November 30, 2015

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

Re: Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators and National Coverage Determination (NCD) Regarding Ventilator Coverage

Dear Acting Administrator Slavitt:

I am writing on behalf of the Council for Quality Respiratory Care (CQRC) to express concerns regarding two issues of the utmost importance to Medicare beneficiaries and to providers and manufacturers of durable medical equipment (DME). Both of the issues relate to unilateral changes made by the Centers for Medicare and Medicaid Services (CMS) and/or DME Medicare Administrative Contractors (DME MACs) to longstanding, important reimbursement rules regarding non-invasive ventilators without giving statutorily required notice or opportunity to comment by stakeholders.

The CQRC is a coalition of the nation's eight 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.

In brief, the first issue involves a significant rate change that was announced informally by means of a listserv rather than by notice-and-comment rulemaking proceedings as required by the Administrative Procedures Act (APA), 5 U.S.C. §§ 501 et seq., and as confirmed by the United States Supreme Court in 2015 and places at risk those Medicare beneficiaries who increasingly rely upon non-invasive ventilators in their homes.
The second issue involves what appear to be coordinated decisions by the DME MACs to reject ventilator claims that fall squarely within the scope of coverage of a governing National Coverage Determination (NCD) and prior coverage decisions. This mistaken and misguided effort of the DME MACs in seeking to apply coverage criteria for invasively ventilated patients in the non-invasive setting is having and will continue to have a palpably negative clinical effect on Medicare beneficiaries.

Previously, beneficiaries could receive ventilator care only in an institutional setting, but recent technological advances now allow more beneficiaries to use these devices in the home setting. As a result, beneficiaries with severe chronic respiratory failure are experiencing significant quality of life improvements as these devices have the life-giving effect of "freeing" patients from their hospitals beds and returning home. This shift to the home setting has corresponded with a significant reduction in Part A costs. In fact, one of our members, a leading respiratory provider, has observed an approximately 70 percent reduction in preventable respiratory admissions in the first 16 months of its non-invasive ventilation program. Research demonstrates that these Medicare beneficiaries are also subject to lower rates of morbidity and mortality and that they receive enhanced clinical benefits stemming from use of non-invasive ventilators. We provided highlights of the research studies in our previous letter, which I have also attached.

I. CMS' Proposed Fee Schedule Changes Constitute a Rate Cut and Requires APA Notice-And-Comment Rulemaking Procedures To Be Implemented.

On June 25, 2015, the CQRC submitted comments regarding CMS' June 4, 2015 announcement entitled "Internal Healthcare Common Procedure Coding System (HCPCS) Decision Regarding Codes for Ventilators." This announcement proposed (1) a recalibration of HCPCS codes for invasive and non-invasive ventilators, including retirement of certain codes and introduction of two new consolidated codes; and (2) a payment reduction whereby the resulting new codes would be reimbursed at lower rates than the rates paid previously for the same DME items. This constitutes a rate cut for those items ranging from $505.79 to $664.07 per month based on the 2016 floor and ceiling fees published in the CMS Medicare Fee Schedule. This effectively reduces ventilators to the reimbursement level CMS paid nearly 30 years ago (1986-87), when ventilator technology was much less developed, and despite the increase in the costs and efficacy of ventilator products and therapy since then. CMS made the announcement by means of a listserv, rather than through the notice-and-comment rulemaking process that is required by the APA. CMS announced on Friday, November 6, 2015, that it has decided to move forward with the coding recalibration element of this proposal. CQRC acknowledges CMS' long-standing authority to undertake coding system recalibrations without notice or comment under the APA. However, CMS indicated in its initial announcement that in addition to the coding recalibration, it proposed to implement the payment alteration, effectively cutting the reimbursement rates. This rate cut constitutes a substantive change under the APA and, therefore, should be made through notice-and-comment rulemaking.

Unilateral changes to DME payment parameters cannot be made without proper notice to and opportunity for comment by stakeholders. The APA requires that administrative agencies provide notice of proposed rulemaking in the Federal Register, allow for a comment period of at least 30 days during which interested stakeholders may submit their comments, and issue a final rule containing a concise general statement of the rule's basis and purpose. 5 U.S.C. § 553. "Rules" are defined to include "the approval or prescription for the future of rates. . ."; as such, rate changes or fee schedule adjustments fall under the definition of a "rule." There are two exceptions to the notice-and-comment rulemaking requirements:

1. Interpretative rules, general statements of policy, or rules of agency organization, procedure or practice; and

2. When the agency for good cause finds (and incorporates the finding and brief statement of reasons therefore in the rules issued) that notice and public procedure are impracticable, unnecessary, or contrary to the public interest.

In March 2015, the Supreme Court held that agencies are required to follow notice-and-comment rulemaking procedures upon amendment or repeal of their substantive rules. *Perez v. Mortgage Bankers Ass'n*, 135 S.Ct. 1199 (U.S. 2015). In articulating a definition adopted by the Supreme Court, the Court of Appeals for the D.C. Circuit has stated that substantive rules are "ones which grant rights, impose obligations, or produce other significant effects on private interests . . . or which effect a change in existing law or policy." *Perez* at 1204*, citing American Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1045 (D.C. Cir. 1987). The types of rules that fall under the "interpretive" exception are those that "merely clarify or explain existing law or regulations . . . [and are] essentially hortatory and instructional . . . [and] do not have the full force and effect of a substantive rule but [are] in the form of an explanation of particular terms." *American Hosp. Ass'n* at 1045.

The difference between substantive and interpretive rules is well demonstrated by two recent cases from the D.C. Circuit Court of Appeals. In *American Hosp. Ass'n v. Bowen*, the D.C. Circuit held that manuals setting forth an enforcement plan for Department of Health and Human Service agents in monitoring various operations were interpretive rules because they simply implemented an existing framework which had already been set forth by Congress and did not add any new standards or presumptions that would alter the rights of the parties. *Id.* In contrast, in *Mendoza v. Perez*, 754 F.3d 1002, 1024 (D.C.Cir. 2014), the court held that certain Training and Employment Guidance Letters issued by the Department of Labor constituted substantive rules, not procedural rules, because, rather than simply setting forth an enforcement plan, the regulations "alter[ed] the standards imposed on herding employers seeking H-2A certification. They are not procedural, but substantive rules." *Id.* at 1024. The changes to the noninvasive ventilation codes and rates include a 35 percent reimbursement reduction on the items billed under the E0464 code assigned to Pressure Support Ventilators (non-invasive).

The reimbursement rate reduction will "effect a change in existing law or policy" and will produce a "significant effect on private interests" and, thus, falls squarely within the definition of "substantive rules" articulated by the Supreme Court. Specifically, the payment reduction "effects a change in existing law or policy" in that implementing the proposed payment change is not in accordance with the existing substantive rules governing reimbursement for DME items set forth at 42 U.S.C. § 1395m(a)(2)-(3) and 42 C.F.R. § 414.200 – 414.232. Furthermore, the proposed change will produce a "significant effect on private interests." These interests include the estimated 100,000 to 200,000 Medicare oxygen patients who may also benefit from NIV therapy to maintain their independence and enhance their quality of life, as well as home respiratory therapy providers and manufacturers. Accordingly, implementation of the payment reduction is contrary to the requirements of the APA because CMS has not adhered to the notice-and-comment rulemaking requirements. In light of the negative impact on beneficiaries being able to access this critical therapy that these proposed changes are certain to have, in addition to statutory requirements, we urge CMS to rescind the announcement and issue a notice of proposed rulemaking that allows for a full comment period. After the comment period, CMS should objectively evaluate the policy based on the comments received and finalize it only if the comments support doing so.

II. The Impermissible Deviation from the NCDs Issued by CMS for Ventilator Coverage also Threatens Beneficiary Access to Non-Invasive Ventilation Therapy.

The NCD for DME Reference List (280.1) states that ventilators are covered for treatment of neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure consequent to COPD, including both positive and negative pressure types. Under federal law, "An NCD is binding on all Medicare carriers, fiscal intermediaries, QIOs, HMOs, CMPs, HCPPs, the Medicare Appeals Council, and ALJs." 42 C.F.R. § 405.732(a)(4). Moreover, Section 13.5.1 of the of the Medicare Program Integrity Manual, Chapter 13, "Local Coverage Determinations," (the PIM), " states that [o]nce published in a CMS program instruction, an NCD is binding on all Medicare carriers/DMERCS, FIs, [etc.] . . . The contractor shall apply NCDs when reviewing claims for items or services addressed by NCDs."

Despite the broad coverage for ventilators set forth in the NCD, in a rapid, dramatic departure from long-standing reimbursement policy and practice, the four DME MACs have recently, and in most cases, without prior notice to suppliers, rejected claims for ventilators covered by the NCD. For example, Noridian released a "Questions & Answers" (Q&A) document in September 2015 (see Attachment 2) stating that "[i]t is expected that a beneficiary being provided a ventilator would require usage 24 hours per day, 7 days per week for a condition that is life-threatening if there were to be interruption in respiratory support." As an exemplar of the types of denials our members are currently receiving, we have also included a copy of a ventilator services claim rejection from Noridian (see Attachment 3). (Note that this rejection document erroneously references a substantively inapplicable, and, in fact, retired, Local Coverage Determination (LCD) as a basis for the rejection). The scope of coverage articulated in these documents is significantly narrower than the scope of ventilator services covered under the NCD. The NCD makes no reference to any requirement for 24/7 usage or any time-restriction language at all. Presumably, Noridian views the Q&A cited above as providing some basis upon which to justify denials for ventilator services for reasons of medical necessity. However, the PIM states that:

> "Contractors shall develop LCDs when they have identified an item or service that is never covered under certain circumstances and wish to establish automated review in the absence of an NCD or coverage provision in an interpretive manual that supports automated review." PIM at § 13.4(A).

We were not able to locate an LCD issued by Noridian or any of the DME MACs which sets forth this new "24/7" requirement. To the extent that the DME MACs wish to create a blanket policy for denials, they are required by the PIM to develop an LCD stating so. The PIM sets forth required procedures for developing such an LCD, including (in certain cases) notice-and-comment and other procedural requirements. PIM at § 13.1.4. DME MACs are not authorized to skirt the requirements for development of LCDs while adopting what is, in practice, an LCD which drastically reduces the coverage of the NCD and renders many claims outside the scope of coverage that were previously within the scope of coverage.

The CQRC urges CMS to instruct the DME MACs that they are bound by the scope of the NCD and that, if they choose to develop automated denial mechanisms incorporating clinical criteria not set forth in the NCD, they are legally obligated to develop LCDs to implement such restrictions. It is not permissible for the MACs to implement automated denials when they have not set forth a clear policy upon which to predicate these denials and when they have not developed LCDs providing guidance regarding these coverage decisions.

III. Conclusion

The CQRC appreciates the opportunity to share our concerns regarding the policy changes that are dramatically impacting access to non-invasive ventilators. In sum, we ask that (1) CMS rescind the subregulatory guidance modifications to the codes and rates for non-invasive ventilators and if it wishes to adopt such changes follow the notice-and-comment rulemaking requirements set forth in the APA; and (2) CMS instruct the DME MACs to stop denying claims for non-invasive ventilators by applying criteria that are not included in the current NCD and to abide by the required process for developing LCDs if they believe there should be other criteria for reviewing such claims. We would welcome the opportunity to discuss these concerns with you in more detail as well. Please do not hesitate to contact me at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions.

Sincerely,

Kathy Lester

Kathy Lester
Executive Director
Council for Quality Respiratory Care

cc: William Schultz, General Counsel, Department of Health and Human Services
Janice Hoffman, Associate General Counsel, Centers for Medicare and Medicaid Services
Sean Cavanaugh, Deputy Administrator & Director, Center for Medicare
Laurence Wilson, Director, Chronic Care Policy Group, Center for Medicare
Megan Worstell, Acting Director and Chief Financial Officer
Melanie Combs-Dyer, Director, Provider Compliance Group