

PROPOSED RULES

Proposed rules include new rules, amendments to existing rules, and repeals of existing rules. A state agency shall give at least 30 days' notice of its intention to adopt a rule before it adopts the rule. A state agency shall give all interested persons a reasonable opportunity to submit data, views, or arguments, orally or in writing (Government Code, Chapter 2001).

Symbols in proposed rule text. Proposed new language is indicated by underlined text. ~~[Square brackets and strikethrough]~~ indicate existing rule text that is proposed for deletion. "(No change)" indicates that existing rule text at this level will not be amended.

CHAPTER 110



22 TAC §110.16

The State Board of Dental Examiners (Board) proposes new rule §110.16, concerning Sedation/Anesthesia of High-Risk Patients. This new rule will require dentists to undergo additional didactic and clinical training prior to providing levels 2, 3, or 4 sedation/anesthesia to high-risk patients. This rule is being proposed to comply with the requirements of S.B.313.

Tyler Vance, Interim Executive Director, has determined that for the first five-year period the proposed rule is in effect, there will not be any fiscal implications for state or local government as a result of enforcing or administering the rule.

Tyler Vance has also determined that for the first five-year period the proposed rule is in effect, the public benefit anticipated as a result of this rule will be the agency's compliance with legislative directives and increased public safety as a result of increased training requirements for dentists.

Tyler Vance has also determined that an economic impact statement and regulatory flexibility analysis for small businesses, micro-businesses, and rural communities is necessary for this rule. The Board has approximately 3,400 permit holders affected by this rule across the State of Texas. Many of these permit holders are considered small or micro-businesses in that they are independent practitioner-business owners employing fewer than 100 employees. Many of them practice in rural communities, defined as municipalities with fewer than 25,000 people. Small businesses, micro-businesses, and rural communities will almost certainly experience an adverse economic effect from this proposed rule. Informal comments presented at stakeholder and committee meetings estimate the cost of the new additional training program will be in the range of \$10-20,000. Permit holders will have to take at least 16 hours out of their schedule for the didactic training and obtaining the necessary clinical training will likely require even further time, travel, and expense. As for rural communities, it is an inevitable consequence of this regulation that there will be fewer providers of moderate sedation and above for these patients throughout the State of Texas. There are already fewer of these providers in rural areas than in urban areas and presumably that gap will grow wider due to the costs associated with this regulation. A provider in a rural area who only does these procedures a few times a year likely will not go through the additional training required to continue doing so. As a result, rural patients may have to seek out someone else who is qualified to perform the procedures, likely in a more urban setting that will require additional time and expense. As such, rural communities will likely experience an adverse economic impact from this proposed regulation.

That said, this rule is being proposed due to a legislative mandate in Senate Bill 313 (85th Legislature) that requires these practitioners to undergo "additional didactic and clinical training", as defined by the Board. The legislature has mandated further training to protect the health and safety of all Texans. The Board was charged with defining "additional training" and after many discussions about alternatives they arrived at the requirements that are being proposed. The proposed requirements could be higher or lower, but either way, the legislature has mandated "additional training" and any amount of "additional training" is going to have an adverse economic effect on small businesses and rural communities. It would not have been acceptable to the Board of the legislature to have proposed one standard for rural providers and another for urban providers. The Board believes the proposed rule strikes a good balance between protecting the public health and safety and keeping the new regulation economically feasible for those who wish to provide or receive this service.

Tyler Vance has also determined that for the first five-year period the proposed rule is in effect, the following government growth effects apply: the rule does not create or eliminate a government program; implementation of the proposed rule does not require the creation or elimination of employee positions; the implementation of the proposed rule does not require an increase or decrease in future appropriations; the proposed rule does not require an increase or decrease in fees paid to the agency; the proposed rule creates a new regulation; the proposed rule expands an existing regulation; the proposed rule increases the number of individuals subject to it; the proposed rule does not adversely affect the state's economy.

Comments on the proposed new rule may be submitted to Tyler Vance, Interim Executive Director, 333 Guadalupe, Suite 3-800, Austin, Texas 78732, Fax (512) 305-9364, tvance@ts-bde.texas.gov no later than 30 days from the date that the proposed rule is published in the Texas Register.

This rule is proposed under Texas Occupations Code §254.001(a), which gives the Board authority to adopt rules necessary to perform its duties and ensure compliance with state laws relating to the practice of dentistry to protect the public health and safety.

No statutes are affected by this proposed rule.

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§110.16. Sedation/Anesthesia of High-Risk Patients.

(a) "High-risk patient" means a patient who has a level 3 or 4 classification according to the American Society of Anesthesiologists Physical Status Classification System (ASA).

(b) For the purposes of this chapter, ASA classifications are defined as follows:

- (1) ASA I: a normal healthy patient
- (2) ASA II: a patient with mild systemic disease
- (3) ASA III: a patient with severe systemic disease.
- (4) ASA IV: a patient with severe systemic disease that is a constant threat to life.

(c) A permit holder may not administer sedation/anesthesia under a level 2, level 3, or level 4 permit to a high-risk patient unless the permit holder has:

- (1) completed a university or hospital-based residency at least 12 months in length; or
- (2) completed a board-approved education program that includes a minimum of sixteen (16) hours of didactic training and instruction in sedation/anesthesia of high-risk patients. Successful completion of the program must include passing an examination covering the course components. Didactic education must include:

(A) pre-anesthetic patient assessment/evaluation for medically compromised and geriatric patients;

(B) physical evaluation and medical history of high-risk patients, including obesity, pregnancy, and obstructive sleep apnea syndrome, cardiovascular disease, metabolic or genetic disorders, hematologic disorders, and other systemic diseases/conditions affecting sedation/anesthesia;

(C) high-risk patient anatomical and physiological differences;

(D) medical consultations;

(E) high-risk respiratory assessment, including airway anatomy, physiology, and management;

(F) informed consent by patient, parent, or guardian;

(G) sedation/anesthesia pharmacology;

(H) sedation/anesthesia management of patients identified with special health care needs;

(I) high-risk patient monitoring;

(J) peri-operative complications and emergencies;

(K) emergency management of high-risk patients, including high-risk anesthesia equipment and resuscitation supplies;

(L) sedation/anesthesia technique;

(M) sedation/anesthesia record keeping;

(N) patient recovery and discharge;

(O) appropriate patient selection; and

(3) completed satisfactory management of sedation/anesthesia in at least ten (10) cases involving high-risk patients sedated/anesthetized at the highest level of permit held. At least five (5) of the cases must involve the hands-on administration of sedation/anesthesia as the primary provider. No more than five (5) cases may be observed. The ten (10) cases must involve either live patients and/or high-fidelity emergency sedation/anesthesia simulations. All of the cases must be performed and documented under the on-site instruction and direct supervision of a licensed dentist authorized to administer sedation/anesthesia to high-risk patients.

(d) A permit holder is authorized to administer sedation/anesthesia under a level 2, level 3, or level 4 permit to a high-risk patient if they have completed the requirements above. The permit holder must attest to their advanced training in high-risk patients on their initial and/or renewal permit application and they will be required to produce proof of completion as part of a permit inspection or an investigation of a complaint involving sedation/anesthesia of a high-risk patient.

(e) The education hours described in subsection (c)(2) of this section can be applied towards the permit holder's continuing education requirement for maintaining a sedation/anesthesia permit.

(f) The didactic and clinical training described in subsection (c)(2) and (3) of this section may not be fulfilled by the same didactic and clinical training used to fulfill the requirements for initial permit issuance.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on February 26, 2018.

TRD-201800808

Tyler Vance

Interim Executive Director

State Board of Dental Examiners

Earliest possible date of adoption: April 8, 2018

For further information, please call: (512) 475-0977

