



December 16, 2018

*Submitted electronically via DMEPOS@cms.hhs.gov*

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
200 Independence Ave., S.W.  
Washington, D.C. 20201

**Re: Comments on CMS' Proposal to include Ventilators in DME Competitive Bidding program**

Dear Administrator Verma:

On November 1, 2018, the Centers for Medicare and Medicaid Services (CMS) posted online a request for public comments to include more product categories in the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program (CBP). CMS identified ventilators as a product category that may be phased-in for the next round of competitive bidding, expected to be effective around January 1, 2021. The American Association for Homecare (AAHomecare) strongly opposes the inclusion of ventilators in the CBP.

AAHomecare members include a cross section of suppliers, manufacturers, and other industry stakeholders that assist, make or furnish DMEPOS items that beneficiaries use in their homes. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services.

CMS is proposing to add the following ventilator devices to the CBP:

- E0465: Home ventilator, any type, used with invasive interface (*e.g.*, tracheostomy tube)
- E0466: Home ventilator, any type, used with non-invasive interface (*e.g.*, mask, chest shell)
- E0467: Home ventilator, multi-function

American Association for Homecare  
241 18<sup>th</sup> St. South, Suite 500, Arlington, VA 22202  
aahomecare.org

Ventilators are medical devices that provide mechanical ventilation to assist with or replace patients' spontaneous breathing. Mechanical ventilation is typically categorized based on the interface used, such as a tracheostomy tube for invasive ventilation, or a mask for non-invasive ventilation. AAHomecare vigorously opposes the inclusion of all ventilators in the CBP for the following reasons:

- Ventilators Are Life Support Systems: Ventilators are life support systems that replace or support normal ventilatory lung function. An individual who is on a ventilator requires mechanical aid for breathing to augment or replace spontaneous ventilatory efforts to achieve medical stability or to maintain life. Individuals who require ventilation support cannot breathe on their own, they are quite fragile and require a significant amount of ongoing clinical and other care. Many patients requiring home ventilator services have significant neuromuscular conditions, for example, Amyotrophic Lateral Sclerosis (ALS) which is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord. The progressive degeneration of the motor neurons in ALS eventually leads to their demise. When the motor neurons die, the ability of the brain to initiate and control muscle movement is lost. With voluntary muscle action progressively affected, people may lose the ability to speak, eat, move and breathe.

Patients using ventilators require careful assessment, ongoing monitoring and titration of the equipment. The ongoing clinical oversight and management of these patients on ventilators is far more significant than any other product categories in the CBP. In order to provide the therapy, suppliers are required to complete significant training. Due to the fragility of patients requiring ventilators, and the intensive service required, it would be very risky for the Medicare program to include these items in competitive bidding since it focuses far more on low prices than on quality of care.<sup>1</sup>

- Ventilators are Classified as “Frequent and Substantial Servicing” Items: Medicare’s DME payment system classifies ventilators as items that require “frequent and substantial servicing,” recognizing the intensive and continual service these items require “in order to avoid risk to the patient’s health.”<sup>2</sup> To date, Medicare has not included any other “frequent and substantial servicing” items in the CBP, and to do so would be a significant departure and place ventilator-dependent beneficiaries at risk.
- Issues Specific to Invasive Ventilator Services: The logistical complexity of providing invasive ventilation is significant; including these items and services in competitive bidding will decrease access, meaning that patients who require these items will likely instead be placed in acute care settings, significantly increasing the cost of providing care to these patients. As a life-sustaining therapy, invasive ventilator therapy requires a high

---

<sup>1</sup> See American Association for Respiratory Care Clinical Practice Guideline: “*Long-Term Invasive Mechanical Ventilation in the Home – 2007 Revision and Update*” for detailed clinical practice guidelines on providing mechanical ventilation to patients in their homes.

<sup>2</sup> 42 C.F.R. §414.222, See CMS MLN Matters SE 1513 (Revised June 6, 2017)

level of respiratory therapist interaction with the patient and caregivers. If a limited number of suppliers receive contracts to provide these items and services, patients may be at risk due to the suppliers being required to cover a large geographic area or a high population density area in a lower-cost structured model. If discharge planners have difficulty safely discharging beneficiaries who require ventilator services, hospitals will have increased lengths of stay. The risk of suppliers winning contracts who do not have an effective local presence is a significant issue due to the hands-on needs of these fragile patients.

- Issues Specific to Non-Invasive Ventilator Services: Recent advances in non-invasive ventilator technology has enabled many more patients who would otherwise be in a health care institution to remain at home. These ventilators are now used routinely in the home setting because they reduce morbidity, mortality and improve quality of life. The newer technologies dynamically adjust to patient needs and permit a wider range ventilatory options than bi-level machines, improving compliance and promoting outcome improvement. There are multiple clinical studies showing the clinical benefits of using non-invasive ventilators in the home, including significant reduction in respiratory and all-cause rehospitalization.
- Issues Specific to Multi-Function Ventilators (HCPCS Code E0467): CMS has just established the E0467 HCPCS code and a new payment formula for these devices which are brand new to the Medicare program.<sup>3</sup> Given that there is no utilization information, nor any practical experience with Medicare coverage and payment for these new devices, including them in the CBP is wholly inappropriate. In addition, CMS' lead item pricing methodology would link bid prices for these items with other ventilator codes; and the devices are very different. Finally, due to the vulnerable beneficiary population that would benefit from these devices, CMS should never include these items in the CBP.
- Impact on Medicaid Pediatric Patients: Including ventilators in the CBP will negatively impact patients who require ventilators who have state Medicaid programs as their primary payor. Many of the state Medicaid recipients on ventilators are children with multiple serious chronic conditions. Because decreased Medicare payment levels will result in decreased Medicaid payments for these services, CMS must be particularly mindful of the likely serious negative impacts for these frail and vulnerable individuals. Medicaid rates mirror the rates published under Medicare, and the federal portion of Medicaid funding would decrease if ventilators are included in CBP. (Current law prohibits Medicaid reimbursement to states for certain DME expenditures that are, in the aggregate, in excess of what Medicare would have paid for such items, effective January

---

<sup>3</sup> CMS Final Rule, *Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury End-Stage Renal Disease Quality Incentive Program, DMEPOS Competitive Bidding Program and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations to the CBP for Certain DMEPOS* (83 Fed. Reg. 56922, Nov 14, 2018)

1, 2018.<sup>4</sup>) Any resulting reduction in the rates for Medicaid will cause potential access problems for these medically frail individuals as well.

- CMS Should Instead Establish More Specific Coverage Criteria: Instead of including ventilators in the CBP, CMS should establish a Local Coverage Determination (LCD) for these items. Clinical organizations have previously recommended that CMS establish an LCD due to the limited and vague current coverage criteria. Currently, the CMS National Coverage Determination Manual (Internet-Only Manual, Publ. 100-3) in Chapter 1, Part 4, Section 280.1 states that ventilators are covered for the following conditions: “neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease.” This is a very limited and vague basis on which to determine whether a patient meets the Medicare program’s coverage criteria and needs to be substantively improved before Medicare makes any other changes to this benefit, such as including these items in the CBP.

More detailed and clear coverage criteria would provide the medical community and DMEPOS suppliers better guidance regarding which beneficiaries are the most appropriate for home ventilator services. Without more coverage criteria clarity, DMEPOS suppliers are at risk for improper payments, and this problem would be exacerbated if ventilators were included in the CBP. The current Medicare coverage criteria for ventilator-related disease groups overlap conditions described in the Respiratory Assist Devices LCD used to determine coverage for bi-level PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator versus a bi-level PAP device, is made based upon the specifics of each individual beneficiary’s medical condition. In the event of a claim review, it is likely that reviewers will disagree given the lack of clear-cut coverage criteria for the different devices. Therefore, AAHomecare strongly urges CMS to develop more detailed coverage criteria for ventilator services before making any other changes to this benefit such as including ventilators in the CBP.

- Ventilators Should Not Be Added to the CBP Due to Overutilization Concerns: CMS does not identify its reasons for proposing to include home ventilation therapy in the Medicare DME CBP. While the Office of Inspector General and the Medicare Payment Advisory Commission (MedPAC) have recommended adding these items to the CBP, those agencies are not fully informed about the reasons for the increased utilization, which we posit has been entirely appropriate and based on true medical need. There are significant recent technological advances that have enabled many more patients to be treated at home, where previously they would be forced to remain in a health care institution. These newer ventilator devices, in comparison to the older technology, have algorithms that allow the devices to adjust dynamically to the patients’ needs, promoting significant improvements

---

<sup>4</sup> Section 503 of the Consolidated Appropriations Act, 2016, and section 5002 of the 21<sup>st</sup> Century Cures Act of 2016

in quality of life. Increases in the use of new technology are entirely appropriate when it enables more patients to be cared for in the comfort and quality of their homes, rather than in more costly health care institutions such as nursing homes and hospitals.

- Including Ventilators in the CBP Would Create Access Issues: There are currently relatively few DME suppliers that are capable of providing ventilator services to Medicare beneficiaries due to the significant complexities associated with providing these items and services. Since the CBP is designed to limit the number of suppliers providing items and services, decreasing the number of viable suppliers who can provide these services would put beneficiaries and other patients requiring ventilators at risk.
- CMS Should Not Compound the Complexity of Implementing Unnecessary Additional Changes to the CBP: Beginning as early as January 1, 2021, CMS will be implementing some positive changes to the CBP, including changing the bidding methodology to lead item pricing, as well as other reforms. CMS should not introduce unnecessary changes, such as adding ventilators to the program, during this period in which CMS is making a series of changes to the bidding program.

For these reasons, AAHomecare strongly recommends that CMS not include ventilators in the DME CBP. We appreciate the opportunity to provide these comments and are happy to answer any questions or provide more detailed information. Please do not hesitate to contact me with additional questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom Ryan". The signature is fluid and cursive, with a long horizontal stroke at the end.

Tom Ryan  
President & CEO