VIA ELECTRONIC SUBMISSION VIA DMEPOS@CMS.HHS.GOV

December 17, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments on Competitive Bidding of Off-the-Shelf Orthoses and Ventilators

Dear Administrator Verma:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition Steering Committee appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS's") new product categories, including the corresponding Healthcare Common Procedure Coding System ("HCPCS") codes, that are proposed to be phased-in under all competitive bidding areas in the next round of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program ("CBP").[1] Given the importance of the DMEPOS CBP, we also appreciate the extension of the public comment period to December 17, 2018.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. On behalf of our members who represent individuals with a wide range of disabling conditions, as well as the providers who serve them, we wish to express our concerns regarding the proposed inclusion of what CMS refers to as "off-the-shelf" ("OTS") spinal and knee orthoses (L0450, L0455, L0457, L0467, L0469, L0621, L0623, L0625, L0628, L0641, L0642, L0643, L0648, L0649, L0650, L0651, L1812, L1830, L1833, L1836, L1848, L1850, L1851, L1852) as well as ventilators (E0465, E0466, E0467) in the next round of DMEPOS CBP.

The ITEM Coalition has had a long-standing concern that the DMEPOS CBP limits access, choice, and quality of care, and we have seen the negative implications of this program in the area of complex rehab technology (CRT). We believe that CMS's proposal to expand competitive bidding to certain orthoses and ventilators will similarly jeopardize Medicare beneficiaries' ability to receive care that best meets their unique medical and functional needs. Therefore, we respectfully request that CMS exclude all orthoses that are not truly "off-the-shelf" as well as ventilator codes from the next round of the DMEPOS CBP. If CMS proceeds with its proposal in this area, we respectfully request that CMS establish certain safeguards in the

[1] CMS, *Public Comments on New Product Categories*, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Comment-Period.html (last modified Nov. 27, 2018).

DMEPOS CBP to help ensure that beneficiaries continue to have access to the most appropriate, high-quality care.

I. CMS Should Exclude Orthoses that Are Not Truly OTS from the DMEPOS CBP and Should Ensure that Certain Safeguards Are in Place

We believe that most of the orthotic codes listed by CMS do not truly describe OTS orthoses that can be used safely by the patient with "minimal self-adjustment," the standard established in the Medicare statute to define which orthoses are considered off-the-shelf. In authorizing competitive bidding, Congress intentionally limited the scope of competitive bidding to OTS 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."[2] Congress explicitly exempted custom-fitted and custom-fabricated orthoses from competitive acquisition and all limb prostheses because of the clinical, service-oriented, and customized nature of most orthoses and prostheses. Congress recognized that the quality of care would be materially impacted if competitive bidding applied to such a clinically-oriented and customized service.

However, CMS subsequently regulated the meaning of the term "minimal self-adjustment" and, contrary to our recommendations and Congressional intent, expanded the scope of orthoses subject to competitive bidding by writing the word, "self," out of minimal self-adjustment. The regulation defined minimal self-adjustment to mean, "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 . . . or an individual who has specialized training."[3] Now, CMS is proposing to expand the DMEPOS CBP to orthoses that fall outside of Congress's definition of OTS orthoses subject to competitive bidding.

Of the twenty-four knee and spinal orthotic HCPCS codes proposed to be included in the next round of the DMEPOS CBP, the clinical orthotic organizations believe that only two codes (L0621 and L1830) fall within Congress's definition of OTS orthoses that should be subject to competitive bidding. The remaining twenty-two HCPCS codes, require clinical expertise to properly fit and customize these orthoses to the patient.

Competitively bidding these twenty-two HCPCS codes would compromise the quality of patient care because unlicensed/non-certified/non-accredited suppliers will be able to "drop ship" to patients' homes what Medicare perceives as OTS orthotics which, in reality, are custom-fitted orthoses requiring clinical and professional involvement to meet the broad spectrum of individual patient needs. The ITEM Coalition is concerned that CMS's proposal will result in patients receiving orthoses in a box with no services from a physician, clinician or orthotist to appropriately fit the orthosis to meet patients' therapeutic needs. This will result in poor patient outcomes, possible injury to the patient, and Medicare waste and abuse.

Furthermore, we are concerned that competitively bidding these orthoses will lead to widespread patient confusion. Unlike other DMEPOS items that are primarily furnished by DME suppliers, OTS orthoses are furnished by a wide variety of providers, including physicians, therapists, orthotists, orthotic fitters, orthotic manufacturers and suppliers, and others. If these orthoses are

[2] 42 U.S.C. § 1395w-3(a)(2)(C).
[3] 42 C.F.R. § 414.402.

subject to competitive bidding, patients will be forced to navigate and understand the bureaucratic DMEPOS CPB scheme to determine who may provide the most appropriate orthosis. We believe this will lead to serious confusion in the beneficiary population, a lack of access to appropriate care, and Medicare waste and abuse.

Because of this confusion, if CMS proceeds with competitive bidding of the proposed orthotic codes, we urge CMS to exempt orthotists from the DMEPOS CBP, just as physicians and other health professionals are expected to be exempt. This would allow patients to obtain orthoses from an orthotist who does not have a DEMPOS CBP contract. This would be particularly efficient when one patient has a need for a custom-fabricated orthosis on one part of his or her body and a need for an OTS orthosis on another. Orthotists have made a substantial commitment to the profession of orthotics, as reflected by the completion of the rigorous requirements for education, training, clinical residency, national testing, state licensure and the certification and accreditation processes. We believe that CMS should recognize orthotists in the same manner they recognize physicians and other professionals who treat the orthotic needs of Medicare beneficiaries by exempting orthotists from the DMEPOS CBP.

II. CMS Should Exclude Ventilators from the DMEPOS CBP

The ITEM Coalition strongly opposes CMS's proposal to include ventilators in the DMEPOS CBP. Ventilators are life support systems that are essential to the patients who use them. In most cases, ventilators replace or support normal ventilator lung function to achieve medical stability or even to maintain life. As such, the patients who use ventilators are often frail and require intensive management from trained clinicians, including respiratory therapists, in the home. Introducing ventilators to the DMEPOS CBP would increase medical risks for patients, as competitive bid pricing could impact the availability of quality devices, and subject vulnerable patients' medical stability to a program designed to cut costs with limited regard for quality.

Additionally, if a limited number of providers receive contracts through the DMEPOS CBP, patients may be at further risk as fewer providers may be available in service areas in which they reside, limiting access to these important devices and services. The risks to patient safety and well-being should strongly impact CMS's decision making, especially for life-sustaining medical devices such as ventilators. We strongly urge CMS to reconsider its inclusion of ventilator codes in DMEPOS CBP.

If you have any questions, please contact the ITEM Coalition coordinators, Peter Thomas, at Peter.Thomas@powerslaw.com or Leif Brierley at Leif.Brierley@powerslaw.com, or call 202-466-6550.

Sincerely,

ITEM Coalition Steering Committee Members
Amputee Coalition
Christopher and Dana Reeve Foundation
National Multiple Sclerosis Society
Paralyzed Veterans of America
United Spinal Association