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# Taking a Bite into Oral Appliance Therapy

**by Daniel B. Brown, Esq**

**Legal and regulatory considerations for providers of oral appliance therapy.**

The rise in oral appliance therapy for the treatment of obstructive sleep apnea is becoming more than an alternative to positive airway pressure (PAP) treatment. It is also becoming a natural adjunct to many dental practices.

But bringing sleep into dentistry and dentistry into sleep demands the coordination of two sets of distinctively different professional skills—medicine and dentistry. Practitioners must also be sensitive to the reimbursement requirements and limitations of each. The key to a successful sleep dentistry program is for both the dentist and the sleep physician to know their roles and perform them in concert for the patient's benefit.

The opportunities in sleep dentistry are real. Oral appliance therapy has been shown to be an effective treatment for mild or moderate OSA. Furthermore, both Medicare and many commercial insurance companies will reimburse the dentist for fitting and delivering the oral appliance.

The principal code applicable to oral appliances for the treatment of obstructive sleep apnea is HCPCS E0486. The code describes a custom oral appliance that fits only the individual patient. The dentist takes the patient's upper and lower impressions and sends them to a licensed dental laboratory for fabrication. Upon return of the custom device, the dentist fits the patient, makes any necessary adjustments, and instructs the patient on a home titration schedule.

Noridian Administrative Services, LLC, the Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC) for Jurisdiction D, is the first Medicare carrier to announce an allowable reimbursement amount for oral appliances billed under Code E0486. That amount is $1,290.63 per service.

The four DME MACs have issued a Local Coverage Determination (LCD) describing the criteria that a device must meet to qualify for payment under E0486. These criteria state that the device must:

1. Have a mechanism that is hinged or jointed at the sides, front, or palate.
2. Have a mechanism that allows the mandible to be advanced.
3. Be able to protrude the mandible beyond the front teeth at maximum protrusion.
4. Be adjustable by the beneficiary in increments of one millimeter or less.
5. Retain their adjustment setting when removed.

The LCDs also state that tongue retaining devices and noncustomized oral appliances do not meet medical necessity standards for treatment of obstructive sleep apnea. Therefore, Medicare will not reimburse dentists for so-called "boil and bite" or other noncustomized appliances. Dentists must discriminate between these covered and noncovered devices and bill CPT Code E0486 appropriately. The DME MACs have adopted device code verification requirements effective September 1, 2011, to ensure proper coding.

The oral appliance LCDs state that a single reimbursement for the appliance encompasses all components of the appliance and related services. The single payment includes all time, labor, materials, professional services, radiology, and lab costs incurred in fabricating and dispensing the device, as well as all fittings, adjustment, and professional services required during the 90 days following the initial placement.

Finally, Medicare will pay for the oral appliance only if the patient has a positive diagnosis of OSA as determined by a Medicare-covered sleep test. Since dentists are not licensed to perform sleep tests or interpret their results, the dentist and the treating physician must coordinate their efforts to ensure proper care and reimbursement for the patient. "Dentists should develop protocols for working with sleep physicians to coordinate a patient's OSA treatment through oral appliance therapy," says Sheri Katz, DDS, president of the American Academy of Dental Sleep Medicine.

### COORDINATION IS KEY

Dentists who dispense oral appliances for OSA therapy must coordinate with the physician or lab that performs the diagnostic sleep test. Just like PAP, Medicare will pay for customized oral appliances only if the patient first has a face-to-face clinical evaluation with the treating physician prior to the sleep test. The dentist cannot be the "treating physician" to assess the patient for OSA for this purpose.

Next, the test must show OSA by measurement of the patient's AHI or RDI. If the AHI or RDI is greater than 30, then oral appliance therapy is indicated only if the patient is shown to be intolerant of CPAP or if the treating physician determines that the use of PAP is contraindicated. Note that some commercial payors cover the oral appliance only when the patient is intolerant of PAP.

### PLAYING BY THE DME RULES

Medicare reimburses the dentist for the device under the DME fee schedule. That means that the dentist must enroll in Medicare as a DME supplier to be eligible for Medicare reimbursement for billing a customized oral appliance.

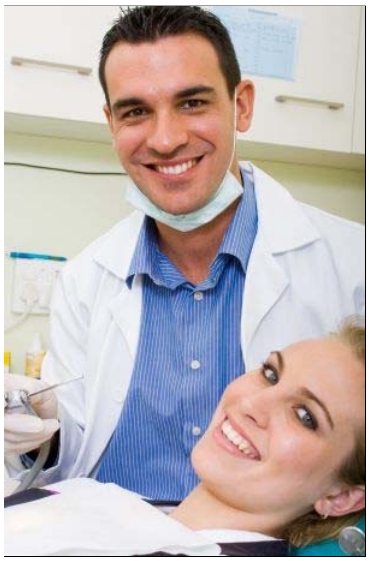
DME suppliers cannot generate their own order for therapy equipment. So the dentist cannot bill Medicare for fabricating a custom oral appliance unless a treating physician orders the therapy following a diagnosis of OSA obtained from a Medicare-eligible sleep test. Like other DME suppliers, the dentist must have documentation of the treating physician's written order as well as copies of the patient's records showing the need for the oral appliance. Dentists should not bill Medicare for the appliance under the KX modifier unless all documentation for payment of the appliance is in hand or otherwise available.

Dentists enrolling in Medicare's DMEPOS program should be aware of Supplier Standards governing participation by other DMEPOS suppliers. Fortunately, dentist-suppliers of DME are exempt from the Supplier Standards requiring accreditation as a DME supplier and the posting of a $50,000 surety bond. This is true only for so long as dentists dispense the Medicare oral appliances to their own patients as part of their own dental practices.

### ACCREDITATION

Quite apart from the accreditation required of Medicare DME suppliers is the new accreditation of Dental Sleep Medicine Facilities by the American Academy of Dental Sleep Medicine (AADSM). Accreditation of a dental sleep facility is a voluntary process created to evaluate and recognize competency and delivery of optimal care to dental sleep medicine patients. Accreditation as a Dental Sleep Medicine Facility is not currently a condition to practice dental sleep medicine or to receive reimbursement for the oral device. However, we can expect that accreditation will one day be linked to Medicare reimbursement of customized oral appliances, according to Katz.

**LEGAL LANDSCAPE**



Because oral appliance therapy is both the practice of dentistry and the business of running a home medical equipment business, persons entering the field must be familiar and comply with the legal requirements of each. A sampling of some the legal aspects follows.

*Corporate Practice of Dentistry*. Many (but not all) states have adopted the "corporate practice" doctrine. This doctrine requires that licensed professionals who choose to practice in the form of a limited liability entity may do so only if all of the owners of the professional practice are licensed to practice the particular profession being practiced.

The rule has important implications in the oral appliance field because dentists are the ones who supply the device. In corporate practice states, only dentists are entitled to own an interest in a dental practice. That means that nondentist businesspeople are shut out from investing in or owning any part of an oral appliance therapy supplier in corporate practice states. Not all states follow the corporate practice doctrine, so it is best to check with your legal counsel on the rules in your state.

*Fraud and Abuse*. Like other items of Medicare DME, the delivery and billing of customized oral appliances must follow federal and state anti-kickback and self-referral laws. As a threshold matter, the close working relationship between dentists and sleep doctors must be structured to prevent improper patient steering.

For example, many states have patient referral prohibitions for dentists. Most of these laws are clear that dentists may not give, offer, solicit, or receive any gift, payment, or other benefit for the referral of a patient for the dentist's services.

For Medicare purposes, the dentist serves the dual role of dental practitioner and durable medical equipment supplier. Medicare is concerned that DME suppliers might encourage overutilization of Medicare tests or services to increase equipment sales. This concern applies in the oral appliance arena as well.

For example, CMS prohibits Medicare suppliers, such as the dentist-DME supplier, from offering free gifts or services to Medicare beneficiaries if the gift or service is likely to influence the beneficiary's selection of a particular supplier of Medicare services. Suppliers may be liable for civil money penalties of up to $10,000 for each wrongful offer of free items or services to induce patients.

In 2002, the Office of Inspector General of the US Department of Health and Human Services issued a Special Advisory Opinion, which clarified that gifts or services having a retail value in excess of $10 each, and more than $50 in the aggregate annually per patient, would constitute a wrongful inducement. The provision of free goods or services in excess of such amounts to a supplier's existing patients would also be wrongful if the freebie were likely to influence those patients' future purchases of services or items reimbursed by Medicare. Exceptions apply for patients who can indicate their financial need for such services.

This injunction against free service could apply to a dentist's offer of free OSA screenings to their Medicare patients if the cost of the OSA screening exceeds $10 and if the screening is likely to induce the dentist's patient to obtain a Medicare oral appliance from the DME supplier-dentist. On the other hand, if the dentist uses a free OSA screen to confirm the efficacy of the oral appliance after the initial fitting, then the service could be said to be such an integral part of the dentist's fitting service that it is included as part of the single fee DME reimbursement.

Medicare's restrictions on DME supplier involvement with the home sleep test for PAP therapy is analogous as well. Recall that Medicare forbids a PAP supplier from performing any aspect of a home sleep test (HST). That is because Medicare is concerned that DME suppliers might improperly encourage the use of HSTs to drive PAP sales.

The same logic applies to practitioners of dental sleep medicine. Medicare is concerned that the dentist-DME supplier might drive oral appliance sales to their own patients through the use of the HST. The DME MACs seek to forestall this result by forbidding dentists from billing Medicare for an oral appliance if the dentist performs, sets up, delivers, or otherwise touches the home sleep test used to diagnose the patient's OSA.

Perhaps some good news on the fraud and abuse impact of dental sleep medicine relates to the Stark law. The federal Stark law prohibits, in most cases, a physician from dispensing CPAP to their own patients who are Medicare or Medicaid beneficiaries. But that is not the case with dentists who dispense oral appliances to their own Medicare patients.

The reason for this different treatment is not because there is a physician in one case and a dentist in the other. Nor is the distinction due to the nature of the item dispensed. Both PAP devices and customized oral appliances are items of durable medical equipment and are "designated health services" under the Stark law.

Rather, the distinction occurs because of the nature of the referral for the therapy. In the PAP situation, the physician refers the item with the idea that their own practice would dispense the PAP device. In the oral appliance scenario, the dentist does not refer the device—the treating physician makes the referral. Because the dentist-supplier does not refer the oral appliance, there is no Stark problem for a dentist to dispense the customized oral appliance for their own patient from their own practice. Likewise, there would be no Stark issue for a doctor's referral of a Medicare oral appliance to the dentist as long as the referring physician does not have a financial interest in the supplying dentist's practice.

Oral appliance therapy can be a boon to treating underdiagnosed OSA in the general public. Persons who are PAP intolerant are likely to benefit from this dental-oriented therapy. Dentists and physicians can best benefit by respecting the boundaries of their respective licenses and taking the time and effort to work together toward the patient's sleep health care and ongoing management of the patient's OSA.

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