

COMPETITIVE BIDDING PRODUCT CATEGORIES

December 14, 2018

The patient and provider groups identified here welcome the opportunity to comment on the request for public input regarding possible inclusion of home mechanical ventilators in competitive bidding.

The American Association for Respiratory Care
The American College of Chest Physicians
The American Lung Association
The ALS Association
The COPD Foundation International Ventilator Users Network
The National Association for Medical Direction of Respiratory Care
The United Spinal Association

Our comments focus on two areas of concern: 1) the significant impact on patients' lives if ventilators are included in the next round of competitive bids following CMS' gap period; and 2) 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 that we believe have caused increased costs and utilization leading to the recommendation to include ventilators under competitive bidding.

Ventilators Under Competitive Bidding Will Compromise Patients' Lives

Problems Inherent in the Competitive Bidding System

The question of inclusion of home mechanical ventilators in competitive bidding raises important questions and serious concerns from the Medicare beneficiary perspective. First, in all candor, while the Medicare statute considers ventilators as "durable medical equipment," to view these devices and their use as simple commodities similar to wheelchairs and walkers is misplaced and ultimately dangerous; many mechanical ventilators, particularly in the neuromuscular arena, but not solely that landscape, are genuinely life support ventilators. A select group of patients must not be placed at the mercy of the lowest bidders to ensure appropriate 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 dramatically 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, companies will be forced to reduce or even eliminate the respiratory therapist. Home ventilation keeps patients out of the hospital, out of nursing homes, and shifts 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. Just as American hero John Glenn once commented about sitting atop a rocket built by the lowest bidder, we are collectively fearful that such an inherent structure within competitive bidding will lead to serious decline in health care for many beneficiaries.

Add to this the long-standing complication of the vernacular – “home mechanical ventilator.” To the clinical community, a “ventilator” is unquestionably integral to the standard of care for treatment of respiratory failure. “Respiratory failure,” currently NOT defined by CMS despite repeated requests from the clinical community to do so to ensure appropriate usage of these devices, may occur in several distinct clinical scenarios: 24/7 need, nocturnal need, or intermittently during the day when acute events warrant such mechanical support. CMS regulations do not address these important distinctions, and, in the absence of such policies, suppliers would have strong financial incentives (as they do today) to provide devices that are not necessarily optimally suited for the specific patient. Additionally, CMS policy does not reflect classifications of its sister agency within the Department of Health and Human Services, the Food and Drug Administration.

Recent recognition of multi function ventilators also raises important variables where competitive bidding is likely to result in even more problematic unintended consequences. As CMS replaces the multiple stand-alone devices (e.g., a separate ventilator, oxygen concentrator, nebulizer, cough stimulator, and aspirator) with the option of a multi function ventilator, beneficiaries could suddenly face new challenges in having access to the appropriate types of equipment because suppliers will be unable to handle the complexity of their ventilator needs. Moreover, the competitive bidding incentive will be for suppliers to stock the cheapest alternatives regardless of medical need, further putting patient's lives at stake if ventilators are added to competitive bidding

When we add these collective failures of CMS to structure a benefit that reflects not only state of the art technologies but also the utter failure to respond to repeated requests for changes that reflect the standards of care for patients who suffer from a wide range of pulmonary/neuromuscular diseases, the concept of providing ventilators based on the lowest bids signals a scenario that would likely evolve the same way that access to liquid oxygen has dramatically declined under competitive bidding. In the case of liquid oxygen, despite contractual requirements that suppliers provide liquid systems, both stationary and portable, access to these systems are simply no longer readily available to beneficiaries who, in the clinical judgment of the ordering physician, liquid is best suited for the patient’s medical needs.

For example, many pulmonary fibrosis patients today are literally homebound because they do not have access to portable liquid systems that afford not only high flow but continuous O2 therapy. The ONLY variable has been competitive bidding, and Medicare beneficiaries have paid a very high price – virtual elimination of therapy suited to their needs. Sadly, the analogy is almost perfect – a specific device is needed to meet the patient’s needs and the product literally disappears from the marketplace when competitive bidding pricing creates problematic

incentives that impact patient access to care. Medicare data clearly illustrate the precipitous drop in access to liquid systems as competitive bidding took hold:

Stationary Liquid Systems			
Year	Charges	Claims	Patients
2010	\$67,355,848	386,645	32,220
2011	\$59,497,447	349,775	29,148
2012	\$46,893,878	271,233	22,603
2013	\$31,983,339	199,486	16,624
2014	\$19,536,044	136,656	11,388
2015	\$10,829,115	99,252	8,271
2016	\$ 7,482,476	71,377	5,948
Portable Liquid Systems			
Year	Charges	Claims	Patients
2010	\$14,127,684	491,253	40,938
2011	\$12,439,576	442,027	36,836
2012	\$9,728,130	337,668	28,139
2013	\$6,814,689	250,125	20,844
2014	\$4,368,905	173,161	14,430
2015	\$2,455,215	128,727	10,727
2016	\$2,020,306	97,690	8,141

The primary variable for the decline in access to liquid oxygen systems is competitive bidding. There has been no decline in the patient population where liquid systems are clinically appropriate. To the contrary, these easily identifiable patient populations are increasing while payment changes are singularly responsible for the decline in access.

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.

Medicaid Payments

Medicaid covers a significant number of pediatric ventilator patients, and payment is invariably higher than Medicare payments due to documented higher costs. We are fearful that competitively bid prices for ventilators through the Medicare program will have the unintended consequence of driving down Medicaid payments as well, making it more difficult for DME

suppliers to continue to provide the equipment *and* services needed for this vulnerable population.

Revision to Home Mechanical Ventilation (HMV) Policies are Long Overdue

As CMS' Coverage and Analysis Group (CAG) well knows, the pulmonary community has long recommended an important realignment of the home mechanical ventilation benefit under the Medicare program. To recap, a brief chronology is provided below:

- 2014** A white paper on home mechanical ventilation was submitted to the DME MAC Medical Directors in response to their March 2014 request to the NAMDRG/pulmonary physician community. To date there has been no response or action from them or CAG other than to acknowledge receipt of the document.
- 2015** In April, clinical societies and patient groups asked CMS Coverage and Analysis staff to revise or rescind a **2001 Decision Memo** which explicitly indicates that in order to qualify for certain mechanical ventilators the patient must face imminent death upon removal of the device. After meeting with CMS staff to explore regulatory and administrative options in August, CMS indicated in the fall that the only option was the National Coverage Determination pathway.
- 2016** In March, multi-societies submitted a reconsideration request of the current NCD for home mechanical ventilation. While CMS policy indicates a response generally within 60 days, it was September, 180 days after receiving the NCD reconsideration request, before CMS indicated they were not going to act due to other priorities. Also, in that month, the Office of the Inspector General issued a report critical of CMS coverage and payment for HMV.

NCD Recommendations

We continue to push for realistic, clinically supported changes to home mechanical ventilation policy that would improve access as well as, we believe, decrease aggregate costs for the wide range of devices available today. Based on detailed scientific evidence presented in the NCD reconsideration request that both invasive and noninvasive home mechanical ventilation are integral to the treatment of chronic respiratory failure, **we requested that CMS implement the following policies in priority order listed below.**

- 1) Establish specific clinical definitions for chronic respiratory failure, mechanical ventilator and mechanical ventilation;**
- 2) Recognize specific categories of mechanically ventilated patients that acknowledge chronic respiratory failure may occur intermittently, nocturnally, or on an ongoing basis; and,**
- 3) Meld the current LCDs for "respiratory assist devices" into the revised NCD for home mechanical ventilators with three notable changes:**

- a. **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.**
- b. **Eliminate the current requirement for oximetry testing in certain specified scenarios as there is no scientific basis for this requirement.**
- c. **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.**

Agency for Healthcare Research and Quality (AHRQ) Draft Report on HMV

In 2017, following CMS’ response not to act on our NCD reconsideration request, AHRQ was asked to conduct a technology assessment. On September 10, 2018, AHRQ published a draft report based on a systemic review of current evidenced-based literature. Overall the report recognizes the limited peer-reviewed studies that are available to warrant more definitive observations and recommendations. One challenge raised with AHRQ staff in March 2017 is worth reiterating: many of the studies that do examine use of home mechanical ventilators are European-based. Throughout most of Europe, there are strong support systems for home-based services for ventilator dependent individuals, a support system that is tacitly understood by study authors and reviewers even though not specifically referenced. No such support systems exist in the United States. Moreover, it would be inconceivable to suggest that European countries would subject ventilator dependent individuals to a competitive bidding system that can compromise their health all in the name of saving money.

Also notable is a recent home mechanical ventilation home oxygen trail (HMV HOT) published in *JAMA* 2016. The HMV used was a bi-level positive airway pressure (BPAP) device. The point is the difference between the two terms is actually an artificial construct created by CMS definitions that force ventilator square pegs into CMS-created round holes labeled “ventilators” and “respiratory assist devices (RADs)”. This is a primary reason why there are so few studies comparing these entities, although it is far more important to study the specific technical features of the devices to determine what works best to meet patients’ specific needs.

The information above is relevant to the discussion of whether ventilators should be included in the competitive bidding process because we strongly believe that had CMS acted on recommendations as early as 2014 to revise HMV policies, this would not have been an issue in the Medicare Payment Advisory Commission’s (MedPAC) June 2018 report addressing Medicare’s medical device payment policies.

MedPAC Report and Recommendations

In the MedPAC report to Congress in June 2018 relative to medical devices, the Commission reviewed potentially excessive payment rates and found that two ventilator products were

higher than private-payer rates. The products were pressure support ventilator used with non-invasive interface (e.g., mask), HCPCS Code E0464, and pressure support ventilator used with invasive interface (e.g., tracheostomy tube), HCPCS E0463. As noted in the report, beginning in 2016, CMS changed the way it paid for ventilators by collapsing the number of codes from five to two, using its authority to base payment rates on 1986-87 supplier charges for all ventilators. As a result, payment was reduced by 32 percent. The irony is the rise in ventilator billing was due to the fact advances in technologies allow a machine to function as a ventilator, continuous positive pressure airway pressure (CPAP) device, or respiratory assist device. This is an issue the patient and provider community have repeatedly pointed out to CMS as the basis for needed changes to its antiquated coverage policies.

Conclusions and Recommendations

Given the realities of coverage policies that are archaic and use terms such as “respiratory assist devices” that defy definition by CMS, are not recognized by FDA, and uniformly rejected by the clinical community, **it is imperative that CMS take two important steps:**

1. Firmly signal to Medicare beneficiaries that home mechanical ventilators will remain outside of the competitive bidding program in order to protect their lives and ensure access to appropriate equipment that meets their specific needs.
2. Revamp the coverage policies and existing one sentence NCD into policies that reflect standards of care in 2019;