June 25, 2015

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via email

Re: Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators

Dear Acting Administrator Slavitt:

I am writing on behalf of the Council for Quality Respiratory Care (CQRC) to provide comments on the recent announcement entitled "Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators." The CQRC applauds the decision to reverse the phase-in of code E0464 into the DMEPOS competitive bidding program given that it is a Class III medical device that the Congress exempted from the competitive bidding program. However, the CQRC is extremely troubled that the Centers for Medicare and Medicaid Services (CMS) has announced changes to the HCPCS codes for ventilators that will dramatically alter the payment rate without going through notice-and-comment rulemaking. Given the clinical importance of noninvasive ventilators to a subgroup of Medicare beneficiaries, we strongly urge CMS to further review the impact of this change and provide for notice-and-comment rulemaking.

The CQRC is a coalition of the nation's seven leading home oxygen and sleep therapy providers and manufacturing companies. Together we provide in-home patient services and respiratory equipment to more than 600,000 of the more than one million Medicare beneficiaries who rely upon home oxygen therapy to maintain their independence and enhance their quality of life. Similarly, we provide homecare services, equipment and supplies to more than one million Medicare beneficiaries with Obstructive Sleep Apnea (OSA).

While noninvasive ventilators have been part of home respiratory therapy for many years, recent dramatic advances in the technology are allowing more patients who would otherwise be institutionalized to remain at home and in their communities by using these devices. The newer devices have algorithms that allow the devices to adjust more to the patient's dynamic needs, helping promote a significant improvement in the quality of life compared to older technology. As in

hospitals, skilled nursing facilities, and long-term acute care hospitals, noninvasive ventilators are now used routinely in the home setting because they reduce morbidity and mortality. In a recently published retrospective cohort study of a quality improvement initiative, researchers observed that a multifaceted intervention that involved initiation of noninvasive positive pressure ventilation, respiratory care led by respiratory therapists, medication reconciliation, appropriate oxygen therapy initiation, and patient education led to significant reduction in rehospitalization. *See,* Steven Coughlin, Wei E. Liang, Sairam Parthasarathy, "Retrospective Assessment of Home Ventilation to Reduce Rehospitalization in Chronic Obstructive Pulmonary Disease," 11 J Clin Sleep Med 663-70 (2015).

Other studies have also shown the clinical benefit to using non-invasive ventilators. *See*, Jonathan A. Galli, Jason S. Krahnke, A. James Mamary, *et al*, "Home non-invasive ventilation use following acute hypercapnic respiratory failure in COPD," 108 *Respir Med* 1-7 (2014) (finding patients with noninvasive positive pressure ventilation post-hospital discharge had "superior event-free survival" when compared with patients who did not receive the same home therapy); Stefano Nava & Begüm Ergan, "Long-term Non-invasive Ventilation (NIV) for COPD Patients with Chronic Respiratory Failure," 1 *EMJ Respir* 54-63 (2013) (finding that "accumulating evidence suggests that NIV also has a role in the long-term management of patients with stable hypercapnic COPD. Early nocturnal NIV therapy in these patients may reduce hospitalisation rates, improve quality of life, and reduce healthcare costs."); Thomas Köhnlein, Wolfram Windisch, Dieter Köhler, *et al,* "Non-invasive positive pressure ventilation for the treatment of severe stable chronic obstructive pulmonary disease: a prospective, multicentre, randomised, controlled clinical trial," *Lancet* published online (July 25, 2014) (finding that "the addition of long-term NPPV to standard treatment improves survival of patients with hypercapnic, stable COPD when NPPV is targeted to greatly reduce hypercapnia); *see also* Neil R. MacIntyre, Scott K. Epstein, Shannon Carson, *et al*, "Management of Patients Requiring Prolonged Mechanical Ventilation: Report of a NAMDRC Consensus Conference" 128 *Chest* 3937-54 (2005).

We understand that the Agency has expressed concern over the increased utilization of these items and has been seeking a way to better ensure appropriate utilization. Although CQRC agrees that CMS must be cautious and ensure that it is a good steward of federal dollars, CMS should also consider the basis for the increased costs, which results from increased beneficiary services due to advancements in technology. These advancements may increase costs for Part B providers, but reduces costs on the Part A side. Under the Affordable Care Act, hospitals are incentivized to reduce readmissions. For certain patients, noninvasive ventilators allow them to reduce readmissions. Thus, CMS should also engage with hospitals to determine how noninvasive ventilators help them manage patients and keep them from being readmitted and reduce unnecessary Medicare spending. Before

implementing a cut as dramatic as the one set forth in the recent subregulatory guidance, we urge CMS to carefully consider the issues that such a change would have, particularly on beneficiaries.

Without following notice-and-comment rulemaking, CMS announced through the CBIC listserv that it plans to combine the HCPCS codes for invasive and non-invasive ventilators (E0450). This will eliminate the E0464 code currently assigned to Pressure Support Ventilators (non-invasive). It has been estimated that this coding change will result in a $548 per month rate reduction.

Because this email announcement appeared in a less than transparent way that did not reach all stakeholders, we are concerned that despite the fact that CMS may receive comments on the proposal, it will not have all of the information it needs to make an informed decision regarding the appropriate reimbursement rate for noninvasive ventilators. In addition, while some interested parties, including the CQRC, have provided comments, there was insufficient information about the rationale for the change. Most importantly, if the Agency's goal is to address potential abuse of the program, the fact that the concerns of the Agency are not described makes it unlikely that those commenting will have the opportunity to provide advice as to how best to address the problem.

I. Any Change to the Noninvasive Ventilator Coding and Payment Rates Should Be Proposed through Notice-and-Comment Rulemaking

Rather than acting through subregulatory guidance, CMS should have proposed this change through notice-and-comment rulemaking. The Congress has clearly set forth how a federal agency should develop policies that have a significant impact on beneficiaries, providers, suppliers, and other interested parties by enacting the Administrative Procedures Act (APA). The APA governs agency decision-making. It requires that any federal agency provide sufficient notice and an opportunity to comment on proposed policy changes. 5 U.S.C. § 553. These requirements apply except to the extent a policy involves: (1) a military or foreign affairs function of the United States; or (2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts. *Id.* at § 553(a). In addition, unless the agency has "good cause" to find that the notice-and-comment process would be "impracticable, unnecessary, or contrary to the public interest," it must use the rulemaking process to make a rule, which is defined as

> an agency statement of general or particular applicability and future effect [that is] designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and [which] includes the approval or

> prescription for the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefore or of valuations, costs, or accounting, or practices bearing on any of the foregoing.

Id. at § 551(4).

There is also a limited exception when an agency may also avoid notice and comment and issue a final rule when a rule involves internal agency procedures, the rule affects only federal employees, or the rule manages federal property and real estate. These rules, however, may also be subject to notice-and-comment rulemaking if there is a special statutory requirement or the rule has a substantial, or legal, effect on the public. *See Community Nutrition Institute v. Young*, 818 F.2d 943 (D.C. Cir. 1987).

Given that the decision to cut the reimbursement rate for noninvasive ventilators meets the definition of a rule (it prescribes future payment rates), the change is subject to the APA's rulemaking requirements. CMS has not described, and there is not, any "good cause" as to why the rulemaking requirements should not be followed. In fact, providing all stakeholders with notice of the rate change through the *Federal Register* is the path CMS generally takes, and there is not a legitimate reason not to do so in this case. In this instance, rulemaking is neither "impracticable" nor "unnecessary." Proposing the rate change through rulemaking would also be aligned with the public interest in balancing access to noninvasive ventilators with the need to address potential concerns about overutilization. Even if some attempted to argue that the announcement is merely a procedural change, this change could have a substantial effect on beneficiaries, their families, physicians, and other stakeholders. Thus, the exceptions to following the notice-and-comment rulemaking requirements would not apply in this instance.

While it is true that CMS announced the HCPCS code change and provided a comment period, this process does not follow the APA requirements. Among other things, the notice must be published in the *Federal Register* and interested parties must be provided with at least a 30 days to comment on the proposal. 5 U.S.C. §§ 553(b) & (c). In addition, Executive Order 12866 suggests that agencies allow the public at least 60 days to comment for "significant" rules. Providing the announcement through a listserv and allowing substantially less than 30 or 60 days for commenting does not meet these requirements.

II. Cutting Payment Rates Will Not Address the Agency's Underlying Coverage Concerns

We understand that CMS is concerned that under current law, some suppliers may be inappropriately abusing the program. Addressing abuse should be done through program integrity policies rather than trying to stop a few bad actors by cutting payment rates, and potentially restricting beneficiary access to needed services. Others in the industry, including the National Association for Medical Direction of Respiratory Care, the Amyotrophic Lateral Sclerosis (ALS) Association, the American Association for Respiratory Care, the American College of Chest Physicians, the American Thoracic Society, the Cystic Fibrosis Foundation, the COPD Foundation, the International Ventilator Users Network, the Pulmonary Fibrosis Foundation, the Pulmonary Hypertension Association, and the United Spinal Association have recently asked CMS to amend its current policies to clarify the requirements to allow beneficiaries to receive appropriate devices while also reducing abuse of the program. The CQRC supports these efforts and would like to continue working with CMS to develop and implement appropriate coverage policies. Simply cutting rates will not achieve this goal.

In addition, CQRC members are extremely troubled by the concept of retroactively applying the new coverage policy requirements. It is impossible to meet documentation standards that are not promulgated until well after a patient has seen his or her physician. Any policy modifications should be prospective. To follow a different path would be to violate a core value of the American judicial system that prohibits the retroactive application of laws. Following this approach would place patients at risk of losing needed therapy because of administrative issues with capturing needed information after the fact.

CMS should provide all interested stakeholders with the opportunity to provide suggestions on how to address its coding, coverage, and payment concerns and work with the industry to stop abuses of the program, while ensuring that beneficiaries who qualify for it are able to access new technologies.

III. Conclusion

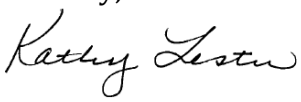
In conclusion, we appreciate the opportunity to share our concerns regarding the announcement to modify the HCPCS codes that apply to noninvasive ventilators. As clinical research has shown, noninvasive ventilators allow more patients who would otherwise be institutionalized to remain at home. This significantly reduces hospital readmissions, and as a result reduces Medicare Part A expenditures.

Rather than finalize this policy, we believe CMS should follow the notice-and-comment requirements set forth in the APA. In doing so, CMS will have the opportunity to obtain comments from all interested parties, not just those that

stumbled upon the announcement. These comments may also provide CMS with better alternatives that will protect Medicare dollars in a more targeted manner and establish an appropriate reimbursement rate.

We look forward to working with you on ways to improve the home respiratory therapy benefit. Please do not hesitate to contact me at klester@lesterhealthlaw.com or (202) 534-1773 if you have any questions about our concerns or would like to discuss other mechanisms for ensuring the appropriate utilization of noninvasive ventilators.

Sincerely,



Kathy Lester
Executive Director
Council for Quality Respiratory Care