



Via Electronic Mail

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Re: Local Coverage Determination for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea

Dear Drs. Hughes, Oleck, Hoover, and Whitten:

The American Association for Homecare is pleased to submit the following comments on the Local Coverage Determinations (LCDs) in Durable Medicare Equipment Medicare Administrative Contractor (DME MAC) Jurisdictions A, B, C and D addressing Positive Airway Pressure Devices (PAP) for the Treatment of Obstructive Sleep Apnea (OSA). The new LCDs were published in July 2008 with an implementation date of September 1, 2008 and make extensive and substantive revisions to the existing LCD for CPAP devices. Specifically, the policy adds new conditions of coverage, including medical necessity criteria without identifying the research sources on which the new coverage criteria are based. The LCD also limits the types of physicians eligible to furnish Medicare covered services and creates unnecessary hurdles to care for Medicare beneficiaries requiring treatment with PAP devices. We are requesting that the four DME MACs substantially revise the LCD to address our concerns and open the new LCD for public comments so that all stakeholders who are affected by the new policy have an opportunity to comment. We also request a delay in the implementation of the policy in all four DME MAC jurisdictions to ensure that physicians and HME suppliers are educated on the new policies and have sufficient time to achieve compliance for the benefit of their patients.

AAHomecare is the national trade association representing the homecare community. The Association represents health care providers and manufacturers that serve the medical needs of Americans who require sleep therapy technologies, oxygen equipment and therapy, mobility assistive technologies, medical supplies, inhalation drug therapy, home infusion, and other home medical equipment, therapies, services, and supplies in their homes. Our membership reflects a broad cross-section of the homecare community including national, regional, and local providers operating approximately 3,000 locations in all 50 states. AAHomecare and its members are committed to advancing the value and practice of quality health care services at home. These comments have been prepared by AAHomecare members who are clinicians with expertise as respiratory care practitioners and experts in Medicare reimbursement.

I. BACKGROUND

Sleep apnea is a disorder characterized by periods of apneas and hypopneas (lack of breathing cessation and reduced flow of breathing respectively). Obstructive sleep apnea is the most common form of sleep apnea and is characterized by the partial or complete collapse of the upper airway during sleep. Symptoms of OSA include daytime sleepiness, fatigue, headaches, and cognitive impairment. OSA can lead to serious health risks, including but not limited to: hypertension, increased risk of stroke, congestive heart failure, coronary artery disease, and increased risk of being involved in a motor vehicle accident.

OSA was clinically recognized more than 30 years ago and is considered today to be a major public health problem in the United States.^{1,2} The prevalence of OSA in North America is estimated to be as high as 1 in 5 adults for mild sleep apnea (defined by the Apnea-Hypopnea Index (AHI) ≥ 5) and 1 in 15 for moderate to severe sleep apnea (defined by AHI ≥ 15).³ Despite the high incidence of the disorder, the vast majority of patients with OSA are neither diagnosed nor receiving treatment.

While there are a number of treatment options for OSA, including surgery, the most prevalent, cost-effective, and preferred form of therapy involves the non-invasive application of positive airway pressure (PAP) to the upper airway.⁴ Types of PAP treatment include continuous positive airway pressure, bilevel PAP, and automatically adjusting PAP (APAP). The PAP device delivers a flow of air at a prescribed pressure through the upper airways using a noninvasive nasal or oral interface. The air, flowing under pressure, produces a splint-like effect that keeps the airway open during both inhalation and exhalation. Since 1987, the Centers for Medicare and Medicaid Services (CMS) have covered the use of PAP devices for patients with “moderate or severe OSA for whom surgery is a likely alternative.” The National Coverage Determination that

¹ Guilleminault C, Tilkian A, Dement WC. The Sleep Apnea Syndromes. *Annu Rev Med* 1976; 27: 465-484.

² Institute of Medicine of the National Academies. Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem. Washington DC; National Academies Press 2006.

³ Young T, Peppard PE, Gottlieb DJ. Epidemiology of Obstructive Sleep Apnea. *Am J Respir Crit Care Med* 2002;165: 1217-1239.

⁴ Gay P, Weaver T, Loube D, Iber C. Evaluation of Positive Airway Pressure Treatment of Sleep Related Breathing Disorders in Adults. *Sleep* 2006;29 (3): 381-401.

CMS issued in 1987 was consistent with the consensus opinion on the diagnostic criteria for OSA at that time.

In 2001, CMS revised the NCD for the use of CPAP and other PAP devices for the treatment of OSA to reflect current diagnostic criteria for OSA. Medicare will cover and pay for PAP for the treatment of adults with OSA who meet the following diagnostic criteria when diagnosed via a laboratory-based, attended comprehensive multi-channel sleep study (polysomnography):

- AHI > 15 events per hour, or
- AHI > 5 and < 14 events per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease or history of stroke.

Last year, CMS undertook a new coverage analysis to determine whether Medicare should pay for PAP devices for the treatment of OSA diagnosed using a home sleep test (HST). In March, CMS published a new NCD that significantly liberalizes Medicare coverage for the use of PAP devices to treat individuals diagnosed with OSA. Treatment of OSA with a PAP device is covered by Medicare for an initial 12 weeks when OSA has been diagnosed using *either* a polysomnography *or* an HST performed with Type II, Type III and Type IV home sleep monitoring devices. The new NCD also revises the AHI criteria necessary for a diagnosis of OSA. In July 2008, the DME MACS published a new LCD for PAP devices to implement the NCD.

II. COMMENTS

A. The DME MACS Must Withdraw The New LCD And Publish a Draft LCD for PAP Devices with an Open Comment Period

The recently released DME MAC LCDs revise coverage and payment policies regarding PAP devices for the treatment of OSA ostensibly to conform the existing policy to the requirements of the new NCD. Medicare carriers are required to adhere to the requirements of Medicare NCDs and all applicable statutes and regulations in developing new or revised coverage policies.⁵ LCDs that contain new coverage criteria that restrict coverage or limit who may furnish a Medicare-covered service must be published in draft form and open for public comment.⁶ Importantly the carriers must publish the research sources on which they based the new policy.⁷ In contrast, LCDs that expand coverage, or merely make technical changes to the policy to conform to other

⁵ Medicare Program Integrity Manual (PIM), Pub. 100-8, Chapter 13, available at: <http://www.cmc.hhs.gov>.

⁶ See 42 USC §1395hh (a) (2) (2008), requiring the Secretary to publish for notice and comment any “requirement or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, payment for services, or the eligibility of individuals, organizations and entities to furnish services” under the Medicare program. For most aspects of the new LCD we do not contend that the LCD must be published for formal notice and comment as §1395hh (a) would require, the new LCD must at least be open for informal comment as required under the PIM based on the criteria identified in this statute.

However, as we describe in our comments below, to the extent the new LCD limits who is eligible to interpret a sleep study, which is service covered by Medicare as diagnostic test, CMS is required by the statute to amend the regulation establishing the conditions of coverage for diagnostic tests via a proposed rule.

⁷ PIM at 13.7.

Medicare changes, (such as new Healthcare Common Procedure Coding System codes (HCPCS codes)) do not need to be open for comment.

Chapter 13 of the Medicare Program Integrity Manual (PIM) establishes specific procedural requirements that must be followed when a new LCD is published or an existing LCD is revised in a manner that restricts coverage for a Medicare benefit. Carriers are required to provide a comment period on the draft LCD of at least 45 days and a minimum of 45 days' notice before implementation of a final LCD. Importantly, contractors are required to solicit comments from the general public, affected members of the clinical community (including both general practitioners and specialists), and are required to provide an open meeting for discussion of the draft LCD.

The new LCD on coverage of PAP devices issued by the DME MACs does more than merely expand the existing policy to conform to the new NCD. In fact, the LCD fits squarely within the PIM criteria under §13.7.2 that require carriers to publish a draft LCD for comment. For example, carriers must publish a draft LCD for comment when a revised LCD adds new non-coverage indications to an existing LCD as is the case with the new PAP LCDs. Under the existing LCD for CPAP Medicare pays for therapy with a CPAP device when the Medicare beneficiary is diagnosed with OSA on the basis of a facility-based polysomnogram that meets either of the following criteria:

- The apnea-hyponea index (AHI) is greater than or equal to 15 events per hour; or
- The AHI is from 5 to 14 events per hour with documented symptoms of
 - Excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or
 - Hypertension, ischemic heart disease, or history of stroke.

Continued coverage of the PAP device beyond the first three months of therapy requires the beneficiary to demonstrate compliance with the therapy no sooner than the 61st day after initiating therapy. To meet this standard, the supplier of the CPAP device is required to ascertain and document from either the beneficiary or the treating practitioner that the beneficiary is continuing to use the device.

In this case, the new PAP LCD was published without a comment period even though it contains significant new and very detailed coverage criteria that restrict access to PAP therapy and limit who is eligible to furnish diagnostic test interpretations which are Medicare-covered services. Specifically the LCD adds the following new criteria for initial coverage of PAP therapy which limit Medicare coverage for PAP devices:

- A requirement for a face-to-face examination of the beneficiary by the treating physician;
- Detailed requirements dictating the scope of the face-to-face examination including:
 - Physical examination that measures neck circumference, BMI, and upper airway system examination;
 - Sleep history and symptoms including, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches; and
 - Epworth Sleepiness scale.

Additionally, for dates of service on or after September 1, 2008, the new LCD also contains an unprecedented requirement that limits who may interpret sleep tests to only physicians who are either:

- A Diplomat of the American Board of Sleep Medicine (ABSM);
- A Diplomat in Sleep Medicine by the American Board of Medical Specialties; or
- An active member of a sleep center or laboratory accredited by the America Academy of Sleep Medicine, or the Joint Commission.

For continued coverage of PAP devices beyond the initial 12 weeks of therapy the LCD requires that no sooner than the 61st day but no later than the 91st day after initiating therapy, the treating physician must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy. Moreover, for dates of service on or after September 1, 2008, documentation of clinical benefit is demonstrated by:

- Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,
- Objective evidence of adherence to use of the PAP device. Adherence to therapy is defined as use of PAP 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.”⁴

1. The DME MACs Must Publish the Data on Which They Based the New LCDs

Inherent in the requirement to solicit public comments on a new LCD (or a draft LCD that restricts coverage) is a requirement that the carriers make publicly available the data on which they have based the LCD. As we noted above, Chapter 13 of the PIM requires carriers to base their LCDs on the best data available; it is impossible to assess whether this standard has been met without an opportunity to review and comment on the data that form the basis of the carriers’ decision.

In the PAP LCD, the DME MACs have established a number of new clinical criteria, but have not stated the basis for their selection. For example, the LCD requires that the face-to face examination include an assessment using the Epworth Sleepiness Scale, but does not explain why this scale should be the standard in the policy given that other assessment tools such as the Berlin scale are used widely by clinicians and sleep laboratories.

Similarly, it is not clear to us on what basis the DME MAC determined to limit who is qualified to interpret diagnostic sleep studies to only physicians board-certified in sleep medicine or active medical staff of sleep centers or labs that are Joint Commission or AASM accredited. Medicare regulations contain specific requirements governing Medicare coverage and reimbursement rules for diagnostic tests, including sleep studies, but these regulations in no way limit who is qualified to interpret a test (although the regulations do address under what circumstances physicians or suppliers of tests may bill for the technical or professional components of the test).

⁴ LCD for Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L11518)

In any case, this limitation on coverage for PAP devices is far too restrictive given that the number of physicians who are board-certified in sleep medicine is small compared to the physicians who are likewise qualified to interpret sleep studies by virtue of their training or experience. This provision in the LCD restricts coverage in a manner that brings the new policy within the standards that would require an open comment period under both § 1871hh and chapter 13 of the PIM. Importantly, physicians and medical societies representing physicians with other training, experience or skills should be given an opportunity to comment on this limitation on their eligibility to furnish a Medicare-covered service.

2. The DME MACs May Not Limit Who is Qualified to Interpret a Sleep Study for Medicare Coverage of PAP Therapy

Given that Medicare coverage and billing for diagnostic tests is not limited to specific practitioners or medical specialties, the DME MACs cannot make coverage of PAP devices contingent on the medical specialty or affiliation of the physician who interprets the test. In fact, at the Medicare Evidence Development and Coverage Advisory Committee meeting on September 12, 2007, Dr. Gregory L. Barkley of the Henry Ford Hospital in Detroit, MI stated:

“I’m unaware of any diagnoses that Medicare allows that some physicians can make and not others, so I think that if we say that clinical impression alone is significant to be able to order CPAP, that means that any provider, physician, nurse practitioner, P.A. [physician assistant], should be able to do this across the country.”

As we noted above, §1395hh (a) (2) states that Medicare requirements or statements of policy that restrict who is eligible to furnish a Medicare-covered service must be established in regulations published by the Secretary. Clearly this means that CMS must publish a proposed rule explaining why PAP devices for Medicare beneficiaries are covered *only* when the sleep study has been interpreted by a physician with specific credentials when Medicare coverage and payment for the technical and professional components of the diagnostic sleep test is not similarly restricted. The DME MACs must withdraw this provision from the LCD before the draft is open to public comments. If CMS wants to change Medicare policy to restrict coverage for PAP devices when the underlying sleep study on which coverage is based was interpreted by someone other than a board-certified sleep physician or a medical staff member of an accredited sleep lab, then it must do so by regulation.

3. The Requirement for a Face-to-Face Evaluation of a Medicare Beneficiary as a Condition for Coverage of PAP Therapy Must be Published by CMS in a Regulation

The Medicare Modernization Act of 2003 (MMA) amended §1834 (a) (1) (E) of the Social Security Act directing CMS to determine Medicare conditions of coverage for items of DME, including a requirement of a face-to-face evaluation of the Medicare beneficiary by a treating practitioner. With respect to the face-to-face evaluation, the MMA directed the Secretary to *require* such an evaluation for Medicare coverage of power mobility devices:

Clinical Conditions for Coverage

(i) In general.—The Secretary shall establish standards for clinical conditions for payment for covered items under this subsection.

(ii) Requirements.—The standards established under clause (i) shall include the specification of types or classes of covered items that require, as a condition of payment under this subsection, a face-to-face examination of the individual by a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) and a prescription for the item.

(iii) Priority of establishment of standards.—In establishing the standards under this subparagraph, the Secretary shall first establish standards for those covered items for which the Secretary determines there has been a proliferation of use, consistent findings of charges for covered items that are not delivered, or consistent findings of falsification of documentation to provide for payment of such covered items under this part.

(iv) Standards for power wheelchairs.—Effective on the date of the enactment of this subparagraph in the case of a covered item consisting of a motorized or power wheelchair for an individual, payment may not be made for such covered item unless a physician (as defined in section 1861(r)(1)), a physician assistant, nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has conducted a face-to-face examination of the individual and written a prescription for the item.

(v) Limitation on payment for covered items.—Payment may not be made for a covered item under this subsection unless the item meets any standards established under this subparagraph for clinical condition of coverage.⁵

CMS subsequently published a proposed rule that would have required a face-to-face examination of the beneficiary by a treating practitioner for all other DME items. In response to public comments, CMS implemented the face-to-face requirement only for PMDs, stating that whether to apply the requirement to other items of DME would be the subject of a subsequent rulemaking.⁶ Given the explicit language of the MMA and CMS' acknowledgement that a requirement for a face-to-face evaluation of a Medicare beneficiary by a practitioner for coverage of a DME item would be determined by regulation, it is beyond the scope of the DME MACs' authority to require a face-to-face evaluation of the Medicare beneficiary by a treating physician as a condition of coverage for PAP devices. Although we do not disagree that Medicare beneficiaries with OSA should be seen by their physicians and closely monitored, the circumstances under which the physician evaluation and monitoring occur is a matter for the Secretary to establish through his rulemaking authority after soliciting public comments. AAHomecare recommends that the face-to-face evaluation should be scheduled at the discretion

⁵ 42 USC § 1395m (a) (1) (E) (2007).

⁶ See Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Calendar Year 2005; 69 Fed. Reg. 66336 (November 15, 2004); Medicare Program; Conditions for Payment of Power Mobility Devices, Including Power Wheelchairs and Power-Operated Vehicles; 71 Fed. Reg. 17021 (April 5, 2006).

of the treating physician depending on his assessment of the relative stability and compliance of the patient.

B. The LCD Creates Unnecessary Procedural Hurdles for Suppliers and Beneficiaries and Contains Numerous Provisions that Require Further Clarification

AAHomecare supports access to care for Medicare beneficiaries diagnosed with OSA, however, the recently released DME MAC LCDs significantly revise coverage and payment policies regarding PAP devices for the treatment of OSA. We believe that changes contained within the DME MAC LCDs will unfairly impose certain administrative and cost burdens on the HME provider and Medicare beneficiary. In addition, AAHomecare is concerned about the ambiguity within certain sections of the DME MAC LCDs, which may leave such sections open to subjective interpretation, particularly by program integrity personnel during post payment audits.

The following comments relate to the aforementioned sections:

1. **Definition of the treating physician.** AAHomecare is requesting that the DME MACs clarify the current language under the initial and continued coverage sections regarding what a treating physician is, specifically if that means a sleep center or laboratory physician or a primary care physician. Many smaller and rural diagnostic facilities do not routinely follow up with patients and often refer them to their primary care physician for management of their diagnosis and therapy.
2. **Scientific basis for the definition of adherence.** The DME MAC LCDs defines adherence as “use of PAP greater than and/or equal to 4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.” This section of all four LCDs is very prescriptive and appears to be based on relatively arbitrary parameters previously used for separating groups of patients in certain clinical studies. This proposed definition of adherence is not universally accepted and/or used by all physicians and other clinicians and is not standardized in any of the professional society clinical practice guidelines or practice parameters. Using such a narrow definition of “PAP adherence” across all LCDs also serves as a *de facto* national coverage determination and will set an inappropriate national benchmark for PAP adherence. Many patients failing to meet this threshold may still be deriving significant clinical benefit from their PAP therapy. Determination of clinically effective adherence to therapy is not solely based on PAP usage and generally requires a more comprehensive assessment and determination by the patient’s attending physician. There are a myriad clinical and subjective data that a physician may use to determine effective therapy and clinically appropriate adherence. AAHomecare believes the determination of clinically effective adherence to PAP therapy be determined by the attending physician as part of the re-evaluation and recommends this definition of adherence be removed from the rule.
3. **Requirement of the use of “downloadable” type PAP devices.** The LCD calls for the use of “objective” adherence data as part of the continued coverage beyond the initial three month period but does not specially require a download. The DME MAC LCDs specially require the use of a download as the objective evidence of adherence. The

HCPCS code E0601 does not require memory systems or download features as criteria for coding and coverage. To the contrary, CMS, on numerous previous occasions has summarily rejected HCPCS coding applications that would provide for separate and distinct HCPCS coding of PAP devices with such features as ramp, downloadable memory systems and auto-titration features. The basis for such rejections has been the lack of scientific evidence supporting the use and specifically improved outcomes as a result of such unique features and benefits. Often referred to as “bells and whistles”, the technical features have not been viewed as medically necessary and not worthy of unique HCPCS coding. Standard PAP devices meeting E0601 typically incorporate a pressure sensitive hour meter that records usage only when the system is pressurized (i.e., the patient is wearing the device) versus simply being turned on. These types of compliance meters are readily available and are standard on most brands and models of PAP. While arguably less sophisticated than software-driven compliance systems, there is no objective scientific evidence that hour meters are any less effective compliance monitoring systems. A thorough review of the scientific literature does not produce any compelling data to support the use of downloadable adherence data as a method of improving adherence to therapy. To the contrary, the majority of literature on PAP adherence suggests clinical and therapy education and early re-enforcement of treatment are the most effective methods to improve PAP adherence.

As AAHomecare has stated previously, in comments submitted to CMS in January 2008, we caution against a Medicare policy that increase the overall costs of furnishing the therapy when other effective alternatives are available. HME suppliers face an additional hurdle if their files must include all the necessary pretesting evaluation metrics. AAHomecare recommends that this documentation come from the physicians’ patient files, not from a form developed later by the HME provider as part of its billing and development process. The documentation requirements should be a condition of coverage for the sleep study, not the PAP.

The requirement for documentation necessitates extensive physician education, making the need for extending the implementation timeline for these LCDs imperative. The implementation timeline is already a concern to the supplier community. Educating patients and physicians is an added service and the additional cost of providing that service should not be ignored nor lie solely with the HME supplier. Cited in ‘Article for Continuous Positive Airway Pressure System (CPAP) LCD – Revised (A47854)’ is the following:

1. If the PAP device was dispensed prior to March 13, 2008, the initial coverage criteria and coverage criteria for use beyond the first 3 months must meet the CPAP policy requirements that were effective January 1, 2008.
2. If the PAP device was dispensed after March 13, 2008 but before September 1, 2008, the initial coverage criteria and the criteria for coverage after the first 3 months must meet the requirements in this revised PAP policy that reflect the CMS NCD requirements outlined in CMS Internet-Only Manual Pub. 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Part 4, Section 240.1.
3. If the PAP device is dispensed on or after September 1, 2008, all requirements in this revised PAP policy must be met.

It is unclear how both suppliers and physicians should comply under these timelines and how suppliers should conduct their invoicing. The new LCDs indicate a patient that is seen after the 91st day cannot be billed for ongoing therapy until the date of the reevaluation. This is contradictory to previous medical policy and practice. Respiratory Assist Devices (RADs) currently require a patient be reevaluated by a physician, however suppliers are permitted to hold their billing and once the patient has been re-evaluated and meets the ongoing requirements, suppliers can bill retroactively for equipment that has been in the home and that the patient has been using. A former similar RAD rule was revised on July 1, 2002 due to the number of supplier concerns. By not allowing this retroactive billing, the supplier is required to restart billing based on the date of the re-evaluation. This is not only a severely cumbersome process, but also an unfair process for suppliers and will complicate claims processing for DME MACs as the current 13-month cap will require the carriers to extend beyond the 13th month based on these guidelines. If suppliers are not in compliance, it is not reasonable to penalize both the HME supplier and the patient because of confusing requirements.

This revised policy may also have the effect of restricting Medicare coverage which is not beneficial to patients. Patient compliance as well as patient access is a challenge across many medical diagnoses, as with diabetic patients, not just in the OSA arena. AAHomecare would like clarification from CMS and the DME MACs regarding reasoning behind why the patient, diagnosed with a chronic medical disorder such as OSA, must return to the physician for a clinical re-evaluation as part of a coverage policy for an appropriately prescribed therapy, such as CPAP. If applied to other chronic medical disorders, it would seem inappropriate and potentially unethical to withhold payment for a drug or medical therapy if a patient failed to meet an arbitrary adherence threshold. Can you imagine not covering diabetic test strips or insulin solely on the basis of a missed adherence measurement? There must be time to educate the suppliers and referral community and to clarify, for example, which entity is responsible and accountable for ensuring that the patient undergoes a face-to-face clinical evaluation 60 to 90 days after the patient is initially evaluated in order to receive continued coverage of their PAP device or which entity is responsible and accountable for ensuring that data is available prior to the patient's second visit with the physician. We would like to understand what the scientific arguments are behind the need for a patient with OSA to have a follow-up visit with a physician and how such a follow-up visit with a physician and how such a follow-up is associated with a payment decision for the prescribed therapy.

AAHomecare is also very concerned that HME suppliers must meet the compliance rules by using downloadable compliance data they must retrieve downloadable compliance data and that causes an unfair and non-compensated administrative and cost burden. In addition to the significant, non-covered costs a provider must incur to dispense a PAP unit with a downloadable memory system (HME supplier costs for such systems may double), there is also a non-reimbursed professional expense associated with the HME supplier's need to retrieve this data. In most cases, HME suppliers will be required to send a clinician or other trained personnel to the patient's home to physically collect/retrieve the PAP adherence data, print the data and forward it to the attending physician for review. Unless CMS is prepared to create a separate HCPCS code and allowed to reimburse suppliers for this extreme increase in cost, we believe that many suppliers will simply choose to not serve the Medicare population.

It also seems as though the rule strategically picks and chooses when a supplier can and cannot provide clinical and diagnostic data. For example, the rule requires the HME supplier to obtain this data for proof of adherence and therefore payment but is prohibited from participating in the initial diagnostic home sleep test (HST). A download of PAP data is, in essence, very similar to a Type IV HST. At the same time, however, in the four LCDs, “no aspect of a HST, including, but not limited to delivery and/or pickup of the device, may be performed by a DME supplier.” This appears to be a contradiction of CMS rules where the same entity, the HME supplier, is providing the testing and the equipment. It is also impractical to expect another HME supplier to perform an objective compliance check on a PAP machine from a different HME supplier. Patient services will suffer due to the confusion and contradictions of who is responsible for what regarding the differences between the DME MAC LCDs and the NCD.

III. CONCLUSION

For these reasons, we are requesting that the new PAP LCDs be open for comment in all DME MAC jurisdictions consistent with the requirements of PIM chapter 13. Additionally, a final LCD published after the comment period must include a reasonable timeline for implementation of at least 90 days to ensure that physicians and HME suppliers are educated on the changed policies and be given sufficient time to achieve compliance for the benefit of their patients. We also request that provisions of the LCD that we identified above be clarified in a draft LCD open for public comments. Alternatively, and at a minimum, the LCD must be clarified and its implementation postponed for 90 days.

We appreciate this opportunity to share our views on this matter. We are available to discuss them further with you and would like to meet with you.

Sincerely,



Tyler Wilson
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American Association for Homecare

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