



AMERICAN ACADEMY OF
ORTHOPAEDIC SURGEONS

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December 17, 2018

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

Submitted electronically via DMEPOS@cms.hhs.gov.

Subject: 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.

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we are pleased to provide comments for 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.

We appreciate that CMS is soliciting comments on the expansion of the DMEPOS Program to include back and knee braces, items of great importance to support the care we provide to our patients with musculoskeletal needs. We are, however, deeply concerned about the manner and time frame in which CMS is submitting new codes and products for public comment.

CMS did not announce the expanded DMEPOS bidding categories in the *Federal Register*, but rather posted the announcement on a CMS site that is not routinely monitored by physicians. In addition, CMS is posting a relatively short public comment period of what amounts to only 30 business days. This unusual rulemaking process deprives us of the opportunity to fully research the ramifications of the new proposal and sets a dangerous precedent of depriving CMS of stakeholder input to guide the finalization of this new DMEPOS policy.

The current proposal would add certain off-the-shelf knee and back orthotics to the DMEPOS Competitive Bidding Program when the program resumes in 2020. Currently walkers, folding wheelchairs and canes are included in the Competitive Bidding Program, but physicians may

provide these items to patients outside of the Competitive Bidding Program. The latest CMS proposal mentions nothing about this exception being extended to back and knee braces. AAOS would like to believe this was simply an oversight on the part of CMS, and we urge CMS to continue the policy of allowing physicians to provide patients with these important assistive devices without being required to go through the Competitive Bidding Program.

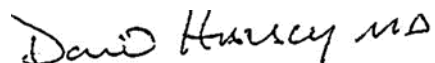
AAOS also encourages CMS to take this opportunity to clarify the definitions of off-the-shelf, custom fitted and custom fabricated orthoses. The current CMS definition of “minimal self-adjustment” removes the determinant of when a product is considered “off-the-shelf” from self-adjustment by the beneficiary to adjustment by someone who does not have “specialized training” for the adjustment of orthotics. The CMS decision to alter the original statutory definition and create parallel “custom fit “codes has led to significant confusion among billers and coders.

We expect to see continued confusion surrounding what constitutes off-the-shelf and custom fit when the new DMEPOS proposal is finalized. Sixteen of the twenty-four “off-the-shelf” back and knee braces identified for inclusion under the Competitive Bidding program have corresponding custom fit codes. This means that most of the codes being proposed are at risk of being misused if definitions are not updated. We urge CMS to adopt the original statutory language where off-the-shelf orthotics are orthotics that require minimal self-adjustment and custom-fit orthotics are orthotics that must be fit by a medical professional.

In discussions held with our members about the new products and codes being added to the DMEPOS program, we are hearing concerns that the proposal may lead to restricting patient access to off-the-shelf medical equipment, reductions in the coordination of care and services provided by our physicians and DME suppliers, and potential pricing disruptions. Again, an extension of the public comment period time will allow us to more fully research these concerns.

Thank you for your time and consideration of the American Association of Orthopaedic Surgeons’ suggestions. If you have any questions regarding our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,



David A. Halsey, MD
President, AAOS

Cc: Kristy L. Weber, MD, First Vice-President, AAOS
Joseph A. Bosco, III, Second Vice-President, AAOS
Thomas E. Arend, Jr., Esq., CAE, CEO, AAOS
William O. Shaffer, MD, Medical Director, AAOS

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

American Orthopaedic Foot and Ankle Society (AOFAS)
American Orthopaedic Society for Sports Medicine (AOSSM)
American Shoulder and Elbow Surgeons (ASES)
American Society for Surgery of the Hand (ASSH)
Cervical Spine Research Society (CSRS)
Limb Lengthening and Reconstruction Society (LLRS)
Orthopaedic Trauma Association (OTA)
Pediatric Orthopaedic Society of North America (POSNA)
Scoliosis Research Society (SRS)