STATE BOARD OF DENTAL EXAMINERS
333 Guadalupe, Tower 3, Suite 800, Austin, Texas 78701-3942
Phone (512) 463-6400 Fax (512) 463-7452

January 4, 2017

Mr. Ken Levine
Texas Sunset Advisory Commission
1501 North Congress ,REJ Building, 6th Floor
PO Box 13066
Austin, TX 78711

RE: Report to the Texas Sunset Advisory Commission by the Blue Ribbon Panel on Dental Anesthesia/Sedation Safety

Dear Mr. Levine:

Enclosed please find the Blue Ribbon Panel on Dental Anesthesia/Sedation Safety's report to the Texas Sunset Advisory Commission.

If I can be of further assistance, please let me know.

Sincerely,

Kelly Parker
Executive Director

cc: Texas Sunset Advisory Commission Members (w/encl.)

Report to the Texas Sunset Advisory Commission

Blue Ribbon Panel on Dental Sedation/Anesthesia Safety of the Texas State Board of Dental Examiners

Panel Members:
Ernest B. Luce, D.D.S., Chairman
Robert G. McNeill, D.D.S., M.D.
David H. Yu, D.D.S., M.S.
Reena Kuba, D.D.S., M.S.
Bryce S. Chandler, D.D.S.
Ronald J. Redden, D.D.S.

January 2017

Agency Contact: Kelly Parker, Executive Director
333 Guadalupe, Tower 3, Suite 800
Austin, TX 78701-3942
Phone (512) 463-6400 Fax (512) 463-7452

Table of Contents

Report to the Texas Sunset Advisory Commission

Blue Ribbon Panel on Dental Sedation/Anesthesia Safety

of the

Texas State Board of Dental Examiners

January 2017

Summary of Recommendations

The Blue Ribbon Panel on Dental Sedation/Anesthesia Safety (BRP) reviewed de-identified data compiled during board investigations in fiscal years 2012 through 2016 involving patient mortalities and patient harm during or following dental treatment at which sedation/anesthesia was administered and evaluated the appropriate substance and application of emergency protocols related to the administration of sedation/anesthesia.

Panel members, with the assistance of SBDE staff, performed an intensive review of 78 cases. Examination of these 78 cases resulted in the determination that 19 of these events were related to mishandled sedation/anesthesia. BRP identified six of the 19 cases as major events. BRP identified 13 of the 19 cases as mishaps. The panel also reviewed other state laws/rules and scientific literature.

A summary of the BRP recommendations are as follows:

Clinical recommendations:

- SBDE shall have full authority to inspect dental offices where any level of sedation/anesthesia is provided with emphasis on assessing competency of the sedation provider;

- Texas dentists should be required to have written emergency protocols and should be required to document that they practice these protocols with office staff through exercises such as "drills" several times per year;

- The SBDE mandate that at least one support staff member assisting with a sedation procedure (level 2, 3, 4) receive training in the recognition and management of sedation/anesthesia related emergencies;

- Texas dentists providing moderate/deep/general anesthesia (levels 2, 3, 4) to children under the age of 8 be required to document to the SBDE age specific sedation training;

- Texas dentists providing moderate/deep/general anesthesia (levels 2,3,4) to "high risk" patients (age 75 and older, BMI greater than or equal to 30, ASA classification 3, 4) be required to document to the SBDE specific training regarding these groups of patients;

- Offices where portable providers practice be required to have basic ventilation equipment onsite; and.

- Capnography and precordial stethoscope be mandated for level 2, 3 and 4 procedures.

Administrative recommendations:

- The SBDE should establish a standing independent sedation advisory panel to continue to review and advise the SBDE regarding sedation/anesthesia issues;

- The SBDE make public de-identified sedation related major events and mishaps;

- The SBDE collect data regarding sedations performed by Texas dentists. (non-accident data);

- The SBDE create a system to evaluate and approve sedation/anesthesia continuing education;

- The SBDE mandate that the sedation record for a dental procedure be a required part of the dental record, even if the sedation provider is a non-dentist;

- The SBDE consider creation of a recurrent sedation/anesthesia written examination covering sedation/anesthesia rules; and

- The Texas Legislature make an effort to encourage other state legislatures to share de-identified sedation/anesthesia data publicly.

Administrative suggestions:

- The SBDE consider creation of a required online sedation/anesthesia rules examination;

- The SBDE consider encouraging or mandating that dentists use a preoperative sedation checklist; and

- The SBDE consider including more detail in the SBDE rules regarding appropriate pre-operative evaluation and an acceptable sedation/anesthesia record.

Report to the Texas Sunset Advisory Commission
of the
Blue Ribbon Panel on Dental Anesthesia/Sedation Safety
Texas State Board of Dental Examiners
January 2017

I. Introduction

On August 22, 2016, the Sunset Review Commission directed the Texas State Board of Dental Examiners (SBDE) to establish an independent Blue Ribbon Panel (BRP) to review dental anesthesia-related deaths and mishaps in Texas. On August 31, 2016, SBDE met to establish the BRP, charging the BRP with:

a. reviewing de-identified investigative data related to dental anesthesia-related deaths and mishaps investigated by SBDE between 2011 and 2016;
b. reporting on trends and commonalities in the de-identified data;
c. reviewing sedation/anesthesia laws, regulations, and studies from other jurisdictions and review relevant published scientific literature;
d. opining on whether present laws, regulations, and board policies are sufficient to protect patients;
e. recommending appropriate changes to the laws, regulations, and board policies related to the administration of sedation/anesthesia to dental patients in Texas; and
f. evaluating emergency protocols.

II. Blue Ribbon Panel Membership and Meetings

The members of the BRP are active sedation providers from various disciplines of dentistry. SBDE selected members of the BRP from its existing dental review panel of licensed Texas dentists who serve as expert reviewers in SBDE's investigations.

The members of the BRP are:

- Dr. Bryce Chandler, DDS, general dentist, level 2 provider
- Dr. Rena Kuba, DDS, pediatric dentist, level 2 provider
- Dr. Ernie Luce, DDS, general dentist, level 3 provider, portable - Chairman
- Dr. Robert McNeill, MD, DDS, oral and maxillofacial surgeon, physician, level 4 provider
- Dr. Ronald Redden, DDS, dentist anesthesiologist, level 4 provider, portable
- Dr. David Yu, DDS, periodontist, level 3 provider

Three of the members, Drs. Kuba, Luce, and Redden teach sedation/anesthesia in a Texas dental school.

The BRP met in person, in meetings open to the public, on four occasions. BRP member attendance at each of the meetings was 100%.

Project Chronology:

22 August, 2016	Sunset Advisory Commission Decision Hearing
31 August, 2016	SBDE open meeting to establish BRP
15 September, 2016	BRP open meeting #1
6 October, 2016	Staff distributed Master Data Set to BRP (123 cases)
25 October, 2016	BRP open meeting #2 – selected cases (78 cases)
6 November, 2016	Staff distributed detailed data on selected cases (78 cases)
15 November, 2016	BRP open meeting #3 – identified major events/mishaps (19 cases)
7 December, 2016	BRP meeting #4 – analyzed data, identified trends and made summary recommendations
4 January, 2017	BRP submitted written report to the Sunset Advisory Commission
11 January, 2017	Sunset Advisory Commission Hearing

III. Definitions

AAOMS - American Association of Oral and Maxillofacial Surgeons

AAPD - American Academy of Pediatric Dentistry

ASDA - American Society of Dentist Anesthesiologists

ASA - American Society of Anesthesiology

ASA 1, 2, 3, 4, 5 - scale created by the American Society of Anesthesiology to make a general assessment of the physical status of a patient

BMI - body mass index, a measure of obesity based on height and weight

High risk - describes patients who are obese (BMI $\geq$ 30, compromised health (ASA 3 and 4) or elderly (75 years of age or older)

IV. Current Sedation Permit Levels

The SBDE formally permits Texas dentists to provide different levels of sedation/anesthesia based on educational experience.[1] The higher the level of sedation, the greater the educational requirements to obtain that permit. The levels are:

Nitrous oxide/oxygen (laughing gas) – typically the lightest level of sedation.

Level 1 sedation (minimal) – a single oral sedative, may be mixed with nitrous oxide, patients become relaxed, but will respond normally to gentle touch. They are very easily awakened.

Level 2 sedation (moderate oral) – multiple oral sedatives are allowed, patients are relaxed but respond purposely to gentle touch. They are easily awakened.

Level 3 sedation (moderate parenteral) – multiple sedatives may be administered by injection (such as an intravenous line). Patients are relaxed but respond purposely to gentle touch, as in level 2. They are easily awakened.

Level 4 sedation/anesthesia (deep sedation/general anesthesia) – multiple sedatives may be administered by any route, including injection. Patients are "asleep". A painful stimulus must be repeatedly applied to the patient in order to elicit a response, if they respond at all. They are difficult or impossible to wake up with physical stimulation.

V. Review and Analysis of De-identified Data – Major Events and Mishaps

The BRP made an in-depth review of 78 cases investigated by SBDE in search of evidence of mishandled sedation/anesthesia.[2] BRP identified six of the 78 cases as major sedation/anesthesia events. BRP identified 13 of the 78 cases as sedation/anesthesia mishaps. Findings were defined as:

a. major events meaning the case resulted in mortality or permanent morbidity *and* was directly related to mishandled sedation/anesthesia

b. mishaps meaning that an adverse event occurred without permanent injury *and* was directly related to mishandled sedation/anesthesia

---

[1] See Appendix 1 for SBDE Sedation/Anesthesia rules.

[2] Seventy-five of the 78 cases were resolved at the time of review. Three of the 78 cases were under SBDE investigation at the time of BRP review but were incorporated into the BRP review due to their high profile nature and relevance to BRP charge.

Major Events – Summary of the Six Major Sedation/Anesthesia Events

Patient Age	Health Status	S/A Provider	Intended Level	Outcome
adult under 75	obese, cardiac dz	Dentist anesth	4, deep IV	mortality
adult under 75	obese, DM, CV dz	Periodontist	3, moderate IV	mortality
child under 8	healthy	General dentist	2, moderate oral	brain damage
child under 8	healthy	Pediatric dentist	2, moderate oral	mortality
child under 8	cardiac disease	MD anesth	4, GA	mortality
child under 8	healthy	MD anesth	4, GA	mortality

BRP Findings Regarding the Six Major Sedation/Anesthesia Events:

a. Every event involved either young children (child under 8) or adults with high risk factors (obese/compromised health/elderly).

b. Highly trained specialists (including physicians) or a general dentist provided the sedation/anesthesia in each of the major events.

c. For the **intended** level 2 and 3 events, the patient almost certainly became more deeply sedated than intended. Once deeply sedated, the patient is difficult or impossible to awaken with physical stimulation. It is at this point that breathing becomes compromised. If not recognized and corrected quickly, brain damage or death ensues rapidly.

d. Poor pre-operative evaluation, drug overdose, not following current monitoring requirements and poor emergency management were also prominent in these cases.

e. Regarding portable providers, a total of four of the major events involved a provider practicing on a portable basis. Two of these four major events involved portable physician anesthesiologists. Being portable did not appear to contribute directly to these major events.

The other two of these four major events involved a portable dentist sedation/anesthesia provider, a level 3 and a level 4 provider. In these two cases, the provider appeared to not have required emergency equipment that would have been useful in the evolving emergency.

It is unknown how many sedation/anesthetics are performed in Texas on a "portable" basis vs. a "non-portable" basis.

Mishaps – Summary of the 13 Sedation/Anesthesia Mishaps

Of the 78 cases studied by BRP, BRP identified 13 cases in which a sedation/anesthesia mishap occurred. Pertinent factors in the mishaps include:

a. Eight of the 13 mishaps involved children under 8 or high-risk adults (obese, compromised health or elderly).

b. Dental specialists (oral & maxillofacial surgeons - one case, dentist anesthesiologist – one case, periodontists - two cases and pediatric dentists - three cases) as well as general dentists - six cases, provided the sedation/anesthesia in these cases.

c. The severity of the mishaps ranged from minor to serious.

d. The nature of the mishaps was also quite varied and included drug overdose, premature discharge, predictable but unanticipated drug interaction due to poor drug selection, bolus drug administration (instead of slow, careful, incremental drug administration), and poor management in the early stages of a developing urgency allowing the condition to further deteriorate to an emergent condition and delayed calls to 911.

e. Some of the mishaps occurred in the office while some developed after what was a premature or inappropriate discharge.

f. When an emergency did develop in the office, poor emergency management was present in almost all cases.

g. Every mishap involving a high risk adult patient also involved inadequate or poorly documented pre-procedural patient evaluation and some element of poor sedation technique (such as bolus drug administration, not utilizing required monitors or not being attentive to monitors that were being used while indicating a developing urgency).

VI. Summary Comments Regarding Trends in Sedation/Anesthesia

The SBDE has 16,719 dentists with an active license, and 7,502 licensees hold a Level 1-4 permit. The SBDE has not been required to collect data on each administration of sedation/anesthesia that occurs during dental procedures in Texas (estimated at 500,000 to 1,000,000 administrations per year below). Lacking this detailed information regarding all sedations done in the state limits the statistical conclusions that can be drawn.

However, the BRP was able to study case specific information of actual adverse events that occurred in Texas by reviewing de-identified data collected in board investigations that occurred between 2011 and 2016 involving patient mortalities and patient harm during or following dental treatment at which sedation/anesthesia was administered and evaluated the appropriate substance and application of emergency protocols related to the administration of sedation/anesthesia.

Many level 1, 2, and 3 sedation providers offer sedation on an episodic basis, ranging from only a few times a year to several cases per day. In contrast, most level 4 providers provide sedation/anesthesia multiple times per day. The OMS National Insurance Company (OMSNIC) estimates that the average AAOMS member in Texas performs 669 sedation/anesthetics per year. If each of the approximately 400 OMFS in Texas performs sedation/anesthesia at this rate, approximately 270,000 sedation/anesthetics are performed by Texas OMFS each year.

The American Society of Dentist Anesthesiologists includes 25 members in Texas (also level 4 providers). Estimates from three of their members suggest that the average dentist anesthesiologist in Texas treats 435 patients per year suggesting that 10,875 anesthetics are performed annually by Texas Dentist Anesthesiologists.

According to the ADA, there are 659 "professionally active" pediatric dentists in Texas. Anecdotal information among active pediatric dentists suggests that, on average, each of these practitioners performs approximately 200 minimal/moderate (mostly level 1 and 2) sedations each year. Based on these numbers, it is estimated that Texas Pediatric Dentists perform approximately 130,000 sedations annually.

Between oral and maxillofacial surgeons, pediatric dentists and dentist anesthesiologists, approximately 411,000 sedation/anesthetics are performed annually in Texas. This group of dentists represents only 1084 of the approximately 7,502 sedation permit holders in the state. Estimating the number of sedation procedures completed by other dentists in Texas (primarily endodontists, periodontists and general dentists) is even more speculative than the estimates above. Likely, the total number of sedation procedures provided by all Texas dentists is somewhere between 500,000 and 1,000,000 annually. For the 5 years of data the BRP evaluated, we estimate between 2,500,000 and 5,000,000 sedation/anesthetic procedures were performed. Five deaths and one brain injury directly related to sedation/anesthesia occurred in that time period.

It is important to or keep in mind that patients receiving nitrous oxide/oxygen, level 1 minimal sedation, level 2 or 3 moderate sedation are either awake or easily roused by quiet voice or gentle touch throughout the sedation. Patients receiving level 4 deep sedation/general anesthesia are difficult or impossible to arouse.

By far, the most common proximate cause of morbidity and mortality in sedation is compromised ventilation. Most of the commonly used sedative drugs will depress ventilation in the sedated patient, sometimes to the point that breathing stops completely. When breathing stops or becomes severely limited, the practitioner must recognize this condition, diagnose the specific reason for the compromise and rectify the situation all within a very few minutes. If panic or indecision sets in, emergency equipment/medications are not immediately available, or there is a lack of familiarity with the equipment/medications, or there is a lack of a clearly understood emergency plan, the chance of a poor outcome rises dramatically. Efficient teamwork among the doctor(s) and support staff is essential to help ensure swift resolution of the situation.

The margin of safety is narrower in certain specific patient groups. In young children, this time period to manage the evolving crisis is dramatically reduced. Obese individuals also decompensate much faster than slender, healthy adults when breathing becomes compromised. Many medically compromising conditions also result in much more rapid decompensation if breathing stops. Young children and elderly/obese/medically-compromised patients pose extra sedation risks.

Almost without exception, when a mortality occurs associated with minimal or moderate sedation (levels 1, 2, 3), the practitioner allowed the patient to reach a level of deep sedation, where the patient became difficult or impossible to arouse by physical stimulation. It is only at this point that ventilation becomes significantly compromised. Minimal and moderate sedation patients that are ***kept*** at a minimal and moderate state ***do not*** develop airway compromise. Therefore the ***root cause*** of minimal/moderate sedation morbidity/mortality is essentially always that the doctor allowed the patient to become deeply sedated. ***Preventing*** the loss of responsiveness will ***prevent*** the vast majority of minimal/moderate sedation adverse outcomes. Accomplishing this single goal will have the greatest impact to reduce adverse outcomes in minimal/moderate sedation.

Current SBDE rules require that any patient considered for sedation/anesthesia be "...suitably evaluated prior to the start of any sedative procedure." and go on to state that, "A focused physical evaluation must be performed as deemed appropriate." Every event (major events and mishaps) in our series involving a high-risk patient also involved very poor pre-operative evaluation and limited or no physical evaluation.

Interestingly, among the cases BRP reviewed involving high-risk patients (both major events and mishaps), **all** of these patients had some sort of medical consultation done prior to the sedation procedure. Lack of medical consultation does not seem to be a factor in the evolution of the mishap or major event in our patients. Data from this patient series does not support the need to mandate enhanced medical consultation.

If the patient becomes more deeply sedated than permitted, current rules require the level 1, 2, and 3 provider to stop the dental procedure and return the patient to the intended level of sedation. The sedation provider is required to continually verify responsiveness and ventilation.

In addition, the current rules mandate that the sedation provider remain in the dental operatory until the patient has reached a defined level of recovery. While unverifiable, there is a strong suspicion that three of the six major events involved the sedation provider leaving the operatory for some period of time while the patient was still sedated, and the crisis developed/evolved during this time period. Leaving a sedated patient unattended is a major contributor to a patient becoming deeply sedated when only minimal or moderate sedation was intended. (The delivery of dental care is stimulating, and this helps keep minimally and moderately sedated patients responsive. If the dental care stops, the stimulation stops and the patient may become

unintentionally deeply sedated and possibly stop breathing. If the patient has been left alone, there is no one available in the room to rescue the patient.)

Current rules mandate that the dentist have emergency protocols/equipment/medications immediately available in the event of an emergency. Unfortunately, there was a pattern of poor emergency management in the BRP's case reviews: of the 12 cases reviewed where an emergency occurred in the office, emergency management by the dentist was judged to be poor or inadequate in 11 of those cases. The emergency failures observed in the major events and mishaps involved cases where:

- emergency drugs were available but given in the wrong dose
- emergency ventilation equipment was available, but was used ineffectively
- emergency ventilation equipment was not available
- supplemental oxygen was available but not administered when indicated
- the provider was slow to activate EMS - (***this was the most common finding***)

Long delays before activation of the emergency medical system (EMS - 911) were common, but not universal in our cases. For some doctors, making the decision to call 911 represents a personal failure and can become a major obstacle for the doctor to overcome. As the potentially liable individual in the office, making the call to summon assistance may, in the eyes of the doctor, open the door to unwanted investigation by a regulatory agency, such as the SBDE, and subsequent fear of punishment. Lack of hands on practice in crisis management likely also contributes to poor performance during an emergency.

For five of the six major events, the sedation provider received his/her training in a university/hospital facility versus a continuing education course. For the mishaps, the majority of the providers were trained in a university/hospital setting. The data does not support the concern that dentists trained outside of the university/hospital setting have more sedation accidents.

VII. Review and Analysis of Dental Rules and Laws in other States and Anesthesia Related Organizations

Dental Board of California: Pediatric Anesthesia Study, Draft July 2016

The Dental Board of California undertook a review of pediatric sedation/anesthesia incidents between 2010 and 2015. During this window of time, nine pediatric deaths were noted with various combinations of local anesthesia, sedation, and general anesthesia. Fifty-six additional pediatric hospitalizations were also described, many of which were still being investigated. Limited details are present in the draft report

regarding the deaths. Attempting to determine the proximate and root cause of death from the report would be speculative. The draft report includes an extensive review of dental sedation/anesthesia rules/laws in United States. Of note, twenty-five states have special requirements for pediatric patients. Nine states have a separate permit for sedation of pediatric patients. States are not consistent in the way they define a child.

Combined statement of the American Academy of Pediatrics and the American Academy of Pediatric Dentistry:
Coté, CJ Wilson S. AMERICAN ACADEMY OF PEDIATRICS, AMERICAN ACADEMY OF PEDIATRIC DENTISTRY. Guidelines for Monitoring and Management of Pediatric Patients Before, During and after Sedation for Diagnostic and Therapeutic Procedures: Update. 2016. Pediatrics 2016;138(1);e20161212

Comments pertinent to BRP's inquiry:

- The use of emergency checklists is recommended.
- A protocol for immediate access to back-up emergency services should be clearly outlined.
- Support staff should be specifically trained to be able to assist with a pediatric emergency.
- All team members should practice emergency protocols periodically.
- In moderate sedation, use of capnography or precordial stethoscope is strongly recommended (required if bidirectional verbal communication not possible).
- In deep sedation, use of capnography is required.

American Association of Oral and Maxillofacial Surgeons (AAOMS) - Parameters of Care: Clinical Practice Guidelines for Oral and Maxillofacial Surgery (AAOMS ParCare 2012) - policy requires that, every five years, members undergo an on-site anesthesia office inspection (by AAOMS inspectors) to ensure proper monitoring and emergency equipment is present as well as to review emergency protocols.

California Dental Board in December 2016 adopted new sedation rules for the sedation of children:

- For deep sedation/general anesthesia-limitations to operator/anesthetist model of practice.

- For moderate sedation - capnography is a required monitor, sedation training equivalent to that of an accredited pediatric dentistry residency, at least one additional staff member trained in Pediatric Advanced Life Support (PALS), for children less than seven years, an additional staff member dedicated to patient monitoring is required.

- (California Legislature and the Governor must approve these rules in order for them to take effect)

October 2016, the American Dental Association (ADA) House of Delegates adopted a resolution to modify their *Guidelines for the Use of Sedation and General Anesthesia in Dentistry.* In part, this resolution includes a mandate for the use of capnography for patients receiving moderate sedation.

Texas State Board of Dental Examiners' Review of State Dental Boards, determined that 36 of the 50 state dental boards require some sort of dental office inspection, but the details regarding implementation and structure of these inspections vary widely from state to state. Literature regarding the effectiveness of office inspections is described in the next section.

June 2014, the Texas Medical Board adopted a plan to inspect medical offices that provide anesthesia services. (Texas Administrative Code 192.5)

TAC 192.6 allows MDs to request an inspection with a non-binding advisory (for a fee)

Sunset Staff Report 2016-2017: Texas Medical Board-comments regarding medical office inspections where anesthesia is administered. The board currently registers 2,482 physicians who provide office-based anesthesia. (Approximately 7000 Texas dentists have some type of sedation permit)

Issue 2, key recommendation: "Authorize the board to establish a risk-based approach to its office-based anesthesia inspection, focusing on the length of time since equipment and procedures were last inspected."

Recommendation 2.9 "The board should focus its efforts on the inspection of equipment and office procedures instead of the registered physician to ensure that the inspectors do not waste time re-inspecting equipment approved and procedures."
(BRP recommendation will emphasize assessing the competency of the provider if office inspections are implemented)

VIII. Review and Consideration of Scientific Literature

Haynes AB et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. New England Journal of Medicine 2009;360:491-9. This article presents the results from a global study to evaluate the effectiveness of a newly

created "checklist" to be used by medical surgical teams prior to the start of a surgical procedure.

Comments pertinent to BRP's inquiry:

- Use of the pre-operative checklist reduced surgically related deaths from 1.5% to 0.8% (highly statistically significant).

- Use of the checklist reduced the overall complication rate from 11.0% to 7.0% (highly statistically significant).

Arriaga AF et al. Simulation-Based Trial of Surgical-Crisis Checklists. New England Journal of Medicine 2013;368:246-53. This article details the results of 17 surgical teams participating in 106 simulated surgical-crisis scenarios.

Comment pertinent to BRP's inquiry:

- Use of an emergency checklist reduced "missed steps" from 23% to 6% in these simulated emergencies using high fidelity human simulators

Ilgen JS et al Technology-enhanced Simulation in Emergency Medicine: A Systematic Review and Meta-Analysis. Academic Emergency Medicine 2013;20:117-127. This article reviews 85 studies, which compare simulation training to conventional training to no intervention at all.

Comment pertinent to BRP's inquiry:

- Simulation based recurrent emergency training was superior to traditional recurrent emergency training and far superior to no recurrent emergency training at all

Shapiro MJ et al. Simulation based teamwork training for emergency department staff: does it improve clinical team performance when added to an existing didactic teamwork curriculum? Quality and Safety in Healthcare 2004;13:417-21. This article reviews the results of a study to determine if adding team training (involving the staff, not just the doctors) would improve team clinical performance.

Comment pertinent to BRP's inquiry:

- Training involving the entire team improved clinical performance of the team

Bhanankar SM et al. Injury and Liability Associated with Monitored Anesthesia Care. Anesthesiology 2006;104:228-34. This article compares closed claims data for monitored anesthesia care (MAC) vs. general anesthesia. Data was abstracted from the Closed Claims database of the American Society of Anesthesiologists. Monitored

anesthesia care in the operating room is similar to level 3 moderate parenteral sedation, possibly becoming level 4 deep sedation at times.

Comment pertinent to BRP's inquiry:

- The most common cause of death/injury in MAC was associated with respiratory compromise - ventilation became inadequate during the procedure but was not adequately addressed or managed by the anesthesia provider.

Gaulton TG et al. Administrative issues to ensure safe anesthesia care in the office-based setting. Current Opinion in Anesthesiology 2013;26:692-697. The authors in this article review the wide variations between states regarding medical office based anesthesia vs. national administrative based structures to regulate office-based anesthesia. They also comment on literature concerning office Inspection/ accreditation and the use of checklists.

Comments pertinent to BRP's inquiry:

- Regarding the effectiveness of **office inspections/accreditation:** little literature exists to improve outcomes in medicine where office based anesthesia is administered. The few studies available suggest a reduction in complications in accredited facilities, but these studies have also drawn criticism concerning methodological limitations. The authors note, "Although the decrease in adverse events did coincide with an increase in practice accreditation, it is impossible to conclude causality."

- Regarding the use of **checklists**, the authors present multiple studies all showing that the use of checklists significantly reduce the incidence of complications. The authors were robust in their endorsement of the use of checklists, also noting that federal regulatory agencies such as Centers for Medicaid and Medicare Services (CMS) require the use of surgical safety checklists in their accredited ambulatory surgical centers (ASCs).

IX. Conclusion and Recommendations

The reasons patients die or become permanently disabled in connection with dental care are quite varied. In the BRP case reviews, only a minority of deaths appeared directly related to mishandled sedation/anesthesia. Each of the six major events in this review included at least one significant failure on the part of the sedation provider to follow traditionally accepted core concepts of proper sedation/anesthesia technique. Failures included: poor pre-operative evaluation, poor technique, poor monitoring, and poor emergency management. In fact, all six of the major events included at least two major failures.

In the six major events studied by BRP, if current rules had been closely followed and the failures avoided, there likely would have been no sedation related event. Every patient would have been thoroughly evaluated pre-operatively for the planned sedation/anesthetic, drugs would have been conservatively and cautiously administered, and keeping patients closely monitored both electronically and personally by the dentist throughout the procedure. For the minimal and moderate sedation providers, patients would never have become unresponsive. If a truly unpredictable emergency event had occurred, the well-trained and practiced team would have worked together to efficiently manage the situation, including a rapid call to 911 when appropriate.

Unfortunately, these events did occur and they appear related to failures by the sedation/anesthesia provider at a basic level: poor preparation, poor technique and poor performance when an emergency did occur. It is unclear why practitioners allow this to happen. Equally challenging is to know how to remedy the situation.

The challenge to this panel is to consider whether or not reasonable changes to laws, rules or enforcement will motivate dentists to not be lax, but be meticulously attentive to each step in the sedation/anesthesia process and maintain the highest standard of safety. Rules changes should not limit access to care and should create a regulatory structure to foster best practices in sedation/anesthesia.

The BRP discussed many possible recommendations and suggestions that might be helpful, some clinical in nature, some administrative.

Clinical recommendations:

The SBDE should have the authority to conduct inspections of dentists administering sedation/anesthesia. Thirty-six states have some type of sedation/anesthesia office provider inspection. The BRP suggests any inspections emphasize evaluation of the competency of the dentist.

The SBDE have the authority to review sedation records of level 2, 3 and 4 providers. Determination that the records did not meet the standard of care would be used as an indicator for an on-site office inspection. In the 19 major events/mishaps, there was a strong correlation between poor documentation and poor performance during an office emergency.

The SBDE mandate that sedation providers have written emergency protocols and that they be required to practice these protocols six times per year.
Of the cases where an emergency occurred in the office, 11 of 13 mishaps were managed poorly. Literature clearly supports not only the use of emergency protocols (checklists) but also the use of pre-operative checklists. This should include a mechanism to encourage rapid activation of EMS when an emergency occurs and assure adequate access for EMS services.

The SBDE mandate that at least one support staff assisting with a sedation procedure (level 2, 3, 4) receive training in the recognition and management of sedation/anesthesia related emergencies. Literature clearly documents that emergency management improves as the entire team is trained as opposed to only the doctor.

The SBDE require level 2, 3, 4 providers who desire to sedate/anesthetize children under 8 years of age to document specific training in the management of this age group of patients.

The SBDE require level 2, 3, 4 providers who desire to sedate/anesthetize high-risk adults (75 years of age and older, ASA 3 or 4, obese - BMI greater than or equal to 30) to document specific training in the management of this group of patients. Each of the major events in this case series involved a child less than 8 years or a high-risk adult.

The SBDE mandate that offices where portable providers function have basic ventilation equipment on-site. Two of the six major events involved a portable provider who attempted to manage an emergency without ventilation equipment.

The SBDE mandate the use of capnography and a precordial stethoscope for level 2, 3 and 4 sedation. Of all the potential recommendations discussed by the BRP, this was the only one that did not garner almost immediate and unanimous support. The recommendation passed but with clear reservation by several members. Valid concerns were raised regarding applicability in level 2 and 3 sedation. Literature support for the use of capnography or a precordial stethoscope in deep sedation is well accepted, but is controversial in moderate sedation. Further consideration and study of the issue is needed by an ongoing committee of the board.

Administrative recommendations:

The SBDE continue to utilize an independent panel of expert sedation/anesthesia providers to advise the Board. This BRP was given only a short period of time to accomplish their assigned task. An ongoing group can continue to discuss and more fully evaluate ideas based on evolving scientific literature that may allow improved patient safety.

The SBDE make public de-identified sedation related major events and mishaps. If other state dental boards would do the same, a much larger pool of information would be available with which to draw better conclusions.

The Texas Legislature make an effort to encourage other state legislatures to share de-identified sedation/anesthesia data publicly. If a majority of states would participate, a much more scientifically valid pool of data would be available for study. This would include both accident data and non-accident data.

The SBDE collect data regarding sedations performed by Texas dentists. (non-accident data)

The SBDE create a system to evaluate and approve sedation/anesthesia continuing education programs.

The SBDE mandate that the sedation record for a dental procedure be a required part of the dental record, even if the sedation provider is a non-dentist.

Administrative suggestions:

The SBDE consider creation of a required online sedation/anesthesia rules examination.

The SBDE consider encouraging or mandating that dentists use a preoperative sedation checklist.

The SBDE consider including more detail in the SBDE rules regarding appropriate pre-operative evaluation and an acceptable sedation/anesthesia record.

APPENDIX 1

Texas Administrative Code

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA

Rules

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.1	Definitions

Unless the context clearly indicates otherwise, the following words and terms shall have the following meaning when used in this chapter.

(1) Analgesia--the diminution or elimination of pain.

(2) Behavioral management--the use of pharmacological or psychological techniques, singly or in combination, to modify behavior to a level that dental treatment can be performed effectively and efficiently.

(3) Board/Agency--the Texas State Board of Dental Examiners, also known as the State Board of Dental Examiners, and, for brevity, the Dental Board, the Agency, or the Board.

(4) Child/children--a patient twelve (12) years of age or younger.

(5) Competent--displaying special skill or knowledge derived from training and experience.

(6) Deep sedation--a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(7) Direct supervision--the dentist responsible for the sedation/anesthesia procedure shall be physically present in the facility and shall be continuously aware of the patient's physical status and well-being.

(8) Enteral--any technique of administration of sedation in which the agent is absorbed through the gastrointestinal (GI) tract or oral mucosa (i.e., oral, rectal, sublingual).

(9) Facility--the location where a permit holder practices dentistry and provides anesthesia/sedation services.

(10) Facility inspection--an on-site inspection to determine if a facility where the applicant proposes to provide anesthesia/sedation is supplied, equipped, staffed and maintained in a condition to support provision of anesthesia/sedation services that meet the minimum standard of care.

(11) General anesthesia--a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(12) Immediately available--on-site in the facility and available for immediate use.

(13) Incremental dosing--administration of multiple doses of a drug until a desired effect is reached, but not to exceed the maximum recommended dose (MRD).

(14) Local anesthesia--the elimination of sensation, especially pain, in one part of the body by the topical application or regional injection of a drug.

(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, previsit sedatives for children aged twelve (12) or younger should be avoided due to the risk of unobserved respiratory obstruction during the transport by untrained individuals.

(17) Moderate sedation--drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. A Level 2 permit is required for moderate sedation limited to enteral routes of administration. A Level 3 permit is required for moderate sedation including parenteral routes of administration. In accordance with this particular definition, the drugs or techniques used shall carry a margin of safety wide enough to render unintended loss of consciousness unlikely. Repeated dosing of an agent before the effects of previous dosing can be fully appreciated may result in a greater alteration of the state of consciousness than is the intent of the dentist. A patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

(18) Parenteral--the administration of pharmacological agents intravenously, intraosseously, intramuscularly, subcutaneously, submucosally, intranasally, or transdermally.

(19) Patient Physical Status Classification:

(A) ASA--American Society of Anesthesiologists

(B) ASA I--a normal health patient

(C) ASA II--a patient with mild systemic disease

(D) ASA III--a patient with severe systemic disease

(E) ASA IV--a patient with severe systemic disease that is a constant threat to life

(F) ASA V--a moribund patient who is not expected to survive without the operation

(G) ASA VI--a declared brain-dead patient whose organs are being removed for donor purposes

(H) E--emergency operation of any variety (used to modify ASA I - ASA VI).

(20) Portability--the ability of a permit holder to provide permitted anesthesia services in a location other than a facility or satellite facility.

(21) Protective reflexes--includes the ability to swallow and cough effectively.

(22) Satellite facility--an additional office or offices owned or operated by the permit holder, or owned or operated by a professional organization through which the permit holder practices dentistry, or a licensed hospital facility.

(23) Supplemental dosing (applies to minimal sedation)--during minimal sedation, supplemental dosing is a single additional dose of the initial dose of the initial drug that may be necessary for prolonged procedures. The supplemental dose should not exceed one-half of the initial dose and should not be administered until the dentist has determined the clinical half-life of the initial dosing has passed. The aggregate dose must not exceed one and one-half times the MRD on the day of treatment.

(24) Time-oriented anesthesia record--documentation at appropriate time intervals of drugs, doses, and physiologic data obtained during patient monitoring. Physiologic data for moderate sedation, deep sedation and general anesthesia must be taken and recorded at required intervals unless patient cooperation interferes or prohibits compliance.

(25) Titration (applies to moderate sedation)--administration of incremental doses of a drug until the desired effect is reached. Knowledge of each drug's time of onset, peak response and duration of action is essential to avoid over-sedation. When the intent is moderate sedation, one must know whether the previous dose has taken full effect before administering an additional drug increment.

Source Note: The provisions of this §110.1 adopted to be effective May 10, 2011, 36 TexReg 2833

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.2	Sedation/Anesthesia Permit

(a) A dentist licensed under Chapter 101 of this title shall obtain an anesthesia permit for the following anesthesia procedures used for the purpose of performing dentistry:

(1) Nitrous Oxide/Oxygen inhalation sedation;

(2) Level 1: Minimal sedation;

(3) Level 2: Moderate sedation limited to enteral routes of administration;

(4) Level 3: Moderate sedation which includes parenteral routes of administration; or

(5) Level 4: Deep sedation or general anesthesia.

(b) A dentist licensed to practice in Texas who desires to administer nitrous oxide/oxygen inhalation sedation or Level 1, Level 2, Level 3 or Level 4 sedation must obtain a permit from the State Board of Dental Examiners (Board). A permit is not required to administer Schedule II drugs prescribed for the purpose of pain control or post-operative care.

(1) A permit may be obtained by completing an application form approved by the Board.

(2) The application form must be filled out completely and appropriate fees paid.

(3) Prior to issuance of a sedation/anesthesia permit, the Board may require that the applicant undergo a facility inspection or further review of credentials. The Board may direct an Anesthesia Consultant, who has been appointed by the Board, to assist in this inspection or review. The applicant will be notified in writing if an inspection is required and provided with the name of an Anesthesia Consultant who will coordinate the inspection. The applicant must make arrangements for completion of the inspection within 180 days of the date the notice is mailed. An extension of no more than ninety (90) days may be granted if the designated Anesthesia Consultant requests one.

(4) An applicant for a sedation/anesthesia permit must be licensed by and should be in good standing with the Board. For purposes of this chapter "good standing" means that the dentist's license is not suspended, whether or not the suspension is probated. Applications from licensees who are not in good standing may not be approved.

Source Note: The provisions of this §110.2 adopted to be effective May 10, 2011, 36 TexReg 2833

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.3	Nitrous Oxide/Oxygen Inhalation Sedation

(a) Education and Professional Requirements. A dentist applying for a nitrous oxide/oxygen inhalation sedation permit shall meet one of the following educational/professional criteria:

(1) satisfactory completion of a comprehensive training program consistent with that described for nitrous oxide/oxygen inhalation sedation administration in the American Dental Association (ADA) Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. This includes a minimum of fourteen (14) hours of training, including a clinical component, during which competency in inhalation sedation technique is achieved. Acceptable courses include those obtained from academic programs of instruction recognized by the ADA Commission on Dental Accreditation (CODA); or courses approved and recognized by the ADA Continuing Education Recognition Program (CERP); or courses approved and recognized by the Academy of General Dentistry (AGD) Program Approval for Continuing Education (PACE);

(2) satisfactory completion of an ADA/CODA approved or recognized pre-doctoral dental or postdoctoral dental training program which affords comprehensive training necessary to administer and manage nitrous oxide/oxygen inhalation sedation; or

(3) is a Texas licensed dentist, has a current Board-issued nitrous oxide/oxygen inhalation sedation permit, and has been using nitrous oxide/oxygen inhalation sedation in a competent manner immediately prior to the implementation of this chapter on June 1, 2011. Any dentist whose Board-issued nitrous oxide/oxygen inhalation sedation permit is active on June 1, 2011 shall automatically continue to hold this permit.

(b) Standard of Care Requirements. A dentist performing nitrous oxide/oxygen inhalation sedation shall maintain the minimum standard of care for anesthesia, and in addition shall:

(1) adhere to the clinical requirements as detailed in this section;

(2) maintain under continuous direct supervision auxiliary personnel who shall be capable of reasonably assisting in procedures, problems, and emergencies incident to the use of nitrous oxide/oxygen inhalation sedation;

(3) maintain current certification in Basic Life Support (BLS) for Healthcare Providers for the assistant staff by having them pass a course that includes a written examination and a hands-on demonstration of skills; and

(4) not supervise a Certified Registered Nurse Anesthetist (CRNA) performing a nitrous oxide/oxygen inhalation sedation procedure unless the dentist holds a permit issued by the Board for the sedation procedure being performed. This provision and similar provisions in subsequent sections address dentists and are not intended to address the scope of practice of persons licensed by any other agency.

(c) Clinical Requirements. A dentist must meet the following clinical requirements to utilize nitrous oxide/oxygen inhalation sedation:

(1) Patient Evaluation. Patients considered for nitrous oxide/oxygen inhalation sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II), this may consist of a review of their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with the patient's primary care physician or consulting medical specialist.

(2) Pre-Procedure Preparation and Informed Consent.

(A) The patient, parent, guardian, or care-giver must be advised of the risks associated with the delivery of nitrous oxide/oxygen inhalation sedation and must provide written, informed consent for the proposed sedation.

(B) The dentist shall determine that an adequate oxygen supply is available and evaluate equipment for proper operation and delivery of inhalation agents prior to use on each patient.

(C) Baseline vitals must be obtained in accordance with §108.7 and §108.8 of this title.

(3) Personnel and Equipment Requirements.

(A) In addition to the dentist, at least one member of the assistant staff should be present during the administration of nitrous oxide/oxygen inhalation sedation in nonemergency situations.

(B) The inhalation equipment must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either:

(i) a functioning device that prohibits the delivery of less than 30% oxygen; or

(ii) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.

(C) If nitrous oxide and oxygen delivery equipment capable of delivering less than 30% oxygen is used, an in-line oxygen analyzer must be utilized.

(D) The equipment must have an appropriate nitrous oxide/oxygen scavenging system.

(E) The ability of the provider and/or the facility to deliver positive pressure oxygen must be maintained.

(4) Monitoring.

(A) The dentist must induce the nitrous oxide/oxygen inhalation sedation and must remain in the room with the patient during the maintenance of the sedation until pharmacologic and physiologic vital sign stability is established.

(B) After pharmacologic and physiologic vital sign stability has been established, the dentist may delegate the monitoring of the nitrous oxide/oxygen inhalation sedation to a dental auxiliary who has been certified to monitor the administration of nitrous oxide/oxygen inhalation sedation by the State Board of Dental Examiners.

(5) Documentation.

(A) Pre-operative baseline vitals must be documented.

(B) Individuals present during administration must be documented.

(C) Maximum concentration administered must be documented.

(D) The start and finish times of the inhalation agent must be documented.

(6) Recovery and Discharge.

(A) Recovery from nitrous oxide/oxygen inhalation sedation, when used alone, should be relatively quick, requiring only that the patient remain in an operatory chair as needed.

(B) Patients who have unusual reactions to nitrous oxide/oxygen inhalation sedation should be assisted and monitored either in an operatory chair or recovery room until stable for discharge.

(C) The dentist must determine that the patient is appropriately responsive prior to discharge. The dentist shall not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

(7) Emergency Management. Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation. The dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of the nitrous oxide, and providing the equipment and protocols for patient rescue. A dentist must be able to rescue patients who enter a deeper state of sedation than intended. The dentist, personnel and facility must be prepared to treat emergencies that may arise from the administration of nitrous oxide/oxygen inhalation sedation.

(8) Management of Children. For children twelve (12) years of age and under, the dentist should observe the American Academy of Pediatrics/American Academy of Pediatric Dentists Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

(d) A dentist who holds a nitrous oxide/oxygen inhalation sedation permit shall not intentionally administer minimal sedation, moderate sedation, deep sedation, or general anesthesia.

Source Note: The provisions of this §110.3 adopted to be effective May 10, 2011, 36 TexReg 2833

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.4	Minimal Sedation

(a) Education and Professional Requirements. A dentist applying for a Level 1 Minimal Sedation permit shall meet one of the following educational/professional criteria:

(1) satisfactory completion of training to the level of competency in minimal sedation consistent with that prescribed in the American Dental Association (ADA) Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students, or a comprehensive training program in minimal sedation that satisfies the requirements described in the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. This includes a minimum of sixteen (16) hours of didactic training and instruction in which competency in enteral and/or combined inhalation-enteral minimal sedation technique is demonstrated; or

(2) satisfactory completion of an advanced education program accredited by the ADA Commission on Dental Accreditation (CODA) that affords comprehensive training necessary to administer and manage minimal sedation, commensurate with the ADA's Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students; or

(3) is a Texas licensed dentist, has a current Board-issued enteral permit, and has been using minimal sedation in a competent manner immediately prior to the implementation of this chapter on June 1, 2011. Any Texas licensed dentist who was issued an enteral sedation permit before June 1, 2011 and whose enteral sedation permit was active on June 1, 2011 shall automatically have the permit reclassified as a Level 1 Minimal Sedation permit on June 1, 2011. A Texas licensed dentist whose permit is reclassified from an enteral sedation permit to a Level 1 Minimal Sedation permit on June 1, 2011 may continue to administer enteral sedation until January 1, 2013. On or before January 1, 2013, the dentist shall either provide proof that adequate education has been obtained by submitting an application for a Level 2 permit on or before that date, or shall comply with the requirements of a Level 1 permit after that date. A dentist shall always follow the standard of care and clinical requirements for the level of sedation he or she is performing.

(b) Standard of Care Requirements. A dentist performing minimal sedation shall maintain the minimum standard of care for anesthesia, and in addition shall:

(1) adhere to the clinical requirements as detailed in this section;

(2) maintain under continuous direct supervision auxiliary personnel who shall be capable of reasonably assisting in procedures, problems, and emergencies incident to the use of minimal sedation;

(3) maintain current certification in Basic Life Support (BLS) for Healthcare Providers for the assistant staff by having them pass a course that includes a written examination and a hands-on demonstration of skills; and

(4) not supervise a Certified Registered Nurse Anesthetist (CRNA) performing a minimal sedation procedure unless the dentist holds a permit issued by the Board for the sedation procedure being performed.

(c) Clinical Requirements. A dentist must meet the following clinical requirements for utilization of minimal sedation:

(1) Patient Evaluation. Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II), this may consist of a review of

their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

(2) Pre-Procedure Preparation and Informed Consent.

(A) The patient, parent, guardian, or care-giver must be advised regarding the procedure associated with the delivery of any sedative agents and must provide written, informed consent for the proposed sedation.

(B) The dentist shall determine that an adequate oxygen supply is available and evaluate equipment for proper operation and delivery of adequate oxygen under positive pressure.

(C) Baseline vital signs must be obtained in accordance with §108.7 and §108.8 of this title.

(D) A focused physical evaluation must be performed as deemed appropriate.

(E) Pre-procedure dietary restrictions must be considered based on the sedative technique prescribed.

(F) Pre-procedure verbal and written instructions must be given to the patient, parent, escort, guardian, or care-giver.

(3) Personnel and Equipment Requirements.

(A) In addition to the dentist, at least one additional person trained in Basic Life Support (BLS) for Healthcare Providers must be present.

(B) A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.

(C) When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either:

(i) a functioning device that prohibits the delivery of less than 30% oxygen; or

(ii) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.

(D) An appropriate scavenging system must be available if gases other than oxygen or air are used.

(4) Monitoring. The dentist administering the sedation must remain in the operatory room to monitor the patient until the patient meets the criteria for discharge to the recovery area. Once the patient meets the criteria for discharge to the recovery area, the dentist may delegate monitoring to a qualified dental auxiliary. Monitoring during the administration of sedation must include:

(A) Oxygenation.

(i) Color of mucosa, skin, or blood must be evaluated continually.

(ii) Oxygen saturation monitoring by pulse-oximetry should be used when a single drug minimal sedative is used. The additional use of nitrous oxide has a greater potential to increase the patient's level of sedation to moderate sedation, and a pulse oximeter must be used.

(B) Ventilation. The dentist (or appropriately qualified individual) must observe chest excursions and must verify respirations continually.

(C) Circulation. Blood pressure and heart rate should be evaluated preprocedurally, post-procedurally and intra-procedurally as necessary.

(5) Documentation.

(A) Documentation must be made in accordance with §108.7 and §108.8 of this title and must include the names and dosages of all drugs administered and the names of individuals present during administration of the drugs.

(B) A time-oriented sedation record may be considered for documentation of all monitoring parameters.

(C) Pulse oximetry, heart rate, respiratory rate, and blood pressure are the parameters which may be documented at appropriate intervals of no more than 10 minutes.

(6) Recovery and Discharge.

(A) Oxygen and suction equipment must be immediately available in the recovery area if a separate recovery area is utilized.

(B) The qualified dentist must monitor the patient during recovery until the patient is ready for discharge by the dentist. The dentist may delegate this task to an appropriately qualified dental auxiliary.

(C) The dentist must determine and document that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory prior to discharge. The dentist shall not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

(D) Post-procedure verbal and written instructions must be given to the patient, parent, escort, guardian, or care-giver. Post-procedure, patients should be accompanied by an adult caregiver for an appropriate period of recovery.

(7) Emergency Management. Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation. The dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation, and providing the equipment and protocols for patient rescue. A dentist must be able to rescue patients who enter a deeper state of sedation than intended.

(8) Management of Children. For children twelve (12) years of age and under, the dentist should observe the American Academy of Pediatrics/American Academy of Pediatric Dentists Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

(d) A dentist who holds a minimal sedation permit shall not intentionally administer moderate sedation, deep sedation, or general anesthesia.

Source Note: The provisions of this §110.4 adopted to be effective May 10, 2011, 36 TexReg 2833

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.5	Moderate Sedation

(a) Education and Professional Requirements.

(1) A dentist applying for a Level 2 Moderate Sedation permit (limited to enteral route of administration) must satisfy at least one of the following educational/professional criteria:

(A) satisfactory completion of a comprehensive training program consistent with that described for moderate enteral sedation in the American Dental Association (ADA) Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. This includes a minimum of twenty-four (24) hours of instruction, plus management of at least ten (10) case experiences in enteral moderate sedation. These ten (10) case experiences must include at least three live clinical dental experiences managed by participants in groups of no larger than five (5). The remaining cases may include simulations and/or video presentations, but must include one experience in returning (rescuing) a patient from deep to moderate sedation; or

(B) satisfactory completion of an advanced education program accredited by the ADA Commission on Dental Accreditation (CODA) that affords comprehensive and appropriate training necessary to administer and manage enteral moderate sedation, commensurate with the ADA's Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students; or

(C) is a Texas licensed dentist who was issued an enteral sedation permit before June 1, 2011 and whose enteral sedation permit was active on June 1, 2011. Dentists in this category shall automatically have their permit reclassified as a Level 1 Minimal Sedation permit on June 1, 2011. A Texas licensed dentist whose permit is reclassified from an enteral sedation permit to a Level 1 Minimal Sedation permit on June 1, 2011 may continue to administer enteral sedation until January 1, 2013. On or before January 1, 2013, the dentist shall either provide proof that adequate education has been obtained by submitting an application for a Level 2 permit on or before that date, or shall comply with the requirements of a Level 1 permit after that date. A dentist shall always follow the standard of care and clinical requirements for the level of sedation he or she is performing.

(2) A dentist applying for a Level 3 Moderate Sedation permit (inclusive of parenteral routes of administration) must satisfy at least one of the following educational/professional criteria:

(A) satisfactory completion of a comprehensive training program consistent with that described for parenteral moderate sedation in the ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students. This includes a minimum of sixty (60) hours of didactic training and instruction and satisfactory management of a minimum of twenty (20) dental patients, under supervision, using intravenous sedation; or

(B) satisfactory completion of an advanced education program accredited by the ADA/CODA that affords comprehensive and appropriate training necessary to administer and manage parenteral moderate sedation, commensurate with the ADA's Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students; or

(C) satisfactory completion of an internship or residency which included intravenous moderate sedation training equivalent to that defined in this subsection; or

(D) is a Texas licensed dentist who had a current parenteral sedation permit issued by the Board and has been using parenteral sedation in a competent manner immediately prior to the implementation of this chapter on June 1, 2011. A Texas licensed dentist whose Board-issued permit to perform parenteral sedation is active on June 1, 2011 shall automatically have the permit reclassified as a Level 3 Moderate Sedation (inclusive of parenteral routes of administration) permit.

(3) A dentist applying for a Level 2 or 3 Moderate Sedation permit must satisfy the following emergency management certification criteria:

(A) Licensees holding moderate sedation permits shall document:

(i) Current (as indicated by the provider), successful completion of Basic Life Support (BLS) for Healthcare Providers; AND

(ii) Current (as indicated by the provider), successful completion of an Advanced Cardiac Life Support (ACLS) course, OR current (as indicated by the provider), successful completion of a Pediatric Advanced Life Support (PALS) course.

(B) Licensees holding Level 2 or Level 3 Moderate Sedation permits who provide anesthesia services to children (age twelve (12) or younger) must document current, successful completion of a PALS course.

(b) Standard of Care Requirements. A dentist must maintain the minimum standard of care as outlined in §108.7 of this title and in addition shall:

(1) adhere to the clinical requirements as detailed in this section;

(2) maintain under continuous personal supervision auxiliary personnel who shall be capable of reasonably assisting in procedures, problems, and emergencies incident to the use of moderate sedation;

(3) maintain current certification in Basic Life Support (BLS) for Healthcare Providers for the assistant staff by having them pass a course that includes a written examination and a hands-on demonstration of skills; and

(4) not supervise a Certified Registered Nurse Anesthetist (CRNA) performing a moderate sedation procedure unless the dentist holds a permit issued by the Board for the sedation procedure being performed.

(c) Clinical Requirements.

(1) Patient Evaluation. Patients considered for moderate sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this should consist of at least a review of the patient's current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

(2) Pre-Procedure Preparation and Informed Consent.

(A) The patient, parent, guardian, or care-giver must be advised regarding the procedure associated with the delivery of any sedative agents and must provide written, informed consent for the proposed sedation. The informed consent must be specific to the procedure being performed and must specify that the risks related to the procedure include cardiac arrest, brain injury, and death.

(B) The dentist shall determine that an adequate oxygen supply is available and evaluate equipment for proper operation and delivery of adequate oxygen under positive pressure.

(C) Baseline vital signs must be obtained in accordance with §108.7 and §108.8 of this title.

(D) A focused physical evaluation must be performed as deemed appropriate.

(E) Pre-procedure dietary restrictions must be considered based on the sedative technique prescribed.

(F) Pre-procedure verbal or written instructions must be given to the patient, parent, escort, guardian, or care-giver.

(3) Personnel and Equipment Requirements.

(A) In addition to the dentist, at least one additional person trained in Basic Life Support (BLS) for Healthcare Providers must be present.

(B) A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.

(C) When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either:

(i) a functioning device that prohibits the delivery of less than 30% oxygen; or

(ii) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.

(D) An appropriate scavenging system must be available if gases other than oxygen or air are used.

(E) The equipment necessary to establish intravenous access must be available.

(4) Monitoring. The dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level, the dentist may delegate a qualified dental auxiliary to remain with the patient and continue to monitor the patient until he/she is discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

(A) Consciousness. Level of consciousness (e.g., responsiveness to verbal command) must be continually assessed.

(B) Oxygenation.

(i) Color of mucosa, skin, or blood must be evaluated continually.

(ii) Oxygen saturation must be evaluated by pulse-oximetry continuously.

(C) Ventilation.

(i) Chest excursions must be continually observed.

(ii) Ventilation must be continually evaluated. This can be accomplished by auscultation of breath sounds, monitoring end-tidal CO2 or by verbal communication with the patient.

(D) Circulation.

(i) Blood pressure and heart rate must be continually evaluated.

(ii) Continuous EKG monitoring of patients sedated under moderate parenteral sedation is required.

(5) Documentation.

(A) Documentation must be made in accordance with §108.7 and §108.8 of this title.

(B) A written time-oriented anesthetic record must be maintained and must include the names and dosages of all drugs administered and the names of individuals present during administration of the drugs.

(C) Pulse-oximetry, heart rate, respiratory rate, and blood pressure must be continually monitored and documented at appropriate intervals of no more than ten (10) minutes.

(6) Recovery and Discharge.

(A) Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.

(B) While the patient is in the recovery area, the dentist or qualified clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation, and level of consciousness.

(C) The dentist must determine and document that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge. The dentist shall not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

(D) Post-procedure verbal and written instructions must be given to the patient, parent, escort, guardian, or care-giver. Post-procedure, patients should be accompanied by an adult caregiver for an appropriate period of recovery.

(E) If a reversal agent is administered before discharge criteria have been met, the patient must be monitored until recovery is assured.

(7) Emergency Management.

(A) The dentist is responsible for the sedation management, adequacy of the facility and staff, diagnosis and treatment of emergencies associated with the administration of moderate sedation, and providing the equipment and protocols for patient rescue. This includes immediate access to pharmacologic antagonists and equipment for establishing a patent airway and providing positive pressure ventilation with oxygen.

(B) Advanced airway equipment and resuscitation medications must be available.

(C) A defibrillator should be available when ASA I and II patients are sedated under moderate sedation. A defibrillator must be available when ASA III and IV patients are sedated under moderate sedation.

(D) Because sedation is a continuum, it is not always possible to predict how an individual patient will respond. If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation. The dentist administering moderate sedation must be able to recover patients who enter a deeper state of sedation than intended.

(8) Management of Children. For children twelve (12) years of age and under, the dentist should observe the American Academy of Pediatrics/American Academy of Pediatric Dentists Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

(d) A dentist who holds a moderate sedation permit shall not intentionally administer deep sedation or general anesthesia.

Source Note: The provisions of this §110.5 adopted to be effective May 10, 2011, 36 TexReg 2833; amended to be effective September 3, 2014, 39 TexReg 6857

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.6	Deep Sedation or General Anesthesia

(a) Education and Professional Requirements.

(1) A dentist applying for a permit to administer deep sedation or general anesthesia must satisfy one of the following criteria:

(A) satisfactory completion of an advanced education program accredited by the American Dental Association (ADA) Commission on Dental Accreditation (CODA) that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia; or

(B) is a Texas licensed dentist who holds a current permit to administer deep sedation or general anesthesia issued by the Board and who has been using deep sedation or general anesthesia in a competent manner immediately prior to the implementation of this chapter on June 1, 2011. A Texas licensed dentist whose Board-issued permit to perform deep sedation or general anesthesia is active on June 1, 2011 shall automatically have the permit reclassified as a Level 4 Deep Sedation or General Anesthesia permit.

(2) A dentist applying for a permit to administer deep sedation or general anesthesia must satisfy the following emergency management certification criteria:

(A) Licensees holding deep sedation or general anesthesia permits shall document:

(i) Current (as indicated by the provider), successful completion of Basic Life Support (BLS) for Healthcare Providers; AND

(ii) Current (as indicated by the provider), successful completion of an Advanced Cardiac Life Support (ACLS) course, OR current (as indicated by the provider), successful completion of a Pediatric Advanced Life Support (PALS) course.

(B) Licensees holding deep sedation or general anesthesia permits who provide anesthesia services to children (age twelve (12) or younger) must document current, successful completion of a PALS course.

(b) Standard of Care Requirements. A dentist must maintain the minimum standard of care for the administration of anesthesia as outlined in §108.7 of this title and in addition shall:

(1) adhere to the clinical requirements as detailed in this section;

(2) maintain under continuous direct supervision a minimum of two qualified dental auxiliary personnel who shall be capable of reasonably assisting in procedures, problems, and emergencies incident to the use of deep sedation and/or general anesthesia;

(3) maintain current certification in Basic Life Support (BLS) for Healthcare Providers for the assistant staff by having them pass a course that includes a written examination and a hands-on demonstration of skills; and

(4) not supervise a Certified Registered Nurse Anesthetist (CRNA) performing a deep sedation/general anesthesia procedure unless the dentist holds a permit issued by the Board for the sedation procedure being performed.

(c) Clinical Requirements.

(1) Patient Evaluation. Patients considered for deep sedation or general anesthesia must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this must consist of at least a review of their current medical history, medication use, and NPO status. However, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

(2) Pre-Procedure Preparation and Informed Consent.

(A) The patient, parent, guardian, or care-giver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and must provide written, informed consent for the proposed deep sedation or general anesthesia procedure. The informed consent must be specific to the deep sedation and/or general anesthesia procedure being performed and must specify that the risks related to the procedure include cardiac arrest, brain injury, and death.

(B) The dentist shall determine that an adequate oxygen supply is available and evaluate equipment for proper operation and delivery of adequate oxygen under positive pressure.

(C) Baseline vital signs must be obtained in accordance with §108.7 and §108.8 of this title.

(D) A focused physical evaluation must be performed as deemed appropriate.

(E) Pre-procedure dietary restrictions must be considered based on the sedative/anesthetic technique prescribed.

(F) Pre-procedure verbal and written instructions must be given to the patient, parent, escort, guardian, or care-giver.

(G) An intravenous line, which is secured throughout the procedure, must be established except as provided in paragraph (7) of this subsection, regarding Pediatric and Special Needs Patients.

(3) Personnel and Equipment Requirements.

(A) Personnel. A minimum of three (3) individuals must be present during the procedure:

(i) a dentist who is qualified to administer the deep sedation or general anesthesia who is currently certified in ACLS and/or PALS; and

(ii) two additional individuals who have current certification of successfully completing a course in Basic Life Support (BLS) for Healthcare Providers, one of which must be dedicated to assisting with patient monitoring.

(B) Equipment.

(i) A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.

(ii) When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either:

(I) a functioning device that prohibits the delivery of less than 30% oxygen; or

(II) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.

(iii) An appropriate scavenging system must be available if gases other than oxygen are used.

(iv) The equipment necessary to establish intravenous access must be available.

(v) Equipment and drugs necessary to provide advanced airway management and advanced cardiac life support must be immediately available.

(vi) If volatile anesthetic agents are utilized, an inspired agent analysis monitor and capnograph should be considered.

(vii) Emergency medications and a defibrillator must be immediately available.

(4) Monitoring. A qualified dentist administering deep sedation or general anesthesia must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

(A) Oxygenation.

(i) Color of mucosa, skin, or blood must be continually evaluated.

(ii) Oxygenation saturation must be evaluated continuously by pulse oximetry.

(B) Ventilation.

(i) Intubated patient: End-tidal CO2 must be continuously monitored and evaluated.

(ii) Non-intubated patient: Breath sounds via auscultation and/or end-tidal CO2 must be continually monitored and evaluated.

(iii) Respiration rate must be continually monitored and evaluated.

(C) Circulation.

(i) Heart rate and rhythm via EKG and pulse rate via pulse oximetry must be evaluated throughout the procedure.

(ii) Blood pressure must be continually monitored.

(D) Temperature.

(i) A device capable of measuring body temperature must be readily available during the administration of deep sedation or general anesthesia.

(ii) The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered.

(5) Documentation.

(A) Documentation must be made in accordance with §108.7 and §108.8 of this title and must include the names, times and dosages of all drugs administered and the names of individuals present during administration of the drugs.

(B) A written time-oriented anesthetic record must be maintained.

(C) Pulse oximetry and end-tidal CO2 measurements (if taken with an intubated patient), heart rate, respiratory rate, and blood pressure must be continually recorded at five (5) minute intervals.

(6) Recovery and Discharge.

(A) Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.

(B) The dentist or clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation, and level of consciousness.

(C) The dentist must determine and document that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory prior to discharge. The dentist shall not leave the facility until the patient meets the criteria for discharge and is discharged from the facility.

(D) Post-procedure verbal and written instructions must be given to the patient, parent, escort, guardian, or care-giver. Post-procedure, patients should be accompanied by an adult caregiver for an appropriate period of recovery.

(7) Special Situations.

(A) Special Needs Patients. Because many dental patients undergoing deep sedation or general anesthesia are mentally and/or physically challenged, it is not always possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. When these situations occur, the dentist responsible for administering the deep sedation or general anesthesia shall document the reasons preventing the pre-procedure management.

(B) Management of Children. For children twelve (12) years of age and under, the dentist should observe the American Academy of Pediatrics/American Academy of Pediatric Dentists Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

(8) Emergency Management.

(A) The dentist is responsible for the sedation management, adequacy of the facility and staff, diagnosis and treatment of emergencies associated with the administration of deep sedation or general anesthesia, and providing the equipment and protocols for patient rescue. This includes immediate access to pharmacologic antagonists and equipment for establishing a patent airway and providing positive pressure ventilation with oxygen.

(B) Advanced airway equipment, emergency medications and a defibrillator must be immediately available.

(C) Appropriate pharmacologic agents must be immediately available if known triggering agents of malignant hyperthermia are part of the anesthesia plan.

Source Note: The provisions of this §110.6 adopted to be effective May 10, 2011, 36 TexReg 2833; amended to be effective September 3, 2014, 39 TexReg 6857

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.7	Portability

(a) A sedation/anesthesia permit is valid for the dentist's facility, if any, as well as any satellite facility.

(b) A Texas licensed dentist who holds the Board-issued privilege of portability on or before June 1, 2011 will automatically continue to hold that privilege provided the dentist complies with the renewal requirements of this section.

(c) Portability of a sedation/anesthesia permit will be granted to a dentist who, after June 1, 2011, applies for portability, if the dentist:

(1) holds a Level 4 Deep Sedation/General Anesthesia permit;

(2) holds a Level 3 Moderate Parenteral Sedation permit and the permit was granted based on education received in conjunction with the completion of a oral and maxillofacial specialty education program or a dental anesthesia program; or

(3) holds a Level 3 Moderate Parenteral Sedation permit and if:

(A) the training for the permit was obtained on the basis of completion of any of the following American Dental Association (ADA) Commission on Dental Accreditation (CODA) recognized or approved programs:

(i) a specialty program;

(ii) a general practice residency;

(iii) an advanced education in general dentistry program; or

(iv) a continuing education program. Dentists seeking a portability privilege designation based on this method of education shall also successfully complete no less than sixty (60) hours of didactic instruction and manage no less than twenty (20) dental patients by the intravenous route of administration; and

(B) the applicant provides proof of administration of no less than thirty (30) cases of personal administration of Level 3 sedation on patients in a primary or satellite practice location within the six (6) month period preceding the application for portability, but following the issuance of the sedation permit. Acceptable documentation shall include, but not be limited to, patient records demonstrating the applicant's anesthetic technique, as well as provision of services by the applicant within the minimum standard of care.

(d) A dentist providing anesthesia services utilizing a portability permit remains responsible for providing these services in strict compliance with all applicable laws and rules. The dentist shall ascertain that the location is supplied, equipped, staffed, and maintained in a condition to support provision of anesthesia services that meet the standard of care.

(e) Any applicant whose request for portability status is not granted on the basis of the application will be provided an opportunity for hearing pursuant to Texas Government Code, Chapter 2001 et seq.

Source Note: The provisions of this §110.7 adopted to be effective May 10, 2011, 36 TexReg 2833

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.8	Provisional Anesthesia and Portability Permits

(a) The Board may elect to issue a temporary sedation/anesthesia and/or portability permit that will expire on a stated date. A full sedation/anesthesia or portability permit may be issued after the dentist has complied with requests of the Board which may include, but shall not be limited to, review of the dentist's anesthetic technique, facility inspection, and/or review of patient records to ascertain that the minimum standard of care is being met. If a full permit is not issued, the temporary permit will expire on the stated date.

(b) A dentist licensed by the Board who is enrolled and approaching graduation in a specialty or General Practice Residency/Advanced Education in General Dentistry (GPR/AEGD) program as detailed in this chapter may, upon approval of the Board or its designees, obtain a provisional permit from the Board to administer moderate parenteral sedation and/or deep sedation and general anesthesia. A dentist licensed by the Board who holds a Level IV permit issued by the Board may, upon approval of the Board or its designees, obtain a provisional permit from the Board to provide anesthesia on a portable basis. To qualify for a provisional permit the applicant must:

(1) meet all requirements under this chapter;

(2) have a letter submitted on the applicant's behalf:

(A) on the letterhead of the school administering the program;

(B) signed by the director of the program;

(C) specifying the specific training completed; and

(D) confirming imminent graduation as a result of successful completion of all requirements in the program.

(3) For the purposes of this chapter, "completion" means the successful conclusion of all requirements of the program in question, but not including the formal graduation process.

(4) Any provisional permit issued under this section shall remain in effect until the next-scheduled regular Board meeting, at which time the Board will consider ratifying the provisional permit.

(5) On ratification of a provisional permit, the status of the permit will change to that of a regular permit under this section.

Source Note: The provisions of this §110.8 adopted to be effective May 10, 2011, 36 TexReg 2833

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.9	Anesthesia Permit Renewal

(a) The Board shall renew an anesthesia/sedation permit annually if required fees are paid and the required emergency management training and continuing education requirements are satisfied. The Board shall not renew an anesthesia/sedation permit if, after notice and opportunity for hearing, the Board finds the permit holder has provided, or is likely to provide, anesthesia/sedation services in a manner that does not meet the minimum standard of care. If a hearing is held, the Board shall consider factors including patient complaints, morbidity, mortality, and anesthesia consultant recommendations.

(b) Fees. Annual dental license renewal certificates shall include the annual permit renewal, except as provided for in this section. The licensee shall be assessed an annual renewal fee in accordance with the fee schedule in Chapter 102 of this title.

(c) Continuing Education.

(1) In conjunction with the annual renewal of a dental license, a dentist seeking to renew a minimal sedation, moderate sedation, or deep sedation/general anesthesia permit must submit proof of completion of the following hours of continuing education every two years on the administration of or medical emergencies associated with the permitted level of sedation:

(A) Level 1: Minimal Sedation - six (6) hours

(B) Levels 2 and 3: Moderate Sedation - eight (8) hours

(C) Level 4: Deep Sedation/General Anesthesia - twelve (12) hours

(2) The continuing education requirements under this section shall be in addition to any additional courses required for licensure. Advanced Cardiac Life Support (ACLS) course and Pediatric Advanced Life Support (PALS) course may not be used to fulfill the continuing education requirement for renewal of the permit under this section.

(3) Continuing education courses must meet the provider endorsement requirements of §104.2 of this title.

Source Note: The provisions of this §110.9 adopted to be effective May 10, 2011, 36 TexReg 2833; amended to be effective September 30, 2012, 37 TexReg 7485; amended to be effective September 3, 2014, 39 TexReg 6857

Texas Administrative Code

Next Rule>>

TITLE 22	EXAMINING BOARDS
PART 5	STATE BOARD OF DENTAL EXAMINERS
CHAPTER 110	SEDATION AND ANESTHESIA
RULE §110.10	Use of General Anesthetic Agents

(a) No dentist shall administer or employ the general anesthetic agent(s) listed in subsection (b) of this section, which has a narrow margin for maintaining consciousness, unless the dentist possesses a valid Level 4 - General Anesthesia or Deep Sedation permit issued by the Board.

(b) The following drugs are general anesthesia agents with a narrow margin for maintaining consciousness and must only be used by a dentist holding a Level 4 - General Anesthesia or Deep Sedation permit:

(1) short acting barbiturates including, but not limited to thiopental, sodium methohexital, and thiamylal;

(2) short acting analogues of fentanyl including, but not limited to remifentanil, alfentanil, and sufentanil;

(3) alkylphenols including precursors or derivatives, which includes, but not limited to propofol and fospropofol;

(4) etomidate;

(5) dissociative anesthetics - ketamine;

(6) volatile inhalation anesthetics including, but not limited to sevoflurane, desflurane and isoflurane; and

(7) similarly acting drugs or quantity of agent(s), or technique(s), or any combination thereof that would likely render a patient deeply sedated, generally anesthetized or otherwise not meeting the conditions of the definition of moderate sedation as stated in §110.1 of this chapter (relating to Definitions).

(c) No permit holder shall have more than one person under general anesthesia at the same time exclusive of recovery.

Source Note: The provisions of this §110.10 adopted to be effective August 25, 2013, 38 TexReg 5262

APPENDIX 2

BLUE RIBBON PANEL
REVIEW OF DE-IDENTIFIED DATA FOR FY 2012-2016

Direction of the Sunset Commission:

As a management action, direct the board to establish in an expedited rule an independent five to 10-member blue ribbon panel that would review de-identified data, including confidential investigative information, related to dental anesthesia deaths and mishaps over the last five years, as well as evaluate emergency protocols. The Committee should make recommendations to the Legislature by the Sunset Commission's January 11, 2017 meeting.

PROJECT SUMMARY

Phase One – Case Identification

Purpose: Staff identifies cases in which a "dental anesthesia death or mishap" may have occurred. Locate dentist expert/consultation report and patient records for such cases.

- September 15, 2016, to October 10, 2016. | **COMPLETED OCTOBER 7, 2016**

Phase Two – Case Selection

Purpose: Blue Ribbon Panel (BRP) defines "dental anesthesia death or mishap." BRP selects cases in which a "dental anesthesia death or mishap" occurred. Identify data points to be analyzed related to selected cases.

- October 10, 2016, to October 25, 2016. | **COMPLETED OCTOBER 25, 2016**

Phase Three – Data Compilation

Purpose: Staff compiles data requested by BRP in Phase Two for the cases selected by BRP in Phase Two.

- October 25, 2016, to November 10, 2016. | **COMPLETED NOVEMBER 10, 2016**

Phase Four – Data Analysis

Purpose: BRP reviews de-identified data compiled in Phase Three and develops recommendations to report to the Sunset Commission.

- November 10, 2016, to January 4, 2017. | **COMPLETED JANUARY 4, 2017**

PROJECT DETAILS

PHASE ONE – CASE IDENTIFICATION

Purpose: Identify cases in which an "anesthesia death or mishap" may have occurred. Locate dentist expert/consultation report and patient records for such cases.

Participants: Staff of the Dental Practice Division

Timeframe: September 15, 2016, to October 10, 2016

Completed: October 7, 2016

Methodology: The database cannot be queried for "anesthesia deaths and mishaps." Anesthesia deaths and mishaps must be identified through manual review of case files.

1. Staff identifies all cases in which sedation/anesthesia was administered and/or identified as a possible concern in the agency's initial case review.
    - Queried database for all cases with the following allegation codes:
      Allegation codes are determined during complaint intake.
        - QOC4 – QOC – Anesthesia
        - SR1 – SR – Self-Report
        - SR2 – SR – Patient Hospitalization
        - SR3 – SR – Patient Mortality
    - Full text search of database for all cases with any of the following words in the summary field:
      Summary field is determined during complaint intake.
        - Nitrous
        - Sedation
        - Anesthesia
        - N2O
        - IV
        - Halcion
        - Overdose
        - Sedate
        - Sedated
        - Over sedated
        - Over sedation
        - Enteral
        - Parenteral
        - Intravenous
        - Anaphylaxis
        - Allergic
        - Allergy
        - Gas

    RESULT: 816 cases

2. Staff eliminates cases with the following attributes:
    - On-going investigation or final adjudication pending (180 cases)
    - Not subject to a written review by an expert dentist (283 cases)
    - Case file purged pursuant to Records Retention Schedule or unable to be located (51 cases)
    - Treatment did not involve the administration of sedation/anesthesia (179 cases)

    RESULT: 123 cases

3. Staff dentist derives summaries of cases identified in Step 2 from the written report of the dentist expert or consultant who participated in the investigation.
    - Narrative summary
    - Complaint source: patient or self-report

RESULT: 123 case summaries provided to BRP on October 7, 2016

PHASE TWO – CASE SELECTION – October 10, 2016, to October 25, 2016

Purpose: Define "dental anesthesia death or mishap." Select cases in which sedation/anesthesia was administered and in which a "dental anesthesia death or mishap" occurred. Identifies data to be compiled concerning cases in which a "dental anesthesia death or mishap" occurred.

Participants: Members of the Blue Ribbon Panel

Timeframe: October 10, 2016, to October 25, 2016

Completed: October 25, 2016

Methodology:

1. BRP determines meaning of "dental anesthesia death or mishap" for purposes of BRP project.
2. BRP reviews narrative summaries and identifies cases that indicate an "anesthesia death or mishap."
3. BRP identifies data to be collected concerning the cases identified in Step 2.
   Detailed data points to be collected on the 75 cases identified by BRP

Respondent Data	**Investigative Data**	**Sedation/Anesthesia Treatment, Cont'd**
Dental school education	Primary planned procedure	Did an emergency occur at the treatment facility? (Y/N/Unknown)
Sedation permit issue date	DRP/expert report notes	Pre-op H&P (who did it, when was it done)
S/A training information	Aggravating factors	Pre-op Vitals
Medicaid provider?	Mitigating factors	Pre-op O2
Self-reported practice area	Notes regarding emergency response	Pre-op airway analysis
Highest S/A permit held	Written emergency protocol? Adequate? Initiated?	NPO
Portability?	SOC violation as per expert review	Duration of S/A (start time : end time)
Patient Data	Anesthesia violation as per expert review	S/A monitoring (vitals, SaO2, RR, capn, ekg, etc.)
Age	SOC anesthesia clinical violation	Delivery method/route
Age category	SOC anesthesia monitoring or documentation violation	Drugs, dosage, route
Gender	**Sedation/Anesthesia Treatment**	Local anesthetic given
Height	Sedation data	Personnel present
Weight	S/A level administered. Did respondent provide s/a (Y/N)	Airway Management - planned or emergency response
BMI	Did respondent provide or intend to provide dental treatment? (Y/N)	IV access - pre-op or emergency response
Patient ASA (respondent)	Was s/a provided using portability permit (Y/N)	**Legal Data**
Patient ASA (other source)	Administrator of S/A	Previous public Board action related to anesthesia
Additional patient information	Treatment facility type	Compliance with prior actions of the Board

RESULT: 75 cases identified and 48 data points identified

PHASE THREE – DATA COMPILATION – October 25, 2016, to November 10, 2016

Purpose: Compile data requested by BRP in Phase Two for the cases selected by BRP in Phase Two

Participants: Staff of the Dental Practice Division

Timeframe: October 25, 2016, to November 10, 2016

Completed: November 10, 2016

RESULT: Specific data (48 data points) regarding 78 cases provided to BRP on November 10, 2016

NOTE: Three additional cases eliminated in Phase One as pending investigation were re-incorporated in Phase Three due to their high-profile nature and relevance to the BRP charge.

PHASE FOUR – DATA ANALYSIS – November 10, 2016, to January 11, 2017

Purpose: Review and analyze de-identified data compiled in Phase Three and develop recommendations to report to the Sunset Commission

Participants: Members of the Blue Ribbon Panel.

Timeframe: November 10, 2016, to January 4, 2017

Completed: January 4, 2017