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**Competitive Bidding Product Categories**
**Comments Opposing Inclusion of Ventilators in the Next Round of Competitive Bidding**

As President of the American Association for Respiratory Care, we offer the following comments regarding CMS' plans to phase-in ventilators in all competitive bidding areas in the next round of the durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) competitive bidding program (CBP). The AARC is a national professional organization with a membership of 47,000 respiratory therapists who treat patients with chronic respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and asthma and whose organizational activities impact over 170,000 practicing respiratory therapists across the country. In addition to these comments, the AARC is also submitting joint comments with other medical societies and patient organizations opposing the inclusion of ventilators under competitive bidding which, if implemented, will compromise patients' lives who depend on these life saving devices.

*Background*

In a June 2018 Report to Congress, the Medicare Payment Advisory Commission (MedPAC) noted Medicare expenditures for DMEPOS under CBP decreased considerably between 2010 and 2015 while products not included in the CBP have continued to increase during that same time period, suggesting Medicare is substantially overpaying for many non-CBP DMEPOS products.

Current Medicare policy covers ventilators, both positive and negative pressure types, for the treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. In its report, MedPAC reviewed potentially excessive payment rates and found that two ventilator products were higher than private-pay rates based on 2015 data. These included pressure support devices with invasive interface (e.g., tracheostomy tube) and noninvasive interface (e.g., mask), E0463 and EO464, respectively. Moreover, the Office of Inspector General reported Medicare paid 85 times more claims for E0464 ventilators in 2015 than in 2009, leading to escalating expenditures and potential abuse. The problem with the rise in ventilator billing for E0464, according to the OIG,

was due to technology advancements that allow a single device to treat numerous conditions by operating in several different modes and ventilator claims by three suppliers that had billing far exceeding the national average. Although CMS reduced the number of ventilator codes in 2016 from five codes to two and changed its payment methodology resulting in a payment reduction of 32 percent, the agency is proposing to phase-in ventilators when the next round of competitive bidding is announced. CMS proposed including noninvasive pressure support ventilators in CBP Round 1 2017 but removed the product before the round began.

**Ventilator patients need the expertise of respiratory therapists to maximize their health and well-being; competitive bidding puts their expertise and patient care at further risk.**

The AARC is strongly opposed to CMS' announcement that it will phase-in ventilators during the next round of the CBP. Ventilators, while meeting the definition of "durable medical equipment" are nothing like other products in the CBP, such as walkers, wheelchairs, hospital beds, prosthetic devices, etc., and to include them under competitive bidding is not only illogical, it is dangerous. For patients with neuromuscular disease, mechanical ventilators are genuinely life-support devices and are designed to replace or support normal ventilatory lung function. These fragile patients should not be placed at the mercy of the lowest bidders to ensure appropriate care.

We have only to look at the drastic reduction in oxygen payments which have been reduced by 55 percent since the inception of competitive bidding, and the extreme lack of beneficiary access to liquid oxygen systems to glimpse the catastrophic outcomes Medicare beneficiaries will face if ventilators become a CBP product category. For example, beneficiary use of stationary liquid systems dropped from nearly 56,000 patients using stationary liquid oxygen systems in 2008 prior to competitive bidding to 16,000 in 2013. The most recent data show that fewer than 6,000 beneficiaries were able to secure stationary liquid systems in 2016, a six-fold decrease since implementation of competitive bidding. The same pattern exists for access to portable liquid systems. In 2008, prior to competitive bidding, approximately 74,000 beneficiaries had access to portable liquid systems; the first year of competitive bidding that number dropped to just under 41,000. In 2016 the number of beneficiaries with access to portable liquid systems has dropped to 8,141.

But payment reduction is not the only thing that has been impacted by competitive bidding. A patient's livelihood is also affected. The lack of reasonable portable oxygen systems to meet patients' needs locks them into their homes and limits their quality of life. Lack of physical activity only worsens clinical outcomes. This is particularly true for patients who lack access to functioning, physically manageable, high flow, portable oxygen systems. If ventilators become a product category under competitive bidding, we fear the same impact on quality of life will happen to those patients who need home mechanical ventilation, which crosses a spectrum of

patients including those with neuromuscular disease, COPD and other hypoventilatory syndromes. Their needs can range from sporadic use, intermittent use, or continuous use. Current CMS policy does not recognize the distinction or need for subcategories of care related to home mechanical ventilation, which, if updated, can assist physicians and suppliers as well as Medicare contractors in recognizing that chronic respiratory failure occurs within different Medication populations. Thus, choosing the cheapest ventilator through competitive bidding will likely have grave consequences for patients whose needs vary depending on their clinical situations. Like patients on oxygen, they could be impacted by limited battery life, comfort with daily activities of life (without pressure support), weight, and monitoring advancements.

A separate clinical issue is the lack of provision for the expertise of a respiratory therapist in the home which may necessitate transfer of some patients with more complex severe chronic respiratory failure to a chronic care facility in order to provide access to adequate clinical management of their ventilator device. The problem is that the current reimbursement policy creates a disconnect between the patient's clinical status/needs and reimbursement because payment policies focus on devices rather than the clinical situation.

Respiratory therapists are the only allied health professionals with education, training and competency testing in all aspects of pulmonary care and are experts in ventilator care. Absent a professional component for the care of these patients under current law, creating a scenario of low-bid, low-cost incentives will undoubtedly create grave clinical risks. The impact of competitive bidding has already seen reduced services by respiratory therapists in the home setting. If reimbursement for home ventilators is cut further because of CMS' proposal to add it to the competitive bid process, suppliers will be forced to reduce or even eliminate the respiratory therapist. Because of their pulmonary skill set, respiratory therapists who treat home ventilator patients can keep them out of the hospital, out of nursing homes, and shift the bulk of the caregiving burden to families, thus saving the Medicare program money. Reducing reimbursement by sending home vent patients to the lowest bidder will ultimately result in patient deaths and increased hospital and nursing home costs.

As with liquid oxygen, competitive bidding will be devastatingly detrimental to the home mechanical ventilator patient community. As with liquid, when the lowest bidder sets the threshold level for payment, access simply disappears for high commodity items. Because these devices can mean the matter of life or death, combined with the almost certain lack of a respiratory therapist's expertise in patient care, we anticipate if CMS moves forward with this initiative not only will patients' health be in serious jeopardy, but the program will incur additional utilization and increased costs due to hospital admissions, readmissions and emergency department visits, which defeats the purpose of saving money through competitive bidding.

**Updating antiquated coverage policies for home mechanical ventilation to reflect standards of care in 2019 can address current payment issues without reverting to competitive bidding as the solution.**

For several years, the AARC together with other pulmonary and patient organizations has repeatedly recommended a revision to home mechanical ventilation policies currently based on a 2001 decision memo issued by CMS' Coverage and Analysis Group. A chronology of actions and a request for reconsideration of CMS' current national coverage determination is detailed in the joint comments referenced earlier. The take away from that discussion is we believe strongly that CMS' lack of response to repeated requests from the clinical community to restructure the home mechanical benefit to reflect state-of-the art peer-reviewed science is directly related to the increase costs and utilization of invasive and noninvasive mechanical ventilators that led to the decision to phase-in ventilators in the next round of competitive bidding.

**Recommendations**

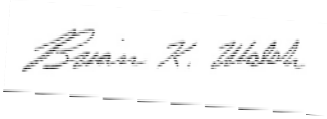
1. The AARC urges CMS to reconsider the inadvisable decision to subject ventilator dependent Medicare beneficiaries to a competitive bidding system that can compromise their health all in the name of saving money. We implore the agency to protect their lives and ensure access to appropriate equipment that meets their specific needs and access to the respiratory therapists' expertise by announcing home mechanical ventilation will remain outside of the competitive bidding program when the next round is announced.

2. In its response to our NCD request in 2016, CMS noted they would not open the request due to a large volume of requests requiring simultaneous review, stating "we prioritize these requests based on the magnitude of the potential impact on the Medicare program and its beneficiaries…" Clearly the OIG findings of an 85-fold increase in claims and $25 million in payments for E0464 with indicators of inappropriate billing based on current coverage policies meets the "magnitude of the potential impact on the Medicare program" criterion; however, simply collapsing the codes and changing the payment methodology is not enough without revisions to coverage policies that reflect today's standards. With the technology assessment completed by the Agency for Healthcare Research and Quality on home mechanical ventilation and the abundance of scientific information provided to CMS by the clinical community between 2014 and 2016, CMS must delay no longer revamping its coverage policies on ventilators to reflect current standards of care. These include the following:

a. **Establishing specific clinical definitions for chronic respiratory failure, mechanical ventilator and mechanical ventilation;**
b. **Recognizing specific categories of mechanically ventilated patients that acknowledge chronic respiratory failure may occur intermittently, nocturnally, or on an ongoing basis; and,**
c. **Melding the current LCDs for "respiratory assist devices" into the revised NCD for home mechanical ventilators with three notable changes:**
    i. **Use medical terminology, i.e., bi-level devices/mechanical ventilators for use in treatment of respiratory insufficiency, recognized by the medical community and the Food & Drug Administration to address coverage of devices for treatment of respiratory insufficiency.**
    ii. **Eliminate the current requirement for oximetry testing in certain specified scenarios as there is no scientific basis for this requirement.**
    iii. **Eliminate the current requirement for a Medicare beneficiary to "fail" therapy of a device without using a backup rate as there is no scientific basis for this requirement.**

We appreciate the opportunity to provide comments to CMS and hope our recommendations will meet with favorable actions.

Sincerely,



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