October 4, 2020

State Board of Dental Examiners
333 Guadalupe Street, Tower III
Austin Texas 78701

Dear Board members,

I am writing as an individual practicing dentist in response to the SBDE request for stakeholder input related to possible rulemaking proceedings with respect to:

1. Benzodiazepine doses, specifically what is acceptable for in office and out of office administration.

2. Existing provisions of the Dental Practice Act and Board rules (with respect to the use of benzodiazepines).

Relevant, existing rules/statutes include:

Texas Occupations Code item 258.152 states:

Rules adopted by the board under this subchapter do not apply to:

(1)
the regional injection of an anesthetic to reduce or eliminate sensation, especially pain, in one part of the body; or

(2)
the administration of 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.

State Board Rule 110.1 (definitions) includes 2 items pertinent to this issue:

(15) Maximum recommended dose (applies to minimal sedation)-FDA maximum recommended dose (MRD) of a drug, as printed in FDA-approved labeling for unmonitored home use.

(16) Minimal sedation--a minimally depressed level of consciousness, produced by a pharmacological method, which retains the patient's ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected. Medication administered for the purpose of minimal sedation shall not

exceed the maximum doses recommended by the drug manufacturer. Nitrous oxide/oxygen may be used in combination with a single enteral drug in minimal sedation. During longer periods of minimal sedation in which the total amount of time of the procedures exceeds the effective duration of the sedative effect of the drug used, the supplemental dose of the sedative shall not exceed total safe dosage levels based on the effective half-life of the drug used. The total aggregate dose must not exceed one and one-half times the MRD on the day of treatment. The use of prescribed, pre-visit sedatives for children aged twelve (12) or younger should be avoided due to the risk of unobserved respiratory obstruction during the transport by untrained

Older versions of SBDE rules also included a definition of "anxiolysis" as distinct from minimal sedation. If memory serves me correctly, it described the state of a patient who has received "small doses of minor tranquilizers" and remains "totally awake" – and that this can be accomplished without a sedation permit as described in 258.152. The current version of the SBDE rules does not include the definition of "anxiolysis".

Benzodiazepines are among the most prescribed medications in the US. In medicine, most are used for chronic disorders, while in dentistry, most are used only episodically, mostly for sedation/anxiolysis. Benzodiazepine use in the management of facial pain is an exception.

Most benzodiazepine use in dentistry is to relieve acute anxiety and produce sedation for the patient who is particularly nervous about a proposed dental procedure. Sometimes the drug is administered in the office, either enterally or parenterally, and sometimes the drug is administered outside the office enterally. Current SBDE rules discourage the use of sedative drugs administered outside the office for children 12 and under, but are silent regarding the use of sedatives outside the office for 13 and older. The Texas (dental) minimal sedation permit allows the permit-holder to administer a first sedative dose up to the MRD either inside or outside the office. This is consistent with current ADA Sedation Guidelines for the Use of Sedation and General Anesthesia by Dentists. The MRD is the *maximum* recommended dose of a given drug for home use as established by the manufacturer and approved by the FDA for home, unmonitored use. Certainly, the dentist can use his/her judgment to reduce that first dose as deemed appropriate in different clinical situations.

The manufacturer, the FDA and the ADA, utilizing a multitude of resources have established this *maximum* dose of a drug – triazolam for example, is 0.5 mg. Considering a different dose (presumably lower) and establishing a new SBDE rule to further limit dosing for outside the office use should be based on new information or research. Is the SBDE aware of examples of patient harm (from a stumble/fall or airway/ventilation) from outside the office use? Are there examples of "near misses"?

If there are a number of examples, I am in favor of considering methods to improve safety, especially if the dentist appeared to have acted in a prudent manner in these examples. In the absence of examples of harm or near harm, I am not in favor of altering the rules away from ADA Guidelines or FDA approved package inserts.

If there is concern regarding benzodiazepine use outside the office, should there also be concern with other CNS depressant drugs, such as opioids? Assuming appropriate consideration of NSAIDs and acetaminophen, opioid use outside the office is considered appropriate for analgesia and is probably used in far greater quantities than benzodiazepines outside the dental office. If new rules are established for benzodiazepine use outside the office, would new rules need to be considered for opioid use outside the office? Would new rules need to be considered for any other controlled substance outside the office, such as non-benzodiazepine sedative hypnotics (zolpidem for instance)? Limiting the use of only one class of drug (or only certain examples within that class) seems to limit any effect a new rule might have.

My request is that the SBDE define the concern with benzodiazepines in more detail with evidence that will help the stakeholder have a better understanding of what the SBDE is trying to accomplish.

We are all interested in patient safety. We do not always agree on the best way to get there, but I am always willing to reconsider rules or standards of practice in the face of new information. I believe the evidence used to establish the existing limits is robust. I am not aware of evidence that suggests we need to reconsider existing standards.

Thank you for the opportunity to comment,

Ernest B. Luce DDS