



May 16, 2019

The Honorable Alex M. Azar
 Secretary
 Department of Health and Human Services
 200 Independence Avenue, SW
 Washington, DC 20201

The Honorable Seema Verma
 Administrator
 Centers for Medicare & Medicaid Services
 7500 Security Boulevard
 Baltimore, MD 21244

Dear Secretary Azar and Administrator Verma:

The undersigned patient and pulmonary organizations and societies are deeply concerned that the Centers for Medicare & Medicaid Services (CMS) is unnecessarily placing an extremely vulnerable group of Medicare beneficiaries at risk due to the recent decision to add noninvasive ventilators (NIV) to the competitive bidding program (CBP).

Polio patients have been using mechanical ventilation at home since the 1950's, although newer technologies have made their care less challenging. Prior to medical breakthroughs in the last two decades, however, patients requiring ventilator care could receive it only in an institutional setting. Today many of these patients can remain at home thanks to the advancements in these technologies. These home mechanical ventilators are very similar to those used in institutional settings. As a result, beneficiaries with debilitating neuromuscular disease and paralyzing conditions such as amyotrophic lateral sclerosis (ALS) and spinal cord injury, thoracic restrictive disorder such as idiopathic scoliosis, and severe chronic respiratory failure due to Chronic Obstructive Pulmonary Disease (COPD) are experiencing significant improvements to their quality of life as these devices have the effect of "freeing" patients from their hospital beds and allowing them to return home.

Patients who require NIV should not have to rely upon the lowest bidder to receive the life-sustaining complex services and equipment necessary to remain in their homes and communities. The impact on Medicare beneficiaries could also lead to unintended consequences for ventilated Medicaid recipients, many of whom are children with multiple serious chronic conditions. Because Medicaid is required to cap reimbursement for durable medical equipment at equivalent Medicare rates, CMS must be particularly mindful of the likely serious negative impact including ventilators under the CBP will have on these frail and vulnerable individuals.

Ventilators require constant vigilance and adjustment as a patient's needs change, as well as frequent maintenance. That is why they are placed under the statute's "frequent and substantial servicing" payment category. Adding these complex devices to the CBP would set a harmful precedent and put fragile patients at risk. These devices require substantial clinical expertise since the patient's condition can deteriorate over time. The accepted standard of care includes the expertise of a respiratory therapist to make regular home visits to ensure that the ventilator settings and interfaces are appropriate for the patient. Since CMS does not pay for the respiratory therapist's services, competitive bidding will result in a devastating reduction in access to both ventilators and the necessary clinical support. As a result, Medicare beneficiaries who rely on these complex devices will experience increased emergency room visits, more frequent and longer admissions to hospitals, and greater use of skilled nursing facilities and long-term care facilities which will result in significantly higher costs to Medicare and a devastating impact on patient care and quality of life.

Since 2014, (see attached time table), the physician and patient communities have repeatedly recommended a revision to home mechanical ventilation policies that are based on a 2001 CMS Decision Memo in order to protect patient access and prevent program abuse. CMS has refused to act, basing their decision on the need to prioritize requests based on the potential impact to the program and its beneficiaries and the need to sort out related national and local policies due to their complexities. In a September 2016 data brief from the Office of the Inspector General [OEI-12-15-00370], the OIG indicated CMS policies have not kept up with technology advances in which devices can operate in multiple modes. We strongly believe CMS' lack of response to repeated requests from the clinical community to restructure the home mechanical ventilation benefit to reflect state-of-the art peer-reviewed science is directly related to the increased costs and utilization of noninvasive ventilators.

Including noninvasive ventilators in the next round of competitive bidding to reduce utilization and costs will not fix the problem. By looking at the drastic reduction in oxygen payments since the inception of competitive bidding and the reduction of beneficiary access to liquid oxygen systems, it is easy to foresee the catastrophic outcomes Medicare beneficiaries will face if ventilators become a CBP product category. Without a substantial revision to current policies, the inclusion of NIVs under competitive bidding could lead to perverse incentives that encourage greater use of artificial airways/tracheostomies to ensure access to clinically appropriate devices.

CMS has made great strides to make policies more patient-centered. Now is the time to take assertive action to support that important principle. We implore you to permanently exclude ventilators from competitive bidding to protect the fragile and vulnerable Medicare and Medicaid populations who rely on these life-sustaining devices.

Sincerely,

Alliance for Patient Access

Alpfa-1 Foundation

ALS Association

American Academy of Neurology

American Association for Respiratory Care

American Lung Association

American Thoracic Society

Boomer Esiason Foundation

CHEST/American College of Physicians

COPD Foundation

CURE SMA

Cystic Fibrosis Foundation

Les Turner ALS Foundation

Muscular Dystrophy Association

National Association for Medical Direction of Respiratory Care

Post-Polio Health International/International Ventilator Users Network

Pulmonary Fibrosis Foundation

U.S. COPD Coalition

United Spinal Association

Attachment

Key Timelines Related to Home Mechanical Ventilation	
March 2014	DME MAC Medical Directors request white paper on home mechanical ventilation.
October 2014	White paper submitted to DME MAC medical directors. To date there has been no response other than acknowledgement of receiving the document.
April 2015	Clinical societies and patient groups ask for revision/rescission of 2001 Decision Memo.
August 2015	Meeting with CAG/CMS staff to explore regulatory and administrative options; CMS agrees to respond by late Fall.
Oct/Nov 2015	CMS indicates only real option for change is the National Coverage Determination pathway.
March 2016	Multi-society submission is sent to CMS for reconsideration of current NCD for home mechanical ventilation. 2013 Federal Register notice indicates generally 60-day response.
August 2016	CMS again signals it is not ready to respond to March submission. At the end of August, it is now 150 days since formal request.
September 2016	OIG issues report critical of CMS coverage and payment of home mechanical ventilators.
September 2016	180 days after receiving request for NCD reconsideration, CMS refuses to act, signaling other issues are more important.