By electronic mail to: ***CodingComments@cms.hhs.gov***

June 25, 2015

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Comments on the Proposed Changes to Coding and Payment to Ventilators

Dear Sir or Madam:

We are responding to your request for comments on a proposal to terminate the existing HCPCS codes for invasive and noninvasive pressure support and volume ventilators, group those devices together under two new codes depending on their interface, and pay for all ventilators at the lowest Medicare allowable for one of the deleted volume ventilator codes. The Centers for Medicare and Medicaid Services (CMS) made this request in a document found under a link in an unrelated announcement disseminated *via* a CBIC push email concerning another topic sent June 4, 2015. Since then, we have become aware that the Agency views its request for comments on the proposed coding and payment changes as part of a "limited demonstration" for:

> [A] web-based notice and comment mechanism allowing public input on requests to discontinue Level II HCPCS codes that are generated internally based on national program operating needs; not the subject of other notice and comment mechanisms; are not replaced by other or new codes.[1]

The Agency added this information to its website on June 4, 2015 under a webpage it called *Internal Coding Decisions* next to links announcing the dates for 2015 public coding meetings required under § 531 (b) of the Benefits Improvements and Protection Act (BIPA).[2] CMS requested comments on the coding change and payment reduction by June 25, 2015.

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[1] http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS-Coding-Decisions.html.
[2] PL 106–554 § 531 (b) (2000).

The American Association for Homecare (AAHomecare) represents over 600 suppliers and manufacturers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Our members are an important part of the continuum of care who works together with physicians, other practitioners and family caregivers to see that beneficiaries receive safe and effective respiratory therapies in their homes. Our members include suppliers, manufacturers, and clinicians, all with extensive education, training or on-the-job expertise working with the patients and ventilators affected by this CMS proposal. The following comments are informed by the knowledge and experience of our members.

First, we must emphasize our surprise in the way CMS handled the dissemination of its request for comments, contending that its actions represent a "limited demonstration" to eliminate obsolete codes and allow for *some form* of public feedback in situations that do not require formal notice and comment.[3] On the contrary, the Agency's actions go well beyond internal coding changes that affect only obsolete codes. There is no rationale that supports CMS' conclusion that the Agency does not have to explain its reasons for reducing Medicare payment amounts by more than 30% for pressure support ventilators without notice and comment in the Federal Register.

AAHomecare is unaware of any authority that would permit CMS to effectuate a 33.5% payment reduction on any item or category of items by way of a coding action. Nor is AAHomecare aware of any "demonstration" authority that permits CMS to by-pass notice and comment for actions that otherwise *require* formal process under controlling statutory authorities, including the Social Security Act (SSA), the Administrative Procedure Act (APA), and federal case law. All of these authorities require CMS to withdraw the proposed coding and payment change and at a minimum publish a proposed notice in the Federal Register with a 60 day comment period, followed by a final notice and a response to the public comments. AAHomecare also recommends that CMS convene a public meeting like the ones the Agency holds for new DME under BIPA § 531 (b). We address these issues in more detail below.

CMS exceeded its authority to administer Level II HCPCS codes by proposing a 33.5% payment reduction in the Medicare allowable for HCPCS E0463 and E0464 ventilators in a notice announcing coding changes for positive pressure support and volume ventilators.

1. **CMS must explain the reasons for its decision to make a 33.5% payment reduction for noninvasive pressure support ventilators, publish the evidence it used to arrive at the decision and allow everyone affected by the payment reduction to submit comments in response to a notice in the Federal Register with a new 60 day comment period.**

2. **A stakeholder meeting similar to those CMS holds for new DME technologies under BIPA § 531 (b) is the only way to adequately address the public concern with the Agency's plan to change coding and reduce payment for noninvasive positive pressure ventilators.**

3. **CMS' proposal to effectuate a payment reduction through a change in coding violates the SSA which establishes separate procedures for coding, coverage, and reimbursement.**

[3] http://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCS-Coding-Decisions.html

Beneficiaries, clinicians and suppliers need to understand the rationale and the evidence supporting CMS' decision to impose a 33.5% payment reduction on noninvasive pressure support ventilators.

There is no authority that would permit CMS to make a 33.5% change to the fee schedule payment amount for a DME item by way of a coding change. CMS may have the authority to manage the HCPCS code set, but the Agency does not have authority to use coding decisions to make large payment adjustments without any transparency or procedural protection for beneficiaries or suppliers. The SSA and the APA, and other Medicare statutory and regulatory authorities require CMS to broadly disseminate notice of this proposal, especially given the magnitude of the payment reduction the Agency plans to impose.[4] This means that CMS must publish a notice in the Federal Register with at least a 60 day public comment period. But in addition to using formal notice and comment, CMS must be specific about the substance of its actions.

For one, CMS must explain how the Agency determined that a 33.5% payment adjustment for E0463 and E0464 ventilators is necessary, and what if, any, evidence CMS considered in arriving at that decision. CMS' rational for the payment reduction is difficult to discern from a straightforward reading of the Agency's notice. The notice states that suppliers have abused E0464 ventilators by furnishing them to beneficiaries with Obstructive Sleep Apnea (OSA), a diagnosis for which the device is not covered by Medicare. This suggests that one rationale is CMS' perceived abuse of noninvasive ventilators. But CMS does not cite any evidence to back this statement except for figures suggesting higher utilization without attribution to a cause.

Imposing a large payment cut on ventilators that are designed for very sick patients in response to perceived abuse punishes beneficiaries without regard to how the reimbursement cuts will affect them. Payment adjustments are an imprecise response to the misuse of program funds. CMS has better, more targeted tools that weed-out unnecessary utilization without jeopardizing adequate care.

One that we suggest is prior authorization which has worked very well in a demonstration with power wheelchairs and both CMS and DME suppliers agree it can be successfully expanded to other areas of the DME benefit.

The differences in technology between pressure support and obsolete volume ventilators require separate coding and reimbursement for each type of ventilator.

We also suggest that CMS convene a stakeholder meeting like the ones the Agency holds for new DME under § 531 (b) BIPA. As noted, CMS also proposes to delete five ventilator HCPCS codes, create two new codes and cross walk the devices in each of the five deleted codes to one of the new codes. CMS will assign the lowest Medicare allowable for the deleted codes as the payment rate for the new codes without any consideration for differences in technology among the devices.

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[4] 42 USC § 1395hh; 5 U.S.C. § 553; *Mercy Med. Skilled Nursing Facility v. Thompson*, 2004 WL 3541332, at 1 (D D.C. May 14, 2004), citing, *Alaska Professional Hunters Association, Inc. v. FAA*, 177 F. 3d 1030 (D.C. Cir. 1999) holding that departures from longstanding agency practice must occur through rulemaking.

The payment amount CMS proposes to use is the current fee schedule payment for products under E0450 and E0461. These codes describe mostly obsolete technology, volume ventilators with no pressure support, that are no longer manufactured, although older devices remain in use. Combining E0463 and E0464 ventilators, which became available in 2005, with obsolete devices that are no longer manufactured contradicts CMS' longstanding interpretation of its own reimbursement rules. These newer, positive pressure ventilators were not then, and are not now, comparable to volume ventilators available before 2005. CMS correctly placed the new ventilators in their own codes when they were introduced in 2005 and they continue to require their own code today.

The new pressure support technology also did not exist when Congress created the fee schedules and CMS calculated them using DME charge date from the fee schedule base year. When this occurs, CMS uses the manufacturer's MSRP data and gap-filling to arrive at a fee schedule payment amount. This longstanding practice is by now an engrained interpretation of CMS' reimbursement rules and CMS cannot depart from the practice without formal notice and comment.[5] E0463 and E0464 ventilators do not belong in the same codes with obsolete volume ventilators and they cannot paid at the same fee schedule rate.

CMS has not considered how the proposed payment reduction will affect beneficiaries who use noninvasive pressure support ventilators. These patients are very sick and require greater time and labor resources from their suppliers, justifying higher levels of reimbursement.

We are surprised that CMS would propose a 33.5% payment reduction for these ventilators without first trying to understand what it takes to care for the patients who use them. These patients have extensive service needs and require ongoing monitoring and device adjustments that are especially intense at the start of care. When determining reimbursement for E0464 ventilators, it is important for CMS to recognize the intensity of the care these patients need in order for suppliers to provide appropriate, timely care of an adequate quality for these patients.

During initial phases of home therapy, patients require careful assessment, ongoing monitoring, and titration of their equipment. Patients who use noninvasive positive pressure support ventilators also require consistent follow-up, typically by respiratory care personnel. In our experience, this early phase is important to achieve effective patient compliance and maximum therapeutic benefit. The patient and family caregivers also receive education on the importance of compliance and equipment use and maintenance during this phase.

After this initial phase, patients are evaluated for their response to therapy and recommendations for changes to the plan of care, if any, are communicated to the treating physician. Follow-up includes assessments for complications and monitoring to ensure adequate compliance with the treatment plan. Ongoing follow-up allows the appropriate member of the health care team to intervene to correct or avoid the potential for serious problems. Many patients, especially end stage patients continue to require intensive monitoring and follow-up. Typically, registered respiratory care personnel perform follow-ups for patients in all phases of treatment.

[5] *Ibid*.

This is a highly simplified version of the steps that go into caring for a patient using noninvasive positive pressure support ventilation. Attached for your reference is a list that summarizes in more detail what suppliers do to care for these very sick patients. CMS must also consider that many fragile pediatric patients use E0463 ventilators and payment reductions will also affect their care.

Although CMS asserts that the internal coding changes at issue now are not subject to *any form* of process, especially because the Agency must remain "nimble," AAHomecare believes that even formal notice in the Federal Register would be insufficient to sort through the differences in the design and special features among ventilators, the appropriate fee schedule determinations for each type of device and the proper level of reimbursement to ensure adequate beneficiary access, choice, and the appropriate level of intensity and quality of services noninvasive positive pressure ventilator patients need. All these concerns should be heard in a stakeholders' meeting where CMS explains the Agency's reasons for reducing payment for positive pressure ventilators by 33.5%, the evidence that supports that decision and listens to and responds to the concerns of clinicians, patients, and suppliers who are affected by the payment cuts.

CMS cannot effectuate a payment change for E0463 and E0464 ventilators simply by deleting the codes and cross walking the ventilators to a new code to which CMS *assigns* the price from one of the older deleted codes for a obsolete ventilators that were on the market many years before 2005 when E0463 and E0464 ventilators were introduced and that are no longer manufactured.

Congress established distinct statutory processes for determining coverage and payment for Medicare covered items under the SSA. For DME items, payment occurs under fee schedules established from the average reasonable charge data from the fee schedule base year 1986–1987. CMS has significant delegated discretionary authority to make national and local coverage determinations, NCDs and LCDs respectively, under the "reasonable and necessary" clause of the SSA. Congress also recognized the distinctions among payment, coding and coverage as it did under BIPA § 531 (b) when it required CMS to convene public meetings to address stakeholders' concerns about CMS' coding and payment decisions for new DME technologies. CMS has reinforced these distinctions, by frequently reminding the public that coding coverage and payment are separate processes.

While CMS may have significant discretion to determine coverage and to administer the HCPCS code system, CMS cannot use either coding or coverage to make payment adjustments. These must occur under the dictates of the fee schedules or other statutory or regulatory processes.[6] Our experience has been that CMS adheres to and applies a strict interpretation of the fee schedule statute and the requirement that DME items fall within the literal terms of that statute for reimbursement purposes. Recently for example, CMS changed the payment category for DME items that were "expensive" and not "routinely purchased at least 75% or more of the time during the fee schedule base year" to the "capped" payment category because the items did not exist during between July 1, 1986 through June 30, 1987.[7]

[6] See *e.g.*, *Hayes v. Sebelius, 589 3d 1279(D. DC< 2009)* (holding that CMS could not use a least costly alternative policy in an LCD to by-pass the statutory reimbursement policy for brand name drugs Congress enacted under the Medicare Modernization Act of 2003).

CMS' longstanding policy has been to use a gap-fill methodology for new technology that did not exist during the DME fee schedule base year.[8] Gap-filling has been in place for as long as the DME fee schedules and its use has been approved by the courts.[9] An agency's use of a longstanding policy like gap-filling becomes engrained like a regulation so that the agency cannot depart from its use without formal notice and comment.

CMS has itself adhered to gap-filling over the years, and the Agency justifiably used gap-filling to determine the payment amounts for E0463 and E0464. These ventilators were introduce in 2005 at a time when ventilators identified under HCPCS codes already in existence had been on the market for many years and are now obsolete and no longer manufacture. Fee schedule payment amount for devices that are no longer made cannot be the reference point for ventilators in use today. In light of this history and current facts, CMS's proposal to cross walk these new sophisticated ventilators to another code, combine them with obsolete technology and simply assign to them a new lower payment based on devices that no one is making directly contradicts years of Agency practice and the Agency's historical interpretation of its the fee schedule regulations. CMS cannot depart from more than 25 years of interpreting and applying the fee schedules and its own reimbursement regulations without a rule making procedure.

We also believe that CMS cannot undertake a payment reduction of this magnitude simply by consolidating HCPCS codes without providing the public any transparency about the data the Agency used. This coding action exceeded CMS' authority to administer the Level II HCPCS code set, set aside its own Agency practice, the interpretation of its own reimbursement regulations, and the dictates of the SSA which recognizes the distinctions among coding, payment and coverage and obligate CMS to keep those processes separate.

Conclusion

CMS has not made the case to support a 33.5% payment reduction for noninvasive pressure support ventilators, has not followed appropriate due process, has not considered the needs of beneficiaries or the differences in technology among pressure support and volume ventilators, and has used a coding decision to make a payment change for a DME item contrary to the reimbursement scheme under the SSA and CMS' longstanding practice of maintaining separate processes for coding, coverage and reimbursement and of using gap-filling to account for new technologies that did not exist during the fee schedule base year.

Taking all of this into consideration, and in light of the short deadline and lack of information we were provided for responding to this request for comments, AAHomecare recommends that CMS withdraw the coding and payment proposal for positive pressure support and volume ventilators and start over with a proposed notice in the Federal Register that explains the reasons for CMS' decision, the evidence

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[7] Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 78 FR 72156-01 (December 22, 2013)

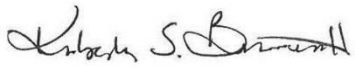
[8] See e.g., Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues , 71 FR 25654-01 (May 6, 2006), discussing the history of gap-filling the fee schedules and the Agency's plan to issue a proposed gap-filling rule. As we have noted throughout these comments, CMS has made no factual finding with respect to the payment amounts for E0463 and E0464 ventilators.

[9] La Casa Del Convaleciente v. Sullivan, 965 F. 2d 1175, 1176 (1st Cir. 1992)

that supports it and the Agency's assessment of how it will affect beneficiaries and suppliers. In addition, AAHomecare recommends that CMS convene a public meeting so that these issues and issues pertaining to the technology and payment rates that support adequate care for beneficiaries can be fully addressed.

Thank you for the opportunity to submit these comments.

Sincerely,



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