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Mark McClellan, MD, PhD  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Ave. SW  
Washington, DC, 20201

Dear Dr. McClellan:

The American Association for Respiratory Care (AARC) understands that the Centers for Medicare and Medicaid (CMS) is poised to finalize a rule to reclassify non invasive positive pressure ventilators (NPP ventilators) from the current frequent and substantial servicing category to that of capped rental.

The AARC, which represents 38,000 respiratory therapists, many of whom treat, assess, evaluate and otherwise care for many of these patients requiring NPP ventilators is opposed to this possible reclassification.

The AARC, joining with many other patient, physician, supplier and provider organizations reiterates the clinical consensus that NPP ventilators are true ventilators, as defined by the Food and Drug Administration (FDA), that the patients who must use these ventilators are among the most medically fragile of the home care patient population, and that reclassification of the ventilators is inappropriate.

Moreover, there have been instances reported to the FDA regarding technical malfunctions and recalls due to failures, fires and other problems. Frequent follow up must be continued as provided by the frequent and substantial servicing classification in order to assure these devices are functioning properly.

The AARC is concerned that CMS may implement this change to address concerns regarding inappropriate placement of patients on these ventilators as well as the concern that suppliers are not fulfilling the Medicare requirements to service and maintain the ventilators at appointed intervals.

While the AARC acknowledges these are legitimate concerns, the solution does not lie in punishing those patients who clinically need the NPP ventilators and the services that are necessary to properly use them in the home environment. CMS must be more aggressive in enforcing the requirements under the frequent and substantial servicing category for

suppliers to adhere to the servicing schedule. As for the inappropriate patient placement on these ventilators, CMS has already tightened the clinical indications that must be met in order for Medicare to reimburse home care companies when providing these ventilators to qualified patients. Since Medicare's more restrictive clinical criteria have been in place, few patients other than those suffering from restrictive thoracic conditions such as Amyotrophic Lateral Sclerosis, Post Polio Syndrome and Muscular Dystrophy now use noninvasive positive pressure ventilators.

Moreover, those patients diagnosed with chronic obstructive pulmonary disease (COPD) must meet more restrictive clinical conditions prior to qualifying for NPP ventilators. Therefore, only those patients who truly require NPP ventilators will now qualify for these ventilators.

The AARC reiterates the concerns it expressed six years ago when this issue was first addressed. Our points are the same.

### **Food and Drug Administration Classification**

NPP ventilators can be readily distinguished from "intermittent assist devices with continuous pressure devices" or other respiratory assist devices currently classified under the "capped rental" category. NPP ventilators are completely different in their structure, function, and potential to fail in service.

The FDA device clearances make unambiguous distinctions between devices that are "intermittent assist devices with continuous pressure devices" and ventilators. The FDA applies the same level of scrutiny to NPP ventilators as it does in determining the safety and effectiveness of invasive ventilators. The FDA clearly recognizes that there are differences in the underlying clinical conditions that are treated with intermittent assist devices and NPP ventilators.

NPP ventilators are indicated for critical, acute, and/or long-term treatment of respiratory insufficiency and respiratory failure, whereas the FDA has cleared intermittent assist devices for obstructive sleep apnea, a less critical condition. NPP ventilators and respiratory assist devices are two mutually exclusive medical products used to treat different patient populations with separate medical protocols and procedures.

The FDA's own assessment and classification of NPP ventilators as ventilators should provide clear and unequivocal evidence that these life sustaining machines are indeed ventilators and should remain in the category of frequent and substantial servicing.

### **Clinical Justification**

There are the clinical reasons that must be taken into consideration during the decision making process. The medical condition of the patients who will require NPP ventilators and the clinical need for services from health care professionals, must be accounted for as CMS addresses this issue.

Reclassification of NPP ventilators from the "frequent and substantial servicing" category to the "capped rental" category for payment purposes will virtually eliminate the key clinical component -- that is the assessing of the patient and the servicing of the ventilator that permits NPP ventilator therapy to be an effective medical intervention.

NPP ventilators are prescribed by the physician for patients suffering from specific and severe respiratory disorders. The ventilators initiate breaths, control intervals between breaths, and inflate the patient's lungs. As with all ventilators, NPP ventilators require frequent servicing, adjustments to the ventilator, and clinical assessment of the patient's medical condition in order to assure (1) that the patient's safety and health are not being jeopardized and (2) that the patient is maximizing the medical benefits of NPP ventilator therapy.

The health risks of substandard servicing and care for patients utilizing NPP ventilators are dangerous. It is the medical standard of care for home care providers to use the skills and knowledge of respiratory therapists in providing frequent patient assessment and servicing of the equipment. Suboptimal settings or ventilator failure for NPP ventilator patients with severe COPD can result in toxic levels of carbon dioxide in the blood, carbon dioxide narcosis, carbon dioxide psychosis, irreversible brain damage, or death.

Respiratory therapists are the essential health care providers employed in servicing the patient on NPP ventilator therapy. The primary purposes of respiratory therapy patient visits are: (1) to assess the patient's physical condition and response to the therapy, (2) to ensure the ventilator is set properly in response to the patient's changing physical condition, (3) to ensure the ventilator is operating properly in a home environment that supports the proper use of the ventilator itself, and (4) to convey to the prescribing physician the patient's clinical and overall response to the NPP ventilator therapy.

It is an accepted medical standard of care that a respiratory therapist will visit the patient five to six times during the first week of therapy, three times during the second week of therapy, twice during the third week of therapy, and once during the fourth week of therapy. Thereafter, it is expected that a respiratory therapist will, at a minimum, assess the patient, the ventilator, and the home environment once every four weeks. Aggressive patient follow-up is considered the most important factor in determining the long-term success of NPP ventilator therapy.

The AARC believes that reimbursement reclassification will place patients, physicians, and at-home care providers in an untenable situation. Physicians will be reluctant to prescribe NPP ventilator therapy in a reimbursement environment that will not support the necessary critical medical assessment and servicing infrastructure. Home care providers will no longer have the financial resources to provide the clinical and servicing structural supports needed for the provision of safe and effective NPP ventilator therapy. Patients who do receive this therapy will be at risk because optimum medical standards of practice will no longer be provided.

The AARC notes as the Medicare program moves towards a competitive acquisition structure, the number of suppliers engaged in providing home care equipment will be limited. Moreover, the mandatory standards the selected suppliers will have to meet in order to be selected will be stringent. Clear and precise requirements for the servicing of all devices in the frequent and substantial servicing categories can be demanded, and monitoring and enforcement will be made easier. This is yet another reason to not move forward with the reclassification of NPP ventilators. We believe the concerns CMS has with suppliers and their responsibilities to the servicing and maintenance of ventilators will soon be eliminated.

The AARC again urges CMS to first look at the impact on the seriously ill Medicare beneficiaries who will be the ones ultimately harmed if the Agency proceeds forward with this reclassification. Demand and enforce that the suppliers of the NPP ventilators meet servicing schedules and provide all the needed documentation. Realize that competitive acquisition is on the horizon. Do not punish the Medicare patients who rely on these life sustaining ventilators in the Agency's quest to route out suppliers of the ventilators who are not meeting the established Medicare regulations.

Sincerely,

John D. Hiser, MEd, RRT, FAARC  
President

cc: Senator Mike Crapo  
Senator Blanche Lincoln