AAHOMECARE
American Association for Homecare

Congress Must Exclude Life-Supporting Non-Invasive Ventilators from Competitive Bidding –H.R. 4945

Background

On March 8, 2019, the Centers for Medicare and Medicaid Services (CMS) announced that it will be adding non-invasive ventilators (NIV) to the DMEPOS (Durable Medical Equipment, Prosthetics, Orthotics, and Supplies) Competitive Bidding Program (CBP) for Round 2021. AAHomecare, along with numerous physician and consumer groups, vigorously oppose the inclusion of NIV. Congress must urge CMS to use its authority to stop this effort to expand Competitive Bidding.

On November 1, 2018, CMS published the ESRD/DMEPOS Final Rule, which temporarily halted a nationwide CBP to make changes to the CBP in response to growing concerns about the long-term viability of the program and Medicare beneficiary access issues. This took effect January 1, 2019.

Prior to the suspension of CBP, 110 of the largest, most densely populated Metropolitan Statistical Areas in the country participated as Competitively Bid Areas (CBAs), which were home to 58% of all Medicare beneficiaries in the nation. Under the CBP, durable medical equipment (DME) suppliers, often called home medical equipment (HME) suppliers, compete for a limited number of contracts to serve Medicare beneficiaries residing in these CBAs through an auction program that awards contracts to those with the lowest bid amounts for select DME, resulting in a drastic reduction in competition for suppliers and opportunity to increase market share. On January 1, 2016, CMS began applying prices derived from these highly populated CBAs to all areas of the country without exception for rural America. Congress intervened multiple times to address growing CBP issues, which were echoed by economists and auction experts as well as consumer groups and other stakeholders.

When CMS announced the temporary suspension of CBP in November 2018, it also posted online a request for public comments about possibly including other product categories such as ventilators in the next round of CBP, expected to be effective around January 1, 2021. Ventilators are life supporting medical devices that provide mechanical ventilation to assist with or replace patients' spontaneous breathing. Over 550 comments were submitted regarding concerns for ventilators being added to the CBP, including physician and consumer groups. However, on March 8, 2019, CMS released a Fact Sheet confirming that non-invasive ventilators (NIV) will be included in Round 2021.

Understanding the Role of NIV in Assisting Medically-Fragile Patients

NIV offers the ability for high-need patients with serious degenerative conditions to remain at home and have a higher quality of life with the supportive services of a highly trained DME supplier instead of requiring more costly institutional care.

- ***NIV Requires Service-Intensive Monitoring of Medically Fragile Patients***
  Non-invasive ventilators are used by high-need, medically fragile patients, like Amyotrophic Lateral Sclerosis (ALS), who require careful assessment, ongoing monitoring, and titration by highly trained suppliers. This type of oversight and management is far more significant than other product categories in the CBP. Reducing the number of viable suppliers who can provide these services would create access issues for those requiring NIV and other types of ventilation. Adding NIV to the CBP is very risky under a program that focuses more on low prices than quality of care.
- ***No Other "Frequent & Substantial Servicing" Items are Included in CBP***
  CMS has already recognized the intensive and continued services that certain items like NIV require to "in order to avoid risk to the patient's health" under its DME payment classification system category of "frequent and substantial servicing". This is a testament to the high-touch nature of NIV

and heightened risk for patient harm if not properly maintained. NIV will be the only product in this category that has been added to the CBP, which is a significant departure from historic recognition of the inappropriateness of these types of products being included.

- ***Adding NIV to CBP Negatively Impacts Medicaid Pediatric Patient Access***
  Since part of Medicaid funding for CBP items is limited to Medicare pricing under the 21st Century CURES Act and many Medicaid rates mirror those published under Medicare, decreased Medicare payment for NIV will result in decreased Medicaid payment for these services. Many of the state Medicaid recipients on ventilators are children with multiple serious, chronic conditions. Adding NIV to CBP would likely have serious negative impacts for these frail, vulnerable individuals.
- ***NIV Leverages Technology to Offer Clinical Benefits at Home and Reduce Re-Hospitalization***
  Recent advances in NIV technology has enabled many more patients who would otherwise be in a health care institution to remain at home. NIV is routinely used in a home setting and reduces morbidity and mortality while improving quality of life. Newer technologies dynamically adjust to patient needs, permitting a wider range of ventilatory options that improve compliance and promote positive outcomes.

Subjecting these highly specialized, service-intensive products to a reimbursement methodology that is designed to find the lowest-cost suppliers will limit access for this vulnerable patient population as CBP further narrows an already relatively low number of companies that provide NIV.

Solution

Alternative Way to Address Utilization While Ensuring NIV Patient Access

CMS does not identify its reasons for proposing to include NIV in CBP. While the Office of Inspector General and Medicare Payment Advisory Commission (MedPAC) have recommended adding NIV to CBP, those agencies are not fully informed about the reasons for increased utilization. As noted above, increases in new technology are entirely appropriate when it enables more patients to be cared for in the comfort and quality of their homes at a lower cost to the health care system.

Instead of including NIV in the CBP, CMS should revise the current National Coverage Determination (NCD) and establish a Local Coverage Determination (LCD) for these items. Clinical organizations have previously recommended CMS update the NCD and establish an LCD due to the limited and vague current coverage criteria. 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.

On October 31, 2019, Representatives Morgan Griffith (R—VA) and Peter Welch (D—VT) introduced HR 4945 "Safeguarding Medicare Access to Respiratory Therapy Act" (SMART Act). This legislation will delay the inclusion of ventilators from the Medicare Competitive Bidding Program for Home Medical Equipment for five years and create a technical expert panel to assist the Dept. of Health and Human Services in developing a comprehensive Medicare coverage policy for ventilator products used at home.

Our Ask:

AAHomecare strongly asks Members of Congress to co-sponsor HR 4945 to delay the implementation of NIV in Competitive Bidding for five years and create an expert panel to assist HHS in developing medical policy. Members of Congress should contact the offices of Representatives Morgan Griffith and Peter Welch to become a co-sponsor.

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