

December 7, 2018



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

Subject: Comments on CMS Proposal to Competitively Bid Ventilators and Select Off-the-Shelf Orthotics

Dear Administrator Verma,

VGM Group, Inc. (VGM) appreciates the opportunity to submit comments on the proposal to include ventilators and select off-the-shelf knee and spinal bracing into the competitive bidding program. VGM is a member service organization made up of more than 3,000 durable medical equipment supplier locations, 1,200 accredited orthotic and prosthetic facilities, and other stakeholders within the home medical equipment, complex rehab technology, post-mastectomy, and other post-acute care markets industry since 1986.

### **Ventilation**

Our highly diverse membership of DMEPOS suppliers shares our concerns about the proposal of introducing ventilation equipment into the competitive bidding program. This life-sustaining equipment serves some of the most vulnerable patients in our health care system. With such instability within the marketplace and the relatively few suppliers who provide ventilation, we have major objections to any proposal that includes such vital equipment to the health and safety of a beneficiary. Further reimbursement reductions beyond the scope of the Medicare program would be likely to negatively affect suppliers through other payers for pediatric and adult populations. Without the opportunity to assess the impacts of recent changes to the competitive bidding program stemming from the Final Rule issued by CMS in November, it is in the best interest of Medicare beneficiaries to keep these products removed from the program.

### **Ventilator patients are a highly vulnerable patient population within the Medicare program**

The patients who are dependent on invasive and non-invasive ventilation often times have complex conditions that require highly detailed care plans. Managing this plan with the patients, caregivers, and family members is at the center of keeping a patient out of the hospital and safe in their homes. These patients and caregivers require close monitoring and ample amounts of education between the frequent visits needed. Many of these patients, especially in the case of those requiring invasive ventilation, are dependent on this equipment for extended periods. The long-term relationship between a supplier and these patients is critical to the successful management of a condition. By introducing competitive bidding into the ventilation market, the agency would be potentially subjecting patients to a new supplier every three years, placing the beneficiary and family in a vulnerable position during a transitional phase.

### **Ventilator patients require highly skilled respiratory therapists to properly manage their condition**

Properly managing a ventilator patient requires respiratory therapists to possess skills beyond those needed to manage the average oxygen patient, especially in the cases of invasive ventilation. Monitoring oxygen and carbon dioxide levels, blood pressures, and other clinical components is required to properly maintain ventilation to the area. This is a clinical service currently provided by suppliers at no additional

cost to the Medicare Program as it is considered to be included in the Medicare fee schedule for the rental of the equipment. This is a significant cost to suppliers, and this product category has already recently received a 30% reimbursement reduction; therefore, additional reimbursement cuts could force suppliers to make cuts in service or staffing, putting beneficiaries at further risk for exacerbations, infections, and hospital admissions.

Suppliers employ respiratory therapists with an average salary of \$67,000 per year. RTs develop a plan of care and regularly communicate with patients via telehealth and in-person visits. The equipment is not simply delivered and set up. In many cases, RTs are also compiling clinical data of the outcomes of the equipment, which is relayed back to the physician and is very valuable to assist the physicians caring for these patients. Reduced reimbursement and limited suppliers could negatively impact these important and unique relationships.

### **Ventilation is a small market with few suppliers having proper resources**

Suppliers are not reimbursed based on the high costs of providing the hands-on clinical care necessary to properly service this population. This is a niche market that cannot be easily adopted by every DMEPOS supplier across the country. It is estimated that there are fewer than 400 invasive ventilator suppliers in the United States. Limiting the number of suppliers who can care for a patient puts patients in danger with the types of conditions treated by ventilation.

### **Beneficiaries who require this equipment cannot be subject to delays in care or access issues**

As CMS has admitted and the industry has seen, beneficiaries in CBAs have had both access to care issues as well as significant delays in care for equipment included in competitively bid product categories. In many instances, beneficiaries have been forced to purchase or rent equipment on their own for cash as opposed to receiving the benefit they are entitled to under the Program because of these delays or access issues. The main difference being that most of the current competitively bid items are not considered "life-sustaining." However, beneficiaries requiring this equipment are suffering from severe chronic respiratory conditions that require immediate and complex care. Reducing the number of suppliers able to provide this equipment and/or reducing reimbursement even further puts these Medicare beneficiaries at significant risk of not receiving equipment timely.

### **Off-the-Shelf (OTS) Spinal and Knee Orthoses**

Many Medicare beneficiaries rely on local, independent suppliers and practitioners for orthotics in order to remain active and independent. While VGM recognizes the increased utilization in these products over a period of time, we don't believe that it is in the best interest of the beneficiary to competitively bid these products in order to reduce over utilization of these products. There is a distinct difference between mail-order suppliers driving much of the increases in utilization and abuse of the program and the certified practitioners delivering care directly to the patient.

Orthoses, if not properly fitted to the beneficiary's needs, have the potential to have lasting negative effects. The stringent documentation requirements for suppliers and practitioners already work to protect the safety of the patient and prevent abuse of the Medicare program. Mail-order bracing allows for wide-spread marketing tactics leading to abuse of the program, but this should not come at the cost of in-person, hands-on care of beneficiaries using local providers.

If CMS is going to include OTS spinal and knee orthoses, direct-to-patient suppliers and practitioners must be exempt from this program in the same way that physicians and hospitals are exempt from some competitive bidding requirements. This would address the extreme growth in utilization found by the Office of Inspector General (OIG) primarily driven by several mail-order suppliers, while protecting access and freedom of choice for beneficiaries using a qualified local practitioner.

At Your Service,

A handwritten signature in blue ink, appearing to read 'John E. Gallagher', followed by a horizontal line extending to the right.

John E. Gallagher  
Vice President, Government Relations  
VGM Group, Inc.