TEXASDENTAL association
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Texas State Board of Dental Examiners Stakeholder Input
October 5, 2020: Benzodiazepine Doses

Preface
The Texas Dental Association (TDA) reviewed the October 5, 2020 stakeholder meeting agenda, Texas Occupations Code Chapter D—Administration of Anesthesia, and 22 Texas Administrative Code Chapter 110—Sedation and Anesthesia in preparation for this stakeholder meeting. It is TDA's understanding that the Texas State Board of Dental Examiners (TSBDE) is considering possible rulemaking on Benzodiazepine doses—specifically what is acceptable for in office and out of office administration, and existing provisions of the Dental Practice Act and Board rules pertaining to sedation and anesthesia.

In preparing these informal comments, TDA consulted with its Council on Dental Licensing, Standards & Education, composed of dental faculty at each of the 4 dental schools in Texas—Texas A&M College of Dentistry, the University of Texas School of Dentistry at Houston, the University of Texas Health San Antonio School of Dentistry, and the Texas Tech University Health Science Center Woody L. Hunt School of Dental Medicine.

Comments
Ambiguities in the posted agenda along with broad committee and board discussions prior to this stakeholder meeting make it very difficult for TDA to develop meaningful comment for the TSBDE to consider. Without a clear understanding of the extent of any documented patient concerns related to anxiolysis or sedation, it is impossible to provide targeted feedback. The comments below are intended only to contribute to the discussion that will take place during the actual stakeholder meeting on October 5, 2020.

TDA respectfully asks that if the dental board decides to proceed with rulemaking, it will consider a second stakeholder meeting or other opportunity for stakeholders to submit deliberative feedback to clearly defined goals that the dental board hopes to achieve.

Reason for Possible Rulemaking
TDA has long maintained that changes to statutes and regulations affecting the practice of dentistry must be data-driven and consistent with patient safety and protection. The TSBDE did not report in either the September Anesthesia Committee meeting or subsequent dental board meeting that the decision to consider possible rulemaking is based on patient safety concerns identified by the dental board from complaint data. Instead, this action appears driven by the TSBDE's desire to address what it perceives as ambiguities in regulations.

Dentists' Clinical Judgment
Dentists must be permitted to practice with the flexibility of clinical judgement. The dental board should not become overly prescriptive via rulemaking in a manner that interferes with dentists' autonomy such as potentially writing dosage limitations into rule.

These informal comments by TDA are not all-inclusive and are subject to reconsideration and revision by TDA based upon analysis of any future data and other information and rule drafts publicly released by the TSBDE.

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To use Ativan as an example, the Physicians' Desk Reference (PDR) lists a maximum daily dose of 10mg. For short term anxiety, it states a usual range of 2mg-6mg per day broken up in 2-3 doses. One could conclude an appropriate single dose range for anxiolysis could be considered 0.5-2mg. This is where a dentist must exercise his or her clinical judgment for dosing. Attempting to regulate dosing via rule could prevent dentists from using that clinical judgment. Potential rules would either be so general as to be unnecessary or so restrictive as to limit practitioner autonomy and neither of those are sound rule making practice.

Simply stated, there are simply too many drugs, too many drug classes, and too many different types of patients to regulate dosages. For example, the dose of triazolam that would be "safe" for one patient could be unsafe for a second patient. The number of medications, the effect on various patients, and the positive effect of assisting anxious patients to achieve dental care makes establishing dosage rules difficult.

Benzodiazepine Doses
Clinical guidelines are available when it comes to appropriate dosages for patients. The PDR discusses benzodiazepine dosages for treating short-term patient anxiety. This information is widely available to dentists. Additionally, the Food and Drug Administration (FDA) approves benzodiazepine doses. TDA is hesitant about the dental board taking any regulatory action that deviates from the dosages approved by FDA and found in FDA-approved drug labeling.

Anxiolysis
Texas Occupations Code §258.152(2) authorizes Texas-licensed dentists to administer "anxiolytics and analgesics that are not being used in conjunction with the administration of nitrous oxide and that are administered in doses that do not have the probability of placing the dental patient at risk for loss of the dental patient's life-preserving protective reflexes." Dentists do not need a sedation permit to administer anxiolytics and analgesics in this context.

However, neither the statute nor board rules defines anxiolysis. Below is definition from Malamed.

> **Sedation: A Guide to Patient Management (5th Edition)**
> **Stanley F. Malamed**
> **Publisher: Mosby Elsevier, 2010**
>
> **Anxiolysis**: a minimally depressed level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal commands and that is produced by a pharmacologic or non-pharmacologic method or a combination thereof. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.

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When prescribing benzodiazepines for either anxiolysis or sedation, dentists have the responsibility for ensuring that the drug is properly dispensed with appropriate warnings and directions to patients.

TDA understands that the non-sedation administration of anxiolytics and analgesics by Texas-licensed dentists without a sedation permit is allowed by law but does present a unique situation for the board to regulate. TDA is open to future discussion and deliberation on this topic if data-supported patient safety concerns warrant it. These discussions should potentially include defining anxiolysis in statute or board rule to give dentists a clear understanding of when anxiolysis may become sedation requiring a permit.

Additionally, TDA is open to future discussion and deliberation on whether the board should amend the current minimum standard of care rule (22 Texas Administrative Code §108.7) to define the generally accepted standard of care and minimum requirements when dentists without sedation permits administer benzodiazepines for anxiolysis.

Sedation
TDA also understands that for most benzodiazepines currently on the US market, their use for preoperative sedation of dental patients is "off-label," although it is professionally acceptable. The dosages recommended by the manufacturer for indicated uses, as well as maximum recommended dosages (MRD), appear to continue to be safe when used in dentistry, especially in the context of the recently revamped sedation permit rules and an increasing emphasis on patient monitoring and rescue should an emergency occur.

A case in point is triazolam (Halcion), which is probably the most widely used oral preoperative sedative drug used in dentistry. The package insert information (attached) sets reasonable maximum doses for outpatient use, which are reflected in its application for preprocedural dental sedation.

As the dental board continues to discuss this subject, the TSBDE should keep in mind the development of new benzodiazepines, non-benzodiazepine benzodiazepine receptor agonists, and thienodiazepines that rule language may not be able to anticipate (eg, remimazolam, etizolam).