide comments on the Centers for Medicare and Medicaid Services’ (CMS) proposal to add off-the-shelf back and knee braces to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program.

Our comments will focus on the proposal to move HCPCS codes L0450, L0455, L0457, L0467, L0469, L0621, L0623, L0625, L0628, L0641, L0642, L0643, L0648, L0649, L0650, L0651, L1812, L1830, L1833, L1836, L1848, L1850, L1851, and L1852 to the Medicare DMEPOS Competitive Bidding Program. In short, we believe a policy change like this would be a mistake for the following reasons:

- CMS has not provided adequate information on the proposal;
- There is still much debate surrounding CMS’ definition of off-the-shelf and its expansion of the definition of “minimal self-adjustment” versus the statutory definition;
- The proposal rewards larger suppliers with greater economies of scale and penalizes smaller entities;
- This policy shift is unlikely to remove fraud and abuse from the Medicare program;
- The proposal could lead to a “race to the bottom” for quality of the devices in question; and,
- The proposal threatens to deviate from coordinated, streamlined patient care to a disjointed care delivery system that undermines patient care.

Our comments will address each of these concerns and we hope they are persuasive enough to engage CMS in further discussions on this proposal.

The Current Proposal
On November 5, 2018, the Centers for Medicare and Medicaid Services (CMS) under your leadership, silently\(^1\) released a proposal to move HCPCS codes L0450, L0455, L0457, L0467, L0469, L0621, L0623, L0625, L0628, L0641, L0642, L0643, L0648, L0649, L0650, L0651, L1812, L1830, L1833, L1836, L1848, L1850, L1851, and L1852 to the Medicare DMEPOS Competitive Bidding Program. The Competitive Bidding Program, as you know, was established by statute in 2003 with modifications to the program in 2008. The first round of competitive bidding started in 2011 and saw Medicare reimbursements for durable medical equipment decrease an average of 35% in competitive bidding areas.\(^2\)

The current proposal would add certain off-the-shelf knee and back orthotics to the DMEPOS Competitive Bidding Program when the program resumes (likely December 2020). We have found writing our comments on this to be difficult to say the least. CMS has provided a minimum of information about the proposal. Currently, walkers, folding wheelchairs, and canes are included in the Competitive Bidding Program however, physicians may provide them to their patients outside of the Competitive Bidding Program. CMS’ proposal mentions nothing about this same exception being extended under this proposal. This is a large oversight as its exclusion forces us to oppose this proposal to the letter.

When proposing a policy shift like this, CMS must understand that not only is the care of millions of Medicare beneficiaries put at risk but so are the livelihoods of thousands of Medicare providers, suppliers, and support staff. These people deserve more than a four sentence proposal and list of HCPCS codes. They deserve the full publication of the proposal in the *Federal Register* with a preamble and regulatory text to allow them to understand how this proposal will impact their care, business, and jobs. While this policy shift may not seem economically significant (and thus not require 12866 review), this shift will be significant to the solo orthopaedic surgeon in Kansas City, Missouri who relies on appropriately prescribed off-the-shelf knee and back orthotics sales for ancillary revenue in order to compete with larger practices and health systems. For some practices, particularly small practices, the ancillary revenue generated by patients purchasing their prescribed orthotics from the practice could be the difference between independence and further consolidation of the provider marketplace which threatens to further decimate provider competition.

**The Definition of Off-the-Shelf Orthoses**

CMS has struggled for years to define off-the-shelf, custom fitted, and custom fabricated orthoses and we encourage CMS to complete these definitions before making this policy switch. We believe a lack of a “bright-line” definition will cause further confusion among our members and the Medicare beneficiaries they serve and potentially raise the specter of inadvertent and intentional fraud.

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\(^1\) We are unable to find any communication on the opening of a public comment period on this proposal. If, after our review of CMS’ communications channels, we have incorrectly stated that CMS did not disclose the existence of a public comment period, we would appreciate information on how the public was notified of the existence of a comment period.

In 2014, CMS proposed to expand the definition of “minimal self-adjustment” in the definition of off-the-shelf orthotics to differ from the statutory definition. Section 1847(a)(2)(C) of the Social Security Act defines off-the-shelf orthotics as:

Orthotics described in section 1861(s)(9) for which payment would otherwise be made under section 1834(h) 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’ definition of “minimal self-adjustment” as articulated at 42 CFR 414.402 expands the definition of “minimal self-adjustment” to:

... 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.

Thus, CMS’ revised definition of “minimal self-adjustment” removes the determinant of when a product is considered “off-the-shelf” from self-adjustment by the beneficiary to adjustment by someone who does not have “specialized training” for the adjustment of orthotics. Had this been the intent of Congress in creating the original law, the statute would say so. CMS’ further tinkering with the definition and creation of parallel “custom fit” codes has led to significant confusion among our billers and coders. The new definition also forces physicians to “down-code” the HCPCS code based solely on who fit the brace. This in turns limits CMS’ data validity and undervalues the work of our highly skilled support staff who fit the orthotics.

If CMS does not adequately define off-the-shelf orthotics in-line with the statutory meaning of the phrase, we expect to see further confusion surrounding what constitutes off-the-shelf and custom fit when/if this proposal is finalized. We would additionally expect to see a handful of providers attempt to massage the definition of custom fit to continue to provide off-the-shelf orthotics at their practices but avoid the steep cuts to reimbursement (and potential quality issues) that competitive bidding is likely to bring. This will, in-turn, increase Medicare’s enforcement costs.

Of the 24 off-the-shelf back and knee braces identified in the proposal for movement to the Competitive Bidding Program, 16 have corresponding custom fit codes. This means that a majority of the codes proposed for movement to the Competitive Bidding Program are at significant risk of being misused if definitions are not streamlined and the definitions of custom fit and off-the-shelf orthotics are not provided a “bright-line” separation. We propose that this “bright-line” separation can be accomplished by going back to the statutory language where off-the-shelf orthotics are orthotics that require minimal self-adjustment (meaning the beneficiary or their caretaker can adjust the orthosis) and custom-fit orthotics are orthotics that must be fit by a medical professional.

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3 Emphasis added.
4 Emphasis added.
Off-the-Shelf Orthotics in the Clinical Setting

Off-the-shelf back and knee orthotics are provided to patients in an orthopaedic office based on medical necessity as required by Medicare payment policy. These tools are used by our physicians for many reasons but they are particularly necessary for patients who have undergone invasive surgery and need assistance supporting a portion of the body or suffered a ligament injury with instability. They may be used in conjunction with physical therapy to return a patient to functional status or they may be used until the patient is well enough for the next stage of their recovery.

These braces are particularly helpful in the treatment of compression fractures. The orthotics to treat these fractures are best fit in the office at the time of diagnosis rather than sending a newly diagnosed fracture patient to an additional location to be fit for a brace. Additionally, some physicians require X-rays on the patient following application of a brace for compression fractures; we are, at present, unaware of any DME-only suppliers that are capable of providing X-rays to patients meaning that these patients would then have to travel back to the prescribing physician for an X-ray to confirm brace placement. This would be an onerous and needless exercise in patient shuffling when all of the patient’s needs at present (diagnosis, treatment, and review) are being taken care of in one location.

Our physicians may also use these tools to mitigate the need for surgery altogether. In a survey of AAOE members conducted in November 2018, 87% of respondents indicated that their physicians initially prescribe off-the-shelf knee and back braces to avoid an invasive surgery entirely or until the patient has reduced any comorbidities that may be associated with adverse outcomes.

While discussing the use of off-the-shelf orthotics in our practices, we believe it would be helpful to you to explain how a move like this will likely impact Medicare’s march towards value-based reimbursement. Many of our member practices are participating in some form of value-based care redesign, whether that is one of the Center for Medicare and Medicaid Innovation (CMMI) models or the Merit-based Incentive Payment System (MIPS). These models require physicians to lower the costs of care in order to achieve shared savings or incentive payments from the Medicare program. Many of our physicians have enthusiastically embraced the potential to redesign care in a manner that improves the quality of care provided to our patients while sharing in the savings of an episode of care.

This policy threatens to undermine the advances that we have made in reducing the total cost of care for patients needing to utilize orthotics as part of their care plan. Under the current policy, with fitting in a physician’s office, the continuity of care is maintained and a patient is more likely to sit for a fitting and utilize the orthotic for its intended purpose. Maintaining the continuity of care is important in preventing poor healing, readmissions, and other complications that may come from not utilizing the orthotic. If this proposal is finalized and continuity of care is broken (meaning that patients have to leave the practice and travel to an off-site supplier) we can expect to see fewer patients complying with the care plan and a likely increase in the total cost of care for episodes in which an orthotic is needed. It is likely that we would also see an increase in overall clinical episodes as patients forego the conservative treatment and require more invasive surgeries when a properly fitted and worn orthotic could have prevented or delayed the higher cost episode.
We encourage CMS to maintain the ability of physicians to continue to provide off-the-shelf orthotics to their patients separate from the competitive bidding program with reimbursement tied to the DMEPOS fee schedule. Continuing the current policy will continue to benefit the goals of CMS in moving from volume to value while a change threatens to undermine the entire experiment in value-based care.

**Fraud and Abuse**

We refer you to the Medicare Payment Advisory Commission’s (MedPAC) June 2018 review of DMEPOS payment policy for this discussion of fraud and abuse in the Medicare program. While there are some areas of the MedPAC report we agree with, we disagree with MedPAC’s contention that increasing expenditures on orthotics leads to fraud and abuse. Instead, we believe that CMS must first address the root causes of fraud and abuse in prescribing and distributing off-the-shelf orthotics. Specifically, CMS must address the parallel coding for off-the-shelf and custom fit orthotics created in 2014 and payment policies that encourage the prescribing and distribution of orthotics for financial gain.

MedPAC specifically identifies CMS’ 2014 decision to split orthotic HCPCS codes as a driver of the increased utilization of off-the-shelf orthotics versus custom fit orthotics. As we mentioned in other areas of this letter, we believe that maintaining the parallel coding system and implementing CMS’ proposal is likely to reverse the course and see some suppliers (and bad-actor clinicians) attempt to pass off an off-the-shelf orthotic as custom fit in order to continue business as usual.

Also in this report, MedPAC highlights a troubling trend of a small handful of bad actors engaging in potential fraud and abuse of Medicare’s DME payment policies and exploiting the technological gains our industry has made in delivering remote care to patients who need it. If this behavior is indeed fraudulent and/or abusive, these bad actors should be punished to the fullest extent that federal statutes permit however, we are hesitant that addition of these codes to the Competitive Bidding Program would prevent fraudulent behavior. We support MedPAC’s recommendation that Medicare require a face-to-face visit between the beneficiary and physician or other clinician ordering the orthotic provided exceptions may be made for beneficiaries that are homebound and/or located in rural areas. We believe this change is likely to lower the potential for fraud and may prevent inappropriate utilization.

We should also note that value-based reimbursements under various CMMI models and the MIPS program have the potential to chip away at what perverse incentives may be present in the Medicare program to overutilize and/or fraudulently bill for off-the-shelf orthotics. With physician payment being increasingly tied to value-based care arrangements, the more services provided, the higher the cost of care and thus, the less in shared savings or incentive payments the physician will receive. These arrangements have injected self-regulation into the market and we believe that to further burden clinicians with this proposal would be a mistake and not the market-oriented solution the situation calls for.

Despite our disagreements with MedPAC’s overall analysis, we were heartened to see in the MedPAC report that the Commission found that:

... physicians, hospitals, physical therapists, and orthotists furnished a minority of the off-the-shelf back brace product we studied and are not driving the increase in utilization and
expenditures for such products. Therefore, for the back braces we examined, exempting such providers would likely increase continuity of care without substantially affecting the operation of the CBP.\(^5\)

However, CMS did not propose to create an exception for physicians and other clinicians in its proposal. As we have mentioned previously, because of the lack of information regarding implementation, we are unable to support this proposed policy and encourage CMS to address the root causes of increased expenditures for off-the-shelf orthotics namely, the parallel coding for off-the-shelf and custom fit orthotics and payment policies that encourage the prescribing and distribution of orthotics for financial gain. Once these root causes are addressed, CMS can revisit the need to include these codes in the Competitive Bidding Program through standard notice and comment rulemaking.

Quality of Devices

Currently, there is significant diversity of quality in the field of off-the-shelf orthotics. We are concerned that should CMS finalize this policy, it will inadvertently be creating a “race to the bottom” as low quality manufacturers outbid higher quality manufacturers. Beneficiaries would then be subjected to treatment with orthotics that have little to no clinical value and Medicare and the beneficiary would be stuck with the bill.

In the event this “race to the bottom” becomes our new reality, many physicians would then turn to the non-competitively bid custom fit orthotics and/or the more expensive custom made orthotics to provide the best support. Both of these outcomes are likely to increase total costs to both Medicare and the beneficiary and are likely to result in lower patient adherence with care plans which in turn will further raise the costs of care.

Proposal Timeline

We thank CMS for extending the timeline for comments on this proposal to be submitted but reiterate that we do not believe enough time for substantive comment was provided. CMS posted this proposal on the CMS website on November 5 and set a comment deadline for only 18 business days from the proposal date. The 18 day time period is unacceptable to say the least but when paired with the lack of notification to stakeholders through MLN Connects or some other Medicare communication device, it borders on outrageous.

Opaque public policy is counter to what we believe as Americans. We encourage future policy changes to be submitted via normal notice and comment rulemaking processes and not simply placed on a remote section of the CMS website. While we are appreciative of the extension of the comment period, we continue to encourage CMS to extend the comment period deadline to February 5, 2019.

We appreciate the opportunity to provide comments on this proposal and look forward to hearing that our concerns have been addressed. Should you have any questions, please do not hesitate to contact AAOE’s manager of government affairs, Bradley Coffey, MA at bcoffey@aaoe.net or 317-749-0629.

Thank you,

Karen Sollar, CMPE
2018-2019 President
American Alliance of Orthopaedic Executives

CC: Addy M. Kujawa, CAE, Chief Executive Officer, AAOE
Kitchi Joyce, 2018-2019 President-Elect, AAOE

This letter has received sign-on from the following associated societies:

BONES Society of Florida
BONES of PA, Inc.
Georgia Association of Orthopaedic Executives
Midwest AAOE
South Carolina Association of Orthopaedic Executives
Texas Orthopedic Administrators Society (T-BONES)
The OrthoForum