American Academy of Sleep Medicine

April 15, 2016

Rodolfo G. Ramos Jr., DDS, PC
Board Presiding Officer
Texas State Board of Dental Examiners
333 Guadalupe, Tower 3, Suite 800
Austin, Texas 78701-3942

Dear Dr. Ramos:

The American Academy of Sleep Medicine (AASM) appreciate the opportunity to provide comments to the Texas State Board of Dental Examiners (TSBDE) regarding the proposed regulations for Texas Administrative Code (TAC) *§108.12, Dental Treatment of Sleep Disorders*. The AASM is a professional society representing a membership of 11,000 physicians, scientists, allied health professionals, and accredited sleep centers and is the leader in setting standards and promoting excellence in sleep medicine health care.

The AASM recognizes the role that dentists can play in the provision of custom fabricated oral appliances for select patients with obstructive sleep apnea (OSA) when oral appliance therapy (OAT) has been prescribed by a physician. Although the proposed rule issued by the TSBDE on March 18, 2016 is an improvement from previous proposals, the AASM respectfully requests that additional amendments be incorporated into the proposal:

Our organization requests that changes are made to the language in Section §108.12 (a), which states that, "A dentist shall not independently diagnose obstructive sleep apnea (OSA). A dentist may fabricate an oral appliance for treatment of OSA only in collaboration with a licensed physician." Instead, the AASM recommends that Section §108.12 (a) be replaced with the following:

> "A dental history, questionnaire, or oral examination that suggests increased risk for obstructive sleep apnea (OSA) should lead to a referral to a licensed physician, rather than independent testing or diagnosis of OSA or habitual snoring, which are medical disorders, by a dentist. A dentist may fabricate an oral appliance for treatment of OSA only after referral from a licensed physician and confirmation from a dental perspective that the patient is a good candidate for the device. A dentist shall be responsible for monitoring and maintaining the oral appliance to ensure the patient's dental health, while the referring physician should be responsible for monitoring the patient's medical condition."

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While we agree with the proposal's intent to prohibit a dentist from diagnosing OSA, further language must be included to specify that a dentist is not allowed to order a screening test for or diagnose a patient with OSA or snoring and may fabricate an oral appliance for OSA *only after referral* by a Texas licensed physician.

Research has demonstrated that having sleep apnea increases a patient's risk of having heart attacks, strokes, hypertension, and diabetes. Therefore, patients can be put at significant medical risk if this disorder is misdiagnosed or if the severity is underestimated. Accurate diagnosis of OSA includes interpretation of a sleep test (in-lab PSG or home sleep apnea test), as well as a comprehensive assessment of symptoms. Screening is the first step in the process of establishing a medical diagnosis, in this case, either the presence or absence of OSA. Distinguishing snoring or other sleep-related breathing disorders from OSA requires a comprehensive evaluation by a physician, objective diagnostic testing ordered by a physician, and sleep study interpretation and diagnosis by a board-certified sleep medicine physician. For the safety of the patient, ordering a sleep test and establishing a diagnosis for this ***medical*** disorder must be done by a physician, not a dentist.

We also insist that the fabrication of an oral appliance by a dentist can be performed only after the patient has been referred by a Texas licensed physician. Due to significant symptom overlap and similar pathophysiology, snoring, OSA, and other sleep-related breathing disorders are only distinguishable after evaluation by a physician and objective testing by polysomnography or home sleep apnea testing (HSAT). This sleep study data must be gathered by medical professionals and interpreted by a board-certified sleep medicine physician who has the training and expertise to make an accurate diagnosis while ruling out all possible differential diagnoses.

Only after ensuring that the patient has been first evaluated and diagnosed by the physician for a sleep disorder can the patient be referred to a dentist for an oral appliance. This course of treatment is not only in compliance with the Texas Medical Practice Act and Texas Medical Board Rules, but in all medical practice acts which establish well-defined boundaries that restrict the dentist's involvement in treating sleep-disordered breathing. We have attached an outline of each state's medical and dental practice act, clearly demonstrating the distinct and appropriate roles of the physician and dentist.

These boundaries are delineated further by the "Local Coverage Determination (LCD) for Oral Appliances for Obstructive Sleep Apnea (L28620)" that is published by CGS Administrators LLC, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) with jurisdiction in Texas, and by the "Policy Statement on the Diagnosis and Treatment of Obstructive Sleep Apnea," which was developed by the AASM. These boundaries respect the distinct differences between the practice of medicine and dentistry, and they also ensure that patients receive care from licensed providers with the most appropriate training and expertise.

In addition, we also request that the language in Section §108.12(b) be deleted and replaced with language from our *Clinical Practice Guideline for the Treatment of OSA with OAT* (attached), which includes a more rigorous continuing education recommendation for dentists.

- "certification in dental sleep medicine by a non-profit organization, designation as the dental director of a dental sleep medicine facility accredited by a non-profit organization, or a minimum of 25 hours of recognized continuing education in dental sleep medicine (e.g., American Dental Association Continuing Education Recognition Program [ADA CERP] or Academy of General Dentistry Program Approval for Continuing Education [AGD PACE]) provided by a dental sleep medicine focused non-profit organization or accredited dental school in the last two years."

Finally, we ask that the proposal be amended to include an additional section to address follow-up. We ask that the proposal incorporate the follow-up language from our *Clinical Practice Guideline for the Treatment of OSA with OAT*.

- 4.2c Recommendation: We suggest that qualified dentists provide oversight—rather than no follow-up of oral appliance therapy in adult patients with obstructive sleep apnea, to survey for dental-related side effects or occlusal changes and reduce their incidence. (GUIDELINE)
- 4.2e Recommendation: We suggest that sleep physicians and qualified dentists instruct adult patients treated with oral appliances for obstructive sleep apnea to return for periodic office visits—as opposed to no follow-up—with a qualified dentist and a sleep physician. (GUIDELINE)

We urge the TSBDE to amend the proposed rule as advised. Please direct any questions or comments about the AASM's position to Executive Director Jerome A. Barrett at 630-737-9700.

On behalf of the AASM, I thank you for taking our input into consideration.

Sincerely,
Nathaniel F. Watson, MD, MSc
AASM President

cc: Kelly Parker, TSBDE Executive Director
Michael Arambula, M.D., Pharm.D, Texas Medical Board President
A. Tomas Garcia III, MD, Texas Medical Association President
Jerome Barrett, AASM Executive Director