Nutter

David S. Szabo
Direct Line: 617-439-2642
Fax: 617-310-9642
E-mail: dszabo@nutter.com

August 18, 2008

Via Electronic Submission

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on CMS-1403-P, Medicare Program; Revisions to Payment Policy Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009

Dear Sirs:

Please accept this letter as my comments on the above referenced proposed rule. My comments specifically concern proposed revisions to the regulations governing DMEPOS supplier enrollment set forth in 42 C.F.R. § 424.57.

OTHER ISSUES – SLEEP TESTS.

The proposed rule change would establish a payment prohibition barring a DME supplier from receiving Medicare payment if that supplier, or an affiliate, is directly or indirectly the provider of a sleep test used to diagnose a Medicare beneficiary with obstructive sleep apnea. This comment is submitted in opposition to the proposed rule.

The proposed rule has been adopted based on public comment and prior agency experience to the effect that "the interests of beneficiaries can be harmed if the provider of a diagnostic test has a vested interest in the outcome of the test itself."[1] The commentary also states:

> . . . we believe that the individual or entity that directly or indirectly administers the sleep test and/or provides the sleep test device used to administer the sleep test (referred to hereinafter as the 'provider of the sleep test') has a self-interest in the result of that test if that provider, or its affiliate, is also the supplier of the CPAP device. . . . **This provides incentive to test more frequently or less frequently**

[1] **73 Federal Register at 38579 (July 17, 2008)**

than is medically necessary and to interpret a test result with a bias that favors self-interest.[2]

CMS should not adopt this proposal.

Background: Comprehensive Sleep Care and OSA.

Obstructive sleep apnea ("OSA") is a serious medical condition that interferes with normal sleep. OSA cannot only interfere with activities of normal living, but can lead to a wide array of adverse health and safety consequences. OSA has generally been under-diagnosed in the United States.

While in some cases OSA can be treated by surgery or by the use of a dental appliance, in many cases the appropriate treatment for OSA involves the use of a continuous positive airway pressure (CPAP) device. CPAP has been recognized by Medicare as a covered treatment for OSA for some time, and those coverage guidelines recently were updated[3]. As noted by CMS, for patients with severe OSA, CPAP is the "treatment of choice."[4] CPAP can be an effective therapy for OSA but it is not a cure for OSA. For many patients, OSA is a chronic condition, and long-term medical management of their condition is needed to prevent serious adverse health consequences.

While sleep disorders have historically been treated by otolaryngologists, neurologists, pulmonary physicians and psychiatrists, sleep medicine now is recognized as a distinct specialty, with its own specialty board recognized by the American Board of Medical Specialties. Proper sleep care involves the coordination of care among sleep specialists, primary care physicians, respiratory therapists and others.

An emerging trend in sleep medicine is the emergence of the comprehensive sleep disorders center as a site of care. A comprehensive sleep disorders center offers the following services:

1. **A medical clinic staffed with board certified-sleep physicians, supplemented with access to specialists in behavioral medicine, dentists, and others as needed. Clinic personnel provide evaluation and management services on referral from primary care**

---

[2] Ibid at 38580.

[3] Decision Memo for Continuous Positive Airway Pressure (CPAP) Therapy for Obstructive Sleep Apnea (OSA) (CAG-00093R2) (March 13, 2008)

[4] Decision Memo, page 5.

physicians, and also might refer patients out for surgical or other types of interventions.

2. **A sleep lab providing polysomnography ("PSG") under the medical direction of a sleep specialist qualified to interpret PSG reports ("sleep studies"). A sleep lab independent of a physicians practice and hospital will be enrolled as an Independent Diagnostic Testing Facility ("IDTF") and subject to the IDTF performance standards.**
3. **A facility for fitting and titration of CPAP, for those patients where CPAP is medically necessary. Since the effectiveness of CPAP requires patient acceptance over an extended period of time, monitoring of the compliance with CPAP under the supervision of a sleep specialist is essential to the long-term effectiveness of therapy.**

In short, superior management of OSA as a chronic disease requires integration of medical evaluation, sleep testing via polysomonography or home sleep testing, and long term management of CPAP compliance, when indicated. The proposed rule would undercut the existence of integrated sleep care for Medicare beneficiaries, by preventing a comprehensive sleep center from providing CPAP to Medicare beneficiaries. This rule would balkanize care for Medicare beneficiaries suffering from OSA, and is not in their interest.

<u>The Underlying Rationale of the Proposal is Flawed</u>

The rationale of the proposal is that if a supplier provides both PSG and CPAP, it will either perform sleep tests more frequently than is needed, or will bias the result of the PSG in favor of the need for CPAP, even when that is not true. This rationale is flawed.

In the first instance, the rulemaking record adduces no objective evidence that any Medicare participating IDTF had attempted to bias the results of PSG, or to engage in unnecessary testing to support a diagnosis of OSA. Without such evidence, such a restrictive change in coverage policy is unwarranted.

Second, the argument proves too much. Essentially, the proposed rule is premised on the theory that an entity that provides a diagnostic test should not be permitted to provide any therapeutic items or services that might be indicated based on test results, due to "conflict of interest." Of course, this "conflict of interest," if it is one, exists in every hospital, every outpatient facility, and in every physician practice that provides both diagnostic services and therapeutic services. Under this rationale, no surgeon could read and MRI and no hospital could offer both angioplasty and open heart surgery. Of course, such coverage rules do not exist, and no factual basis has been demonstrated, or put on the rulemaking record, to single out one diagnostic modality and therapeutic modality for this special restriction.

It should be noted that a qualified physician must interpret the results of PSG and the results documented in the patient's medical record. Further the Medicare coverage criteria for coverage of CPAP are based on objective criteria. Per recent carrier instructions[5], a positive test for OSA is established if, using Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) more than 15 events per hour are observed, or greater than or equal to 5 and less than or equal to 14 events per hour are observed, with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke. The ability of an IDTF to "slant" diagnostic results in light of these clear criteria for CPAP coverage is speculative, at best. The unstated basis of the rule, apparently, is that providers of PSG are more likely to engage in fraud than other healthcare providers. CMS has produced no evidence to suggest that this is true.

Other Program Safeguards Already Exist to Protect Against Program Abuse with Respect to PSG, CPAP and OSA

Of course, a diagnosis of OSA for the purposes of CPAP coverage can only be made by a qualified physician: either the specialist who interprets PSG, or the attending physician who diagnoses OSA based on the results of the sleep study along with the elements of patient history which must be documented in the medical record. Strong program safeguards already exist to prevent DMEPOS suppliers from providing financial incentives to physicians for the ordering or referring of CPAP.

First, under the state regulations a physician cannot have a substantial ownership interest in a DMEPOS supplier and still refer Medicare patients for DME. CMS has made it clear that since CPAP cannot be an in-office ancillary service for a group practice, the only applicable ownership exception will be the "public company" exception[6], which CMS has determined has no potential for program abuse.

A DME supplier, as a provider of "designated health services," cannot compensate a physician who refers a patient for CPAP unless that compensation relationship complies with the Stark regulations. All of the compensation exceptions have strict requirements that the compensation paid to the physician may not vary with the volume or value of referrals for

---

[5] National Coverage Decision Memo, pages 36-37.

[6] For a discussion of CPAP and Stark see 72 Federal Register 51010 (September 5, 2007). The public company exception can be found at 42 C.F.R. § 411.356.

DHS[7]. Thus, a DMEPOS supplier cannot lawfully pay any remuneration to a physician in order to induce the physician to refer patients for CPAP services. If a DME supplier used financial incentives to encourage referrals, both the supplier and the physician would face the risk of civil, administrative, and criminal penalties. In the absence of such incentives, it seems highly unlikely that a physician would skew objective test results and the patient's medical record in order to generate more CPAP referrals.

Additionally, coverage of CPAP is initially limited to a twelve week period to identify beneficiaries diagnosed with OSA who benefit from CPAP, and only beneficiaries who have benefited from CPAP may continue therapy.[8] Thus, the coverage guidelines require additional review and documentation of the benefits of CPAP by the treating physician.

Prevailing Medical Practice Favors Integrated Care for OSA

OSA is a chronic condition, not an acute illness. Thus, coordination among all the members of the patient's care team, including primary care provider, sleep specialist, and respiratory therapist, among others, is essential to the successful management of OSA and related medical conditions. Failure to properly manage OSA can have a variety of adverse health consequences, many of which can lead to greatly increased costs to the patient's insurer.

One of the key issues for successfully managing OSA is compliance with CPAP therapy. Unfortunately, a significant percentage of patients have difficult accommodating to the CPAP device. Compliance is improved if initial fitting of the CPAP device is performed in a sleep laboratory under the medical direction of a sleep specialist physician and if the physician has regular communication with the DME supplier who serves the patient in the home. This communication and long term cooperation cannot be achieved if the sleep center must coordinate with many DMEPOS suppliers, each of whom in turn deals with many physicians. Integration of clinical services, diagnostic services and CPAP therapy can lead to better clinical results and lower costs in the long run.

CMS has not adduced Sufficient Evidence of Program Harm to Justify the Proposed Rule

CMS should not bar the integration of clinical, diagnostic and therapeutic sleep services without good reason. The preamble to the proposed rule does not disclose the nature or magnitude of the harm to patients or the Medicare program that has been documented in the absence of the proposed rule. CMS should not adopt a restrictive new coverage rule without

---

[7] See 42 C.F.R. § 411.353(c) and (d) for the exceptions for employment and service contract relationships, respectively. Neither exception permits compensation based on or related to the volume or value of referrals for designated health services, including CPAP.

[8] Decision Memo, page 30.

clear evidence of the actual (as opposed to theoretical) necessity for the rule and without considering whether less restrictive measures would attain the desired result equally well.

CMS should not adopt the proposed rule. Thank you for your consideration.

Sincerely yours,

David S. Szabo

1749787.1