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PHYSICIAN ADVOCACY FOR EXCELLENCE IN THE DELIVERY OF PULMONARY, CRITICAL CARE AND SLEEP MEDICINE

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NAMDRC welcomes the opportunity to comment on coding decisions regarding home mechanical ventilation. We focus our comments not only on the process used by the HCPCS Alpha Numeric Workgroup but the substance of the coding changes as well.

It appears that the announcement of this coding change was embedded in a separate announcement related to competitive bidding, a pathway unusual for what is a fairly transparent process for the Workgroup. We acknowledge we are not expert in the area of the Administrative Procedures Act and its requirements, and we are only somewhat familiar with requirements tied to regulatory processes tied to inherent reasonableness rules. We do note, however, that the financial impact of this coding change reduces payment by approximately 35% for certain ventilators, an amount that seems to warrant a process other than an announcement directly tied to competitive bidding.

Aside from the process used by CMS to announce these coding changes, we fully recognize that it is impossible to comment in complete detail because of numerous corollary issues that are not addressed and would only be addressed through a broad recognition that CMS policies regarding home mechanical ventilation are archaic and inconsistent with state-of-the-art practice of medicine.

- The code descriptors refer to "home ventilator, any type…." distinguishing between invasive and non-invasive usage. Critically important is the absence of a clinically sound definition of what constitutes a "ventilator." This issue is extremely important as CMS continues to reject/ignore classifications of these devices by the Food & Drug Administration. The absence of a definition that is consistent with the clinical literature and FDA is problematic. This absence of definition becomes even more problematic because the term "ventilator" does appear in the Medicare statute (Section 1834(a)(3)(A)) and it is unclear to the pulmonary medicine community what devices CMS is referring to in its code descriptors.

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Absent a CMS clinical definition of a ventilator, it is imperative that CMS rules and regulations clearly and precisely address the purpose of a ventilator – to treat respiratory failure. Whether a beneficiary suffers from COPD, a neuromuscular disorder or hypoventilation syndrome related to obesity or a variety of mixed cardiopulmonary disorders, the purpose is always the same, whether that medical need is sporadic, nocturnal, or 24/7. Without clarifications on these matters, it is impossible to gauge the impact these proposed coding changes will have on beneficiaries and the physicians who are managing their care.

- A 2001 Decision Memo addresses a distinction between invasive and non-invasive ventilation, a distinction that is not based on current science. Medicare contractors (the DME MACs) continue to refer to and default to that Decision Memo. Specifically, the concept that removal of a ventilator would lead to imminent death is not based on any science or clinical literature. If these codes are required to adhere to that flawed concept, we cannot support this new approach to coding for home mechanical ventilation.

- The coding announcement cites a range of allowed charges for various ventilator codes, along with the average monthly rental fee. While we do not challenge those numbers, the table of utilization is followed by a statement, *"Program abuse is occurring when code E0464 is used inappropriately to bill for pressure support ventilators that can also function as and are used as positive airway pressure devices for treatment of OSA rather than treatment of respiratory failure."* This statement raises numerous issues, and without answers to these questions, it is impossible to determine the impact of the coding changes on appropriately ventilated patients.

    - We do not know of any evidence that indicates to what extent the $181M cited is program abuse. While we agree that the scenario cited is inappropriate and should not be tolerated, it is important to recognize why the dramatic increase in E0464 utilization is occurring.

      We believe that a primary reason for the noted growth is due to barriers to more appropriate devices, devices referred to by CMS as respiratory assist devices (E0470 and E0471). Physicians have learned that it is so difficult and challenging to meet current requirements for these devices that it has forced a change in behavior and more careful diagnoses that lead to a conclusion of respiratory failure. Once a physician has made a diagnosis of respiratory failure, ***and such a diagnosis must be reasonably documented,*** E0464 becomes the preferred treatment pathway. We strongly suspect that more reasonable rules that would improve access to devices the Agency arbitrarily calls RADs would impact the E0464 code total allowed charges.

      Furthermore, as the science of home mechanical ventilation has improved, it has become a useful tool for the physician and the hospital in reducing COPD all cause readmissions. As this program is generally supported by the pulmonary community, it is expected that technological tools now available be utilized to

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reach readmission targets. To view the increase in E0464 without context is flawed and unreasonable.

Importantly, technology in 464 devices have broader and more advanced capabilities that deliver better therapy for both neuromuscular and COPD patients. If a patient is stabilized in the hospital with settings that cannot be satisfied by other ventilators, then it is understandable to see a prescription/order for an E0464 device.

- As noted above, we acknowledge the statutory language that guides much of this subject, and if CMS believes that the current statute restricts the Agency from shaping more reasonable policies toward home mechanical ventilation, then the Agency should work with the pulmonary medicine community and the Congress to craft language more reflective of the state of home mechanical ventilation in 2015. But the common refrain from CMS that "just because FDA calls a device a ventilator doesn't make it a ventilator" is irrational and contrary to the genuine science of mechanical ventilation. Absent clarity of this broad issue makes new ventilator codes nothing more than a means to continue archaic and outdated policies that unfortunately impact Medicare beneficiaries in unacceptable ways.

As CMS's Coverage and Analysis Group (CAG) is aware, NAMDRC and several other societies are committed to requesting a review and updating of existing policies tied to home mechanical ventilation. In anticipation of that formal submission, several societies are meeting with CAG in mid July to review current policies tied to home mechanical ventilation, and these proposed changes are now added to our agenda of discussion points for that discussion.

Sincerely,

Tim Morris, MD
President