March 12, 2020

The Honorable Alex Azar
Secretary
The Centers for Medicare & Medicaid Services
200 Independence Ave S.W.
Washington D.C. 2021

Dear Secretary Azar:

CC: Sen. Charles Grassley, Sen. Ron Wyden

Subject: Seeking leniency with home medical equipment suppliers during the COVID-19 pandemic.

The VGM Group, Inc. (VGM), was founded in 1986 and is a member service organization made up of over 3,000 durable medical equipment supplier locations, 1,200 accredited orthotic and prosthetic facilities, 1,300 complex rehab suppliers, and stakeholders within the home medical equipment, respiratory therapy, post-mastectomy, and other post-acute care markets.

We are writing to you on behalf of our many home medical equipment suppliers that serve the disabled and elderly population in the country. While the HME community is proud to serve this group, they also have growing concerns as COVID-19 spreads into the United States. HME suppliers plan to continue to serve the sick and injured population during this time of crisis, but they are looking for leniency in some of the regulations currently in place in order to help them continue to do business serving those in need.

1) We ask CMS to suspend adding non-invasive ventilators (NIV) from the Round 2021 Competitive Bidding Program to protect access to this therapy.



In 2019, CMS announced the addition of non-invasive ventilators (NIV) to the competitive bidding program. HME suppliers immediately spoke up, reaching out to their members of Congress in order to prevent this from being added to the program. The HME community says ventilators are highly specialized and care-intensive devices that allow fragile, medically complex patients to remain in their home. Even brief delays in access to clinical ventilator support can prove dangerous or even fatal and would likely mean patients are no longer able to receive their care at home. Reps. Morgan Griffith (R-VA) and Peter Welch (D-VT) authored the S.M.A.R.T. Act (Safeguarding Medicare Access to Respiratory Therapy, H.R. 4945. This bill directs CMS to revise outdated home mechanical ventilation policies to reflect evidence-based modern medicine, ensuring patients receive the right device at the right time.

Access to of respiratory therapies, notably non-invasive ventilators during this COVID-19 pandemic is critical. There is growing concern of availability of these products. To avoid any disruption in the supply and be prepared to meet the likely increase in demand for NIV in the home setting, we ask CMS to remove NIV from the Round 2021 competitive bidding program.

2) We ask CMS to extend the current blended rate in rural non-CBAs and initiate a blended rate for non-rural CBAs in 2021 to protect access to critical home medical equipment.

From seniors to those with disabilities or chronic conditions, people across the country rely on HME to go about their daily lives, whether it's to simply walk around without falling or to breathe normally when their lungs can no longer do it on their own. But this equipment cannot save lives if it isn't available to those who need it most, especially in rural communities where barriers to access health care already exist.

Decreased reimbursement rates under competitive bidding have made it especially difficult on rural providers and have threatened access to care for patients in rural America. The number of HME suppliers has decreased by 40% over the past 10 years based of information from a Freedom of Information Act.

<u>Click here</u> to see an infographic of the decrease of DME suppliers over the past 10 years by state.

Home medical equipment, such as wheelchairs, hospital beds, commodes, and respiratory therapy equipment such as non-invasive ventilators, oxygen concentrators, CPAPs, and nebulizers will be in high demand during and after the spread of COVID-19. Equipping the workforce to safely engage with these patients will take more resources than most are anticipating. We encourage CMS in the current rulemaking to indicate that because of the COVID-19 emergency, it will extend the blended rate in rural non-CBAs through at least 2021 for home medical equipment. Taking this step now is important to allowing suppliers and manufacturers to prepare and make sure they have the equipment and supplies in place, have resources for infection control, and are able to avoid potential disruptions in supply and workforce.

3) We ask CMS for leniency with home medical equipment and respiratory suppliers to be able to accept and submit claims when a telehealth visit is performed.

Home Medical Equipment and Respiratory suppliers are required to make sure an inperson, face-to-face visit was performed with a treating practitioner in order to submit claim for payment. The in-person visit is related to all home medical equipment that is being prescribed such as hospital beds, commodes, wheelchairs, and CPAP equipment.

The in-person visit is even required for follow up clinical visits such CPAP equipment. A supplier of home medical equipment cannot proceed with monthly rental billing and receive payment until the clinical visits are completed by the treating practitioner and the patient in person (face-to-face). This particular situation affects cash flow for a supplier that needs to

continue to pay staff, order equipment to care for patients in the home, and to keep the lights on.

During this time of crisis with COVID-19, can there be leniency with home medical equipment and respiratory suppliers to be able to accept and submit claims when a telehealth visit is performed?

According to the CMS Claims Processing manual, Chapter 190 (Rev. 1, 10-01-03), titled "Medicare Payment for Telehealth Services," the telehealth requirements are very restricted for home medical equipment suppliers to where this type of service is not acceptable at all. And, for those beneficiaries living in rural America, the telehealth service is truly limited due to the lack of internet service and proper communication systems. Beneficiaries generally struggle to find a mode of transportation to get to a physician office and now that offices are cancelling appointment and even closing, the beneficiaries are stuck at home. Keeping in mind these are people at high risk for obtaining the COVID-19 virus because of their age and compressed immune systems due to other chronic conditions such as diabetes, emphysema, and heart conditions.

4) We ask CMS to reduce burdensome paperwork on physicians and suppliers (Certificate of Medical Necessity).

The President's Administration has already begun an initiative of "Patients Over Paperwork." As a matter of fact, the President has stated that it's time to "cut the red tape" to reduce burdensome regulations. This mean the initiative needs to be considered for the home medical equipment industry by allowing the Certificate of Medical Necessity, the test results confirming diagnosis of COVID-19, and the prescription to be sufficient documentation for determining medical necessity for patients with a confirmed COVID-19 diagnosis who have been prescribed home medical equipment. The Home Medical Equipment industry is under stringent guidelines for obtaining the correct documentation to meet medical policies (NCDs). During this time of a pandemic (disaster), the barriers to be removed to permit relief to the suppliers providing home medical equipment that allows the beneficiaries to remain at home away from hospitals and the public.

Here is the link for the Patients Over Paperwork initiative:

https://www.cms.gov/About-CMS/story-page/patients-over-paperwork

5) We ask CMS for coverage and reimbursement of necessary home medical equipment, supplies, and services provided to patients with a confirmed COVID-19.

Currently home medical equipment, including oxygen, BiPAP, and ventilators, are covered and reimbursed only for beneficiaries with a diagnosed chronic condition(s). Even though physicians are prescribing necessary medical equipment such as oxygen, Bi-PAP, ventilators, hospital beds, commodes, and mobility devices, COVID-19 is not listed as a covered diagnosis. Access to equipment and supplies at home is necessary, particularly in areas that are lacking access due to the rural health care crisis. Therefore, we ask that CMS waive the current requirement that home medical equipment coverage and reimbursement for Medicare beneficiaries be limited to patients with chronic conditions and allow for the provision and reimbursement of these services if a beneficiary has a confirmed diagnosis of COVID-19 and has been prescribed the home therapy.

6) We ask CMS to prioritize the provision of personal protective equipment (PPE) for home medical equipment suppliers whose workforce are providing equipment and supplies to COVID-19 patients in their homes.

The rising cases of COVID-19 has increased the availability for necessary PPE for all in the country. Home medical equipment suppliers and the staff who are delivering equipment and supplies are in the unique position of having to enter a patient's home and set up the equipment. Some of our members are struggling to get the necessary PPE to safely deliver equipment to homes of potentially infected patients. We ask CMS to help us in allowing HME suppliers prioritized access to PPE. CMS would need to work with the suppliers of PPE to avoid increasing demand, leading to increased costs which would create access issues.

On behalf of VGM and its membership of 3,000+ home medical equipment suppliers and the millions of patients they serve, we greatly appreciate your time and consideration in our requests within this letter. We welcome any further discussions with you and CMS regarding these issues.

Sincerely,

Clint Geffert

President of VGM & Associates

John Gallagher

VP of VGM Government Relations