June 19, 2019

VIA ELECTRONIC SUBMISSION

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Ensuring Patient Access to Non-Invasive Ventilators

Dear Administrator Verma:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition write to express our concerns regarding the Centers for Medicare and Medicaid Services' ("CMS's") decision to include non-invasive ventilators with Healthcare Common Procedure Coding System ("HCPCS") code E0466 (Home Ventilator, Any Type, Used With Non-Invasive Interface, (E.G., Mask, Chest Shell)) in the next round of the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program ("CBP").

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. Our members represent individuals with a wide range of disabling conditions, as well as the clinicians and providers who serve them, including such conditions as multiple sclerosis, paralysis, hearing and speech impairments, cerebral palsy, visual impairments, spinal cord injuries, brain injury, stroke, spina bifida, myositis, limb loss, Osteogenesis Imperfecta, and other life-altering conditions.

As a coalition comprised largely of consumer organizations, many of which represent individuals with debilitating neuromuscular conditions (such as amyotrophic lateral sclerosis (ALS)), spinal cord injury, thoracic restrictive disorder, quadriplegia, chronic obstructive pulmonary disease ("COPD"), and other serious medical conditions, we are concerned that including non-invasive ventilators in the DMEPOS CBP may limit access to this life-saving and life-sustaining care, including the devices and corresponding clinical services. To our knowledge, this is the first time CMS has included in the CBP an item defined as requiring "frequent and substantial servicing." We fear that expanding the DMEPOS CBP to encompass non-invasive ventilators may result in a disruption in service and negatively impact quality of care. Accordingly, the ITEM Coalition strongly urges CMS to reconsider its inclusion of non-invasive ventilators with HCPCS code E0466 in DMEPOS CBP.

Non-invasive ventilators are life support systems that are essential to the patients who use them. In most cases, non-invasive ventilators support normal ventilator lung function to achieve medical stability and reduce the likelihood of declined health leading to respiratory failure, a condition that is immediately life-threatening. Ventilators must be maintained and adjusted as the needs of the patient changes. The individuals who use non-invasive ventilators are often frail and require intensive management from trained clinicians, including respiratory therapists, in the home. These clinicians ensure that the non-invasive ventilator is appropriately calibrated to provide safe and effective care. Reliable access to appropriate ventilators and corresponding services is a critical component of care and allows the patient to remain at home instead of an institutional setting—a goal of many patients who need non-invasive ventilators as well as the Medicare program itself.

Exposing non-invasive 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 rather than ensure quality. CMS's decision sets an alarming precedent by forcing patients to rely upon the lowest DME bidder to receive life-saving ventilators and associated services in the home. If a limited number of suppliers receive contracts through the DMEPOS CBP, patients may be at further risk as fewer suppliers will be available in service areas in which they reside, limiting access to these important devices and related clinical services. DME suppliers curtailed their participation in Medicare under previous rounds of Medicare competitive bidding and we see no reason not to believe they will do the same thing in the future.

The risks to patient safety and well-being should strongly impact CMS's decision making, especially for life-sustaining medical devices such as non-invasive ventilators. The cost of care should not be the driving factor for selecting suppliers of non-invasive ventilators. In fact, we question whether competitive bidding would result in lower costs to the Medicare program. If patients are unable to access high-quality ventilators and clinical support, they may be forced to turn to more costly institutional settings—such as hospitals, skilled nursing facilities, and long-term care facilities—to receive the care they need. This would undoubtedly come at a higher cost to the Medicare program and diminish the patients' quality of life.

Competitive bidding is particularly unwarranted in the context of ventilators. Congress recognized the unique nature of ventilators by classifying these devices as items requiring "frequent and substantial servicing in order to avoid risk to the patient's health." 42 U.S.C. § 1395m(a)(3)(A); *also see* 42 C.F.R. § 414.222(a)(1). Accordingly, ventilators are not subject to the default payment rules for DME; Medicare rental payments for ventilators are made on a monthly basis. 42 U.S.C. § 1395m(a)(3)(A); 42 C.F.R. § 414.222(b). The distinct classification of ventilators for Medicare payment purposes provides further rationale for why ventilators should be exempt from competitive bidding.

Moreover, including non-invasive ventilators in the DMEPOS CBP also has unintended consequences for Medicaid recipients—particularly children with serious chronic conditions—who use ventilators. Medicaid caps reimbursement for DME at equivalent Medicare payment rates, thereby placing access to care at risk for this vulnerable population.

We believe that CMS's expansion of competitive bidding to include non-invasive ventilators will jeopardize patients' ability to receive care that best meets their unique medical and functional

needs. Therefore, we respectfully request that CMS exclude non-invasive ventilators from the next round of the DMEPOS CBP.

We greatly appreciate your attention to this important issue. Should you have further questions regarding the information contained in our letter, please contact the ITEM Coalition coordinator, Peter Thomas, at Peter.Thomas@powerslaw.com or call 202-466-6550.

Sincerely,

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

ITEM Coalition Signatories
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