



Scott Walker, Governor
Laura Gutiérrez, Secretary

**DE 9 & 11 AD HOC COMMITTEE
DENTISTRY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, Madison
Contact: Erin Karow (608) 266-2112
November 7, 2018**

The following agenda describes the issues that the Committee plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions of the Committee. A quorum of the Board may be present during the committee meeting.

AGENDA

8:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. Adoption of Agenda (1)

B. Approval of Minutes – August 7, 2018 (2)

C. 8:00 A.M. APPEARANCE: Presentation from Dr. Anthony Ziebert, D.D.S., M.S., Senior Vice-President of the American Dental Association; and Dr. Joseph Giovannitti, Jr., D.M.D., Professor and Chair of the Department of Dental Anesthesiology (3-31)

D. DE 11, Relating to Anesthesia – Discussion and Consideration (32-124)

- 1) Dentistry Examining Board Comments
- 2) Jurisdiction Review of Legislation & Rules Regarding Anesthesia
- 3) Proposed California Bill Text SB 501
- 4) Report to the Texas Sunset Advisory Commission

E. Public Comments

ADJOURNMENT

MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 4822 Madison Yards Way, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the board's agenda, please call the listed contact person. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112.

**DE 9 & 11 AD HOC COMMITTEE
DENTISTRY EXAMINING BOARD
MEETING MINUTES
AUGUST 7, 2018**

PRESENT: Christopher J. Callen; Matthew Bistan, D.D.S.; Wendy Pietz, D.D.S.

STAFF: Erin Karow, Executive Director; Sharon Henes, Administrative Rules Coordinator; Kate Stolarzyk, Bureau Assistant; and other Department staff

CALL TO ORDER

Wendy Pietz, Chair, called the meeting to order at 9:05 a.m. A quorum of three (3) members was confirmed.

ADOPTION OF AGENDA

MOTION: Christopher Callen moved, seconded by Matthew Bistan, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES – MAY 9, 2018

MOTION: Christopher Callen moved, seconded by Matthew Bistan, to approve the minutes of May 9, 2018 as published. Motion carried unanimously.

ADJOURNMENT

MOTION: Wendy Pietz moved, seconded by Matthew Bistan, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 12:18 p.m.

Proposed ADA Sedation and Anesthesia Guidelines

Council on Dental Education and Licensure 2016

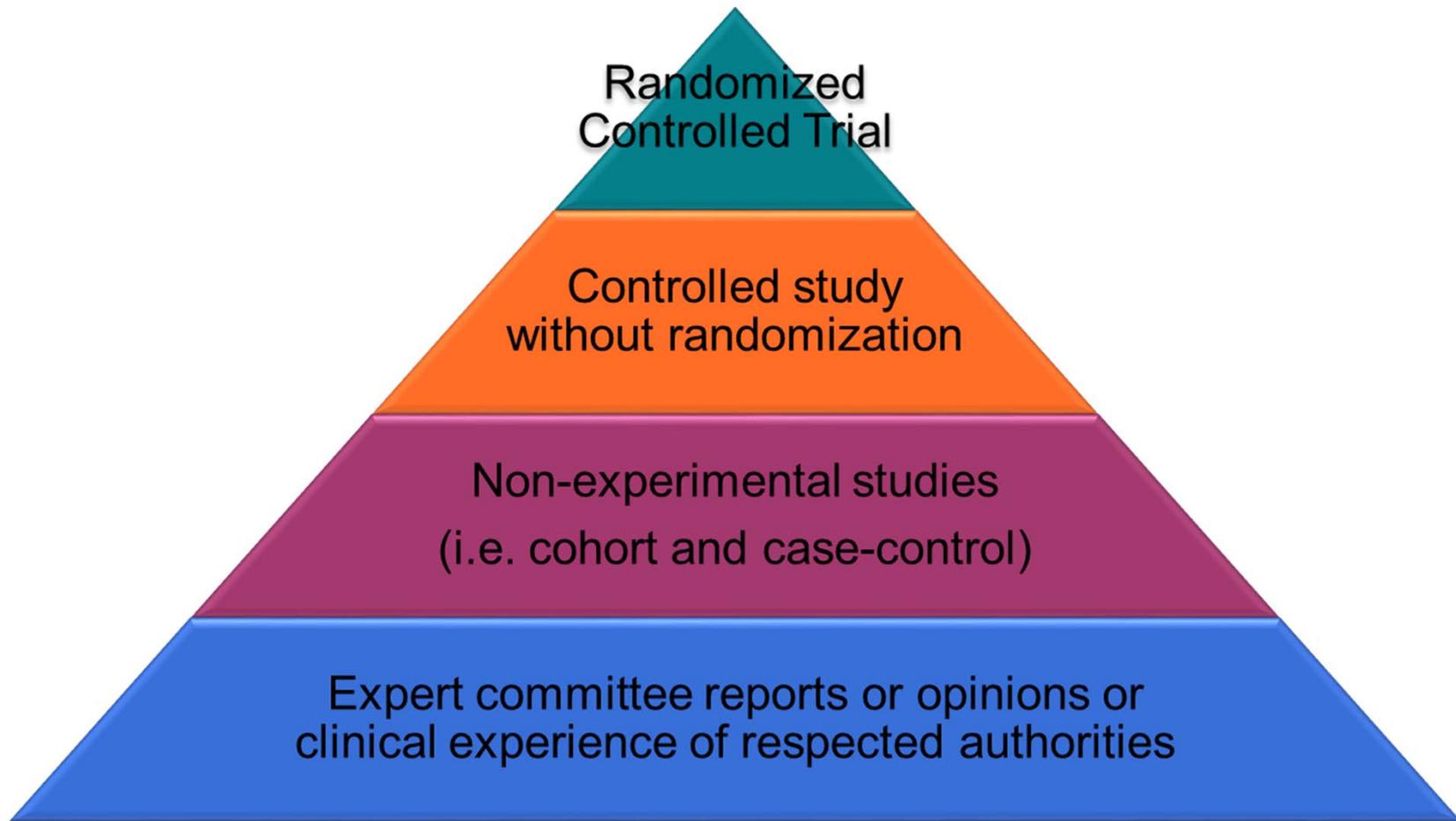
Dr. Daniel Gesek and Dr. David Sarrett

ADA American Dental Association®

Introduction

- CDEL-*Bylaws* subject matter responsibility for:
 - dental education, licensure, continuing education, sedation and anesthesiology issues.
- Sedation and Anesthesia Guidelines managed by CDEL since 1971

Levels of Evidence



CDEL Anesthesiology Committee Experts

- **Dr. David Sarrett**, Committee Chair (Dean, Virginia Commonwealth University School of Dentistry; Member Council on Dental Education and Licensure)
- **Dr. Edwin Ginsberg**, representing the American Academy of Periodontology (Periodontist in Private Practice; Site Director of Periodontics at North Shore-LIJ Health System; faculty member of the Hofstra North Shore-LIJ School of Medicine)
- **Dr. Joseph Giovannitti**, representing the American Society of Dentist Anesthesiologists (Professor and Dental Anesthesiology Department Chair, University of Pittsburgh School of Dental Medicine)
- **Dr. Andrew Herlich**, representing the American Society of Anesthesiologists (Professor of Anesthesiology, Staff Anesthesiologist, University of Pittsburgh Medical Center Mercy)

CDEL Anesthesiology Committee Experts

- **Dr. Bryan Moore**, representing the American Dental Association (General Dentist in Private Practice providing moderate sedation)
- **Dr. Daniel Sarasin**, representing the American Dental Society of Anesthesiology (Oral Surgeon and Partner, Cedar Rapids Oral Surgery; Adjunct Faculty, Department of Oral Diagnosis, Pathology, Radiology and Medicine at the University of Iowa)
- **Dr. Sarat (Bobby) Thikkurissy**, representing the American Academy of Pediatric Dentistry (Professor, University of Cincinnati Department of Pediatrics and Director, Residency Program, Division of Pediatric Dentistry and Orthodontics)
- **Dr. Antwan Treadway**, representing the American Association of Oral and Maxillofacial Surgery (Oral Surgeon, Staff Surgeon and Partner, Atlanta Oral and Facial Surgery; Member, Georgia Board of Dentistry)
- **Dr. William Parker**, 2016 Consultant to the Anesthesiology Committee from the Council on Scientific Affairs

Monitoring end-tidal CO₂ - Moderate sedation

- Lines 458-462
- Evidence and Rationale: “Risks and Benefits of Using Capnography in Dental Patients Undergoing Moderate Sedation” 2016 report by the Council on Scientific Affairs.
- Finding: *Available scientific evidence demonstrates that capnography identifies significantly more respiratory complications during procedural sedation in adults than standard monitoring.*

ADA & AAP/AAPD Guidelines

- ADA proposed Guidelines: specific to adult patients
- AAP/AAPD 2016 Guidelines: specific to pediatric patients

ADA & AAP/AAPD Guidelines (continued)

- Monitoring end-tidal CO₂ during moderate sedation
- End-tidal CO₂ monitoring options in AAP/AAPD guidelines are specific to pediatric patient management purposes
- Proposed ADA Guidelines reflect findings of report from Council on Scientific Affairs and are specific to managing adult patients.

ADA Guidelines: proposed wording

- Proposed ADA 2016 (Moderate Sedation) - The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure or equipment. In addition, ventilation should be monitored by continual observation of qualitative signs, including chest excursion and auscultation of breath sounds with a precordial or pretracheal stethoscope. ~~This can be accomplished by auscultation of breath sounds, monitoring end-tidal CO₂ or by verbal communication with the patient.~~

Moderate sedation is a clinical state

- Issues

- Patients who arrive at a level of moderate sedation by an enteral or parenteral route are in the same clinical state.
- Moderate sedation via either route requires the same management and monitoring.
- Training guidelines for moderate sedation are categorized by the clinical state, not route of drug.
- Consistent with the contemporary definition found in the literature and guidelines of national health care organizations.

Moderate sedation is a clinical state (continued)

- Definition remains the same as 2007/2012:
 - “Moderate sedation - a 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.”

Moderate Sedation Course Duration

- Lines 1340-1350
- “A minimum of 60 hours of instruction plus administration of sedation for at least 20 individually managed patients.”
- Evidence and Rationale:
 - Lack of airway patency is the primary cause of morbidity and mortality during moderate and deep sedation.

Moderate Sedation Course Duration (continued)

- Evidence and Rationale
 - Moderate sedation CE courses (at least 11 providers) meet or exceed 60 hours of instruction and 20 patients.
 - CDEL and its committee experts enumerated new instructional competencies and course director requirements (Lines 1344-1350)
 - Focus on *competency* is consistent with contemporary educational principles.

Moderate Sedation Course Duration (continued)

- More instructional time is warranted (what is different today?):
 - CE and advanced education programs across the country use human simulators to teach *competency* in airway management.
 - Teaching use of capnography equipment for moderate sedation.
 - Attaining *competence* in rescuing a patient from a deeper level of sedation
 - Ongoing updates in sedation and anesthesia pharmacology, **safety procedures and educational expectations.**

Patient Evaluation Provisions

- HOD requested consistency
- e.g., Examine use of BMI and timing of medical history review
- Lines 211 and 983, 293, 388 and 508; 293-313; 388-416; 508-540

Patient Evaluation Provisions (continued)

- Proposed language for Moderate and Deep Sedation/GA:
 - “...undergo an evaluation prior to the administration of any sedative, at least a review at an appropriate time of their medical history, medication use and NPO status... ASA III and IV patients should also require consultation with the primary care physician or medical specialist.”

Patient Evaluation Provisions (continued)

- Proposed language for Moderate and Deep Sedation/GA (not minimal sedation):
 - “Assessment of Body Mass Index (BMI) should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.”

Patient Evaluation Provisions (continued)

- Resources proposed: “BMI category definitions can be obtained from the Centers for Disease Control and Prevention or the American Society of Anesthesiologists.” (to be made available online)

Patient Evaluation Provisions (continued)

- Evidence and Rationale:
 - ASA Patient Physical Status Classifications (cited in ADA Guidelines since 1999) refer to BMI for patient assessment purposes.
 - AAOMS Parameters of Care state “Consider BMI calculation” as part of patient assessment.
 - US Preventive Services Task Force...
“recommends screening all adults for obesity. Clinicians should offer or refer patients with a body mass index (BMI) of 30 kg/m² or higher...”

Operating Dentist & Qualified Dentist

- Lines 187-192
- CDEL proposes new definition of “operating dentist” and revised definition of “qualified dentist.”

Operating Dentist & Qualified Dentist

- Rationale:
 - Defines “operating dentist”...who provides clinical dental care while a qualified anesthesia provider administers sedation/anesthesia.
 - Reflects current law in a few states (reality).

Operating Dentist & Qualified Dentist (continued)

- CDEL did not view this guideline as conflicting with ADA Policy: The Use of Sedation and General Anesthesia by Dentists (Trans.2007:384):
 - “The use of sedation and general anesthesia in dentistry is safe and effective when properly administered by trained individuals. The American Dental Association strongly supports the right of appropriately trained dentists to use these modalities in the treatment of dental patients and is committed to their safe and effective use.”

Questions

- Contact us if your districts have further questions
- We would be pleased to be invited to meet with your districts in Denver
- dsgesek@comcast.net
- dcsarrett@vcu.edu
- Q and A

2016 Proposed Revisions to the *ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists* and the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* (collectively referred to as Sedation and Anesthesia Guidelines)

Q.1. What was the Council's response to the directives of the 2015 House of Delegates?

Monitoring end-tidal CO₂ during moderate sedation: The Council requested the assistance of the Council on Scientific Affairs (CSA), which prepared a detailed report of two systemic reviews and contains this key summary statement “the evidence demonstrates that capnography in conjunction with standard monitoring improved sensitivity of detecting adverse respiratory events and reduces the risk of hypoxemia during moderate sedation compared with standard monitoring alone.” CSA’s report was titled *Report on the Risks and Benefits of Using Capnography In Dental Patients Undergoing Moderate Sedation*. The Council on Dental Education and Licensure also considered comments received and continues to support its proposed language that end-tidal CO₂ must be monitored during the administration of moderate sedation unless precluded or invalidated by the nature of the patient, procedure or equipment. The Council believes that the phrase, “*unless precluded or invalidated by the nature of the patient, procedure or equipment,*” recognizes that the dentist may determine that certain circumstances can present which preclude the use of capnography, e.g., a patient with a nasal deformity, severe intellectual disability or behavioral disorder, or a mouth breather.

Further, the Council and Committee carefully considered the adopted “[Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures: Update 2016](#)” from the American Academy of Pediatrics and the American Academy of Pediatric Dentistry. The ADA Guidelines defer to the AAP/AAPD Guidelines for providing sedation to pediatric patients. Both sets of guidelines are appropriate for care of the targeted patient group – pediatric or adult. Regarding use of a capnograph during moderate sedation, both guidelines allow for professional judgment by the dentist based on the needs of the patient. For example, the AAPD Guidelines notes that monitoring of ventilation by capnography is preferred or amplified, audible pretracheal stethoscope (e.g., Bluetooth technology) or precordial stethoscope is strongly recommended. The ADA proposed Guidelines note that for moderate sedation “end-tidal CO₂ must be monitored during the administration of moderate sedation *unless precluded or invalidated by the nature of the patient, procedure or equipment.*”

Moderate Sedation Course Duration (hours and content): To further clarify depth of minimal sedation versus moderate sedation and clearly outline education and training requirements, the Council proposes a reorganized definition of minimal sedation inserting a statement that level of sedation is independent of the route of administration, and no recommended change to the definition of moderate sedation. Patients who arrive at a level of moderate sedation by an enteral or parenteral route are in the same clinical state. The Council maintains that moderately sedated patients via either route require the same attentiveness and monitoring; there should be no difference in the training requirements because of the routes of administration. In that regard, the Council proposes several competencies that must be certified by a course director, especially regarding rescue and emergency management. The Council has reviewed information on moderate sedation courses offered by universities, associations and continuing education providers, and continues to support course duration as 60 hours of instruction plus 20 patient experiences for moderate sedation.

Consistent Patient Evaluation Provisions: For moderate sedation and deep sedation/general anesthesia the Council believes that the Sedation and Anesthesia Guidelines should require that patients undergo an evaluation prior to the administration of any sedative, at least a review at an

appropriate time of their medical history and medication use, and that ASA III and IV patients should also require consultation with the primary care physician or medical specialist. The Council discussed available evidence demonstrating that patients with elevated BMI may be at increased risk for airway associated morbidity during sedation, particularly if in association with other factors such as obstructive sleep apnea. Therefore, in regard to assessment of BMI, the Council proposes that Body Mass Index (BMI) measurements be considered part of a pre-procedural workup for patients receiving moderate sedation and deep sedation/general anesthesia. Assessment of BMI for patients receiving minimal sedation, is not needed because ventilatory and cardiovascular functions are unaffected during minimal sedation as noted in the definition of minimal sedation.

Q.2. The proposed changes to the Teaching Guidelines, lines 1340-1350, call for the following training in moderate sedation: “A minimum of 60 hours of instruction, plus administration of sedation for at least 20 individually-managed patients.” Also, “Certification of competence in moderate sedation technique(s). Certification of competence in rescuing patients from a deeper level of sedation than intended including managing the airway, intravascular or intraosseous access, and reversal medications. Provision by course director or faculty of additional clinical experiences if participant competency has not been achieved in time allotted. Records of instruction and clinical experiences (i.e. number of patients managed by each participant in each modality/route) that are maintained and available for participants review.” In my practice, only oral sedation is administered. Why does the proposed guideline not outline training by route of administration?

Patients who arrive at a level of moderate sedation by an enteral or parenteral route are in the same clinical state. The Council has carefully studied this matter and maintains that moderately sedated patients via either route require the same attentiveness and monitoring; there should be no difference in the training requirements related to routes of administration. Training techniques for moderate sedation have changed since 2007 when the last major revision of the Guidelines was approved.

Human simulators are now used during training so dentists attain competency in airway management. Course time is needed to instruct dentists in use of capnography equipment for moderate sedation. Course time is needed to attain competence in rescuing patients from a deeper level of sedation than intended. Typically that means working on a human simulator to learn how to insert a laryngeal mask airway or achieve intravascular access to administer an emergency medication.

A review of CE courses was conducted; at least 11 providers currently meet or exceed 60 hours of instruction and 20 patient experiences.

Q.3. Why is the concomitant administration of two different oral medications considered moderate sedation?

Giving more than one drug concomitantly to produce sedation takes advantage of a drug interaction known as potentiation, whereby the clinical effect of the two drugs is much more than just the simple addition of the two. The net effect is more than the MRD of each drug alone. Thus, combining enteral drugs is considered moderate sedation. Further, the current (2012) ADA [Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students](#) indicate that giving enteral drugs above the MRD is considered moderate sedation, whereas giving drugs up to the MRD is clearly defined as minimal sedation. Therefore, exceeding the MRD is already considered to be moderate sedation.

Three published papers are worthy of note. A 2007 paper published in *General Dentistry*¹ attempts to defend the stacking of oral medications during a single appointment. The paper is theoretical, uses half-life data and speculates on clinical results. The only available clinically-applicable study that looks at the implications of stacked dosing on actual subjects was published in 2009 in the *Journal of Clinical*

¹ Donaldson M, Goodchild J. Maximum cumulative doses of sedation medications for in-office use. *General Dentistry* 2007;55:143-8

*Psychopharmacology*², which shows that oral dose stacking results in ever increasing blood levels of triazolam; that is in contrast to the theory published in the *General Dentistry* paper. A third 1986 article published in the *Journal of Clinical Pharmacology*³ demonstrated that the sublingual administration of triazolam results in a 28% increase in bioavailability. Thus, two of these publications clinically demonstrate that when triazolam is given in excess of the MRD and especially when given sublingually, which is often done for supplemental dosing, the patients are at least in a state of moderate sedation.

Q.4. How do the 2016 proposed Guidelines differ from the version considered by the 2015 ADA House of Delegates? The Council upheld the concept proposed in 2015 that the level of sedation (i.e., minimal, moderate, deep sedation/general anesthesia) is independent of the route of administration (i.e., enteral or parenteral, transdermal, transmucosal or inhalation) and that the required training to administer moderate sedation must lead to acquisition of the same competences. This is particularly critical in attaining the competency to rescue a patient that drifts into a deeper level of sedation or anesthesia. The Council also upheld the 2015 proposal to include capnography or end-tidal CO₂ monitoring during moderate sedation unless precluded or invalidated by the nature of the patient, procedure or equipment. What is new in the 2016 proposed revisions is the elimination of references to sedation and anesthesia for children; for pediatric patients, the ADA Guidelines continue to exclusively defer to the updated 2016 "Guidelines for Monitoring and Management of Pediatric Patients Before, During, and After Sedation for Diagnostic and Therapeutic Procedures" from the American Academy of Pediatrics and the American Academy of Pediatric Dentistry.

At the direction of the Speaker of the House of Delegates, the 2015 version of proposed revisions is moot. The Council's 2016 recommended changes are to the current (2012) Guidelines, as shown in Resolution 37.

Q.5. In what ways were the dental anesthesiology communities notified that the Guidelines were under revision? Was there an opportunity to comment on the proposal?

The Council and its Anesthesiology Committee held an in-person and teleconference hearing for ADA members on April 21, 2016. This was promoted via ADA News, on ADA.org, and in the ADA e-publications Leadership Update and Daily Huddle.

The dental anesthesiology communities of interest* received direct email notifications regarding the hearing and the calls for comment. Notices were published in the ADA News, on ADA.org, and in the ADA e-publication Leadership Update.

Two written comment periods were held, one in conjunction with the April 21 open hearing. The second comment period was June 3 through July 4, 2016. A total of 33 written and oral comments were received and systematically reviewed by the Council.

***CDEL Dental Anesthesiology Communities of Interest:**

- ADA Council on Dental Practice
- ADA Council on Scientific Affairs
- ADA Council on Access Prevention and Interprofessional Relations
- ADA Council on Governmental Affairs
- ADA New Dentist Committee
- State dental societies
- Local dental societies
- State Boards of Dentistry

² Pickrell JE, Hosaka K, Jackson, DL, et al. Expanded Studies of the Pharmacokinetics and Clinical Effects of Multi-dose Sublingual Triazolam in Healthy Volunteers. *J Clinical Psychopharmacol* 2009;29:426-31

³ Scavone JM, Greenblatt DJ, et al. Enhanced bioavailability of triazolam following sublingual versus oral administration. *J Clinical Pharmacol* 1986;26:208-10

Recognized dental specialties
Certifying boards of recognized dental specialties
American Dental Education Association
American Association of Dental Boards
Special Care Dentistry
Academy of General Dentistry
American Student Dental Association
American Society of Dentist Anesthesiologists
American Dental Society of Anesthesiology
American Society of Anesthesiologists

Q. 6. Many dentists hold sedation permits issued by a state dental board. Are dentists' sedation permits in jeopardy if the proposed revised ADA Guidelines are adopted?

The state boards determine the requirements for dentists who administer sedation, not the ADA.

State dental boards issue sedation permits, based on their state laws, rules and regulations. The Council believes that the Sedation and Anesthesia Guidelines must reflect current practice and standard of care to guide practitioners, educators and regulatory agencies in assuring patient safety and managing risk. State dental boards establish their own laws and regulations regarding permits and licenses to administer sedation and anesthesia. While the ADA Sedation and Anesthesia Guidelines may be referenced in state law, state legislatures and dental boards have the sole authority to establish permit/license requirements by which dentists with anesthesia permits or licenses must abide.

Q. 7. What CE opportunities are available to meet this new guideline?

The Council is aware of at least 11 CE courses** that may offer the course content and duration as proposed in the Guidelines. The Council is confident that providers of CE on the subject of sedation and anesthesia will enrich their educational offerings to reflect current practice in accord with the proposed guidelines and state regulatory requirements.

****CE Courses with a hands-on component:**

Duquesne University
<http://www.duq.edu/academics/schools/pharmacy/centers-and-programs/center-for-continuing-dental-education>
University of Alabama at Birmingham
https://reg.abcsignup.com/reg/event_page.aspx?ek=0040-0004-ca9117f0c1cf428693a2a514e78920eb
Augusta University (formerly MCG)
<http://gru.edu/ce/dentalce/>
Learn IV Sedation
www.learnivsedation.com
Montefiore Medical Center
<http://www.montefiore.com/for-dental-professionals/continuing-education/>
Conscious Sedation Consulting
<http://www.sedationconsulting.com/>
University of Southern California
<http://dent-web20.usc.edu/ce/>
Miami Valley Hospital, Dayton, OH
Contact: Theresa Cory – 937/208-3844
Rocky Mountain Sedation
<https://rockymountainsedation.com/>
DOCS Education
<http://docseducation.com/>
Western Surgical and Sedation
<http://www.westernsurgicalandsedation.com/index.html>

Q. 8. I provided comment to CDEL; why was my advice overlooked?

All comments received were systematically reviewed. Although the Council did not agree with all points made, all input was considered. Many of the comments requested evidence to support the proposed changes. The Council is aware of the levels of evidence (shown below). The blue section demonstrates that the majority of evidence available is expert opinion. Not all decisions can be informed by the highest level of evidence, however, expert opinion is part of the evidence utilized.



For example, not one controlled clinical study has ever been performed to demonstrate the optimal training time for dentists who provide moderate sedation. Such a study may be nearly impossible to fund or conduct or to be cleared by an institutional review board. The best available evidence in this case is Expert Committee Reports and Expert Opinion.

CDEL members have expertise in contemporary educational principles. We rely on our Anesthesiology Committee experts, who are nationally respected educators and clinicians, to evaluate anesthesiology information and provide CDEL with the best recommendations.

Q. 9. Why is the new definition of operating dentist proposed?

The Guidelines have always included a definition for “qualified dentist.” The new definition of operating dentist, which was proposed in both 2015 and 2016, is for clarity given the reality of how some state legislatures and regulators have defined the clinical operative dentist provider working with an anesthesia provider. ADA has clear policy supporting the rights of trained dentists to administer sedation and anesthesia (*Trans.2007:384*) and the proposed definition in the Guidelines is not in conflict with ADA policy.

Q. 10. How many states currently require dentists to monitor expired CO₂ via capnography during moderate sedation?

The Council is aware of at least 15 states (CO, IA, MD, OR, WY, CT, FL, MA, MT, RI, TX, SC, ND, VA and WV) that mention capnography in their laws or in dental board policy for moderate sedation, either as a requirement, a monitoring option, or as a proposed regulation.

Q. 11. What is the approximate cost of a capnograph?

The cost of capnography equipment varies, depending on regional price variances and the functionality desired (e.g., features such as blood pressure, pulse oximetry, pulse and electrocardiogram). In general, a capnograph can range in price from \$800-\$3,000.

Q. 12. Will these new guidelines increase the cost of dental care or decrease access to care for some patients?

The equipment needed to monitor end-tidal CO₂ (approximate cost range \$800 – \$3,000) should not appreciably increase the cost of delivering moderate sedation or decrease its availability to patients. This is a reasonable investment to identify more respiratory complications and support risk management and patient safety. There is no evidence demonstrating that the cost of care will increase, that patient access to sedation will decrease or that the number of sedation permits will decrease.

Q. 13. When and why were the Sedation and Anesthesia Guidelines developed?

The Sedation and Anesthesia Guidelines were first developed in 1971 and subsequently revised 10 times to reflect emerging practice and scientific principles. The two most recent revisions occurred in 2007 and 2012. The *Guidelines for the Use of Sedation and General Anesthesia by Dentists* assist dentists in the delivery of safe and effective sedation and anesthesia. The *Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* provide a reasonable measure of education program acceptability, applicable to all institutions and agencies engaged in predoctoral and continuing education related to sedation and anesthesia.

Q. 14. What is the process for proposing revisions to the House of Delegates?

Per House directive, the Council reviews the Guidelines at least every five years. In recent years, because of changes in practice and science, the Guidelines have been revised on a more frequent basis. The Council and its Committee on Anesthesiology are responsible for this process, seeking input from the anesthesia communities of interest. The Anesthesiology Committee with representatives from the American Academy of Periodontology, American Association of Oral and Maxillofacial Surgeons, American Dental Society of Anesthesiology, American Society of Dentist Anesthesiologists, American Society of Anesthesiologists, American Dental Association, and American Academy of Pediatric Dentistry, carefully study the issues and provide technical and scientific input to the Council. This year, a member of the Council on Scientific Affairs also participated in committee meetings. The Council considers the Committee's recommendations and circulates proposed revisions to its dental anesthesiology communities of interest. Final adoption is the purview of the ADA House of Delegates.

Q. 15. What information was used to develop the proposed revised Guidelines?

The Committee on Anesthesiology and the Council relied on current standards of care, guidelines of other professional medical and dental organizations, the scientific literature, current state regulations for sedation, and the expertise of practitioners, academicians and state dental board members to formulate the response to the House of Delegates this year.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Sharon Henes Administrative Rules Coordinator		2) Date When Request Submitted: 30 October 2018 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Dentistry Examining Board Ad Hoc Committee on DE 9 & 11			
4) Meeting Date: 11/7/2018	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? A. APPEARANCE: American Dental Association B. DE 11 Relating to Anesthesia – Discussion and Consideration 1. Dentistry Examining Board Comments 2. Jurisdiction Review of Legislation & Rules Regarding Anesthesia 3. California SB 501 4. Report to the Texas Sunset Advisory Commission	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed:			
11) Authorization			
<i>Sharon Henes</i>		10/31/2018	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

DE 11.02 Definitions. In this chapter:

- (1g) “ASA” means American Society of Anaesthesiologists.
- (1s) “Class 1 permit” means a sedation permit enabling a dentist to administer minimal sedation.
- (1t) “Class 2 - enteral permit” means a sedation permit enabling a dentist to administer moderate sedation by enteral route.
- (1u) “Class 2 – paraenteral permit” means a sedation permit enabling a dentist to administer moderate sedation by enteral or paraenteral route.
- (1v) “Class 3 permit” means a sedation permit enabling a dentist to administer deep sedation, moderate, or general anesthesia.
- (2m) “Continual” means repeated regularly and frequently in a steady succession.
- (2r) “Continuous” means prolonged without any interruption at any time.
- (3) “Deep sedation” means 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 maybe impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- (em) “Enteral” means administration by which the agent is absorbed through the gastrointestinal tract or through the oral, rectal or nasal mucosa.
- (4) “General anesthesia” means 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.
- (4d) “Immediately available” means physically located in the dental office or facility and ready for immediate use or response.
- (4h) “Inhalation” means administration by which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.
- (4p) “Minimal sedation” means a minimally depressed level of consciousness, produced by a pharmacological method that 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. Minimal sedation may be achieved by the administration of a drug, either singly or in divided doses, by the enteral route to achieve the desired clinical effect, not to exceed the maximum recommended dose.
- (4t) “Moderate sedation” means a 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. If more than one enteral drug is administered or if an enteral drug is administered at a dosage that exceeds the maximum recommended dose during a single appointment, such administration is considered moderate sedation.
- (7g) “Parenteral” means administration by which the drug bypasses the gastrointestinal tract through intramuscular, intravenous, intranasal, submucosal, subcutaneous, or intraocular methods.
- (7r) “Pediatric patient” means a patient who is 12 years old and under.

DE 11.025 Permit to administer anesthesia. (1) The board may issue an anesthesia permit at the following levels:

- (a) Class 1 is for the administration of minimal sedation.
 - (b) Class 2 - enteral is for the enteral administration of moderate sedation.
 - (c) Class 2 – paraenteral is for the administration of moderate sedation by enteral or paraenteral route.
 - (d) Class 3 is for the administration of deep sedation or general anesthesia.
- (2) A dentist may apply to the board for an anesthesia permit by submitting all of the following:
- (a) Application and fee.
 - (b) Verification of any permit or credential authorizing anesthesia or sedation held by the dentist.
 - (c) Disclosure of any previous anesthesia or sedation related incident, morbidity, mortality or any Board investigation or discipline relating to the delivery of anesthesia or sedation.
 - (d) Evidence of current licensure to practice dentistry in the state of Wisconsin.
 - (e) Evidence of certification in Advanced Cardiovascular Life Support or Pediatric Advanced Life Support through a course that follows the American Heart Association guidelines. Pediatric Advanced Life Support is required if treating pediatric patients.
 - (f) If applying for a Class 3 Permit, evidence of one of the following:
 1. Current board certification or a candidate for board certification by the American Board of Oral and Maxillofacial Surgery.
 2. Diplomate of the American Dental Board of Anesthesiology.
 - (g) If applying for a Class 1 or 2 Permit, evidence of one of the following:
 1. Current board certification or a candidate for board certification by the American Board of Oral and Maxillofacial Surgery.
 2. Diplomate of the American Dental Board of Anesthesiology.
 3. Successful completion of a Board approved education program that provides comprehensive training meeting the requirements in 11.035.
 - (h) If applying for a Class 2 – Enteral and applicant held a Class 1 Permit issued prior to [effective date], evidence of 20 individually managed cases within the last five years.
- (3) A dentist may not administer anesthesia or sedation without a permit at the appropriate level of anesthesia or sedation.
- (4) Nitrous-oxide when used in combination with sedative agent may produce minimal, moderate or deep sedation. During the administration of moderate or nitrous-oxide oxygen sedation, if a patient enters a deeper level of sedation than the dentist is authorized by permit to provide, then the dentist must stop the sedation and dental procedures until the patient returns to the intended level of sedation.

DE 11.35 Board approved education program content. (1) Board approved education program that provides comprehensive training for a Class 1 Permit shall consist of a minimum of 20 hours in administration and management of minimal sedation, including the following course contact:

- (a) Historical, philosophical and psychological aspects of anxiety and pain control.
- (b) Patient evaluation and selection through review of medical history taking, physical diagnosis and psychological profiling.

- (c) Definitions and descriptions of physiological and psychological aspects of anxiety and pain.
 - (d) Description of the stages of drug-induced central nervous system depression through all levels of consciousness and unconsciousness, with special emphasis on the distinction between the conscious and unconscious state.
 - (e) Review of adult respiratory and circulatory physiology and related anatomy.
 - (f) Pharmacology of agents used in enteral and combination inhalation-enteral minimal sedation, including drug interactions and incompatibilities.
 - (g) Indications and contraindications for use of enteral inhalation-enteral minimal sedation.
 - (h) Review of dental procedures possible under enteral and combination inhalation-enteral minimal sedation.
 - (i) Patient monitoring using observation, monitoring equipment, with particular attention to vital signs and reflexes related to consciousness.
 - (j) Maintaining proper records with accurate chart entries recording medical history, physical examination, informed consent, time oriented anesthesia record, including the names of all drugs administered, doses and monitored physiological parameters.
 - (k) Prevention, recognition and management of complications and life-threatening situations.
 - (L) Administration of local anesthesia in conjunction with enteral and combination inhalation-enteral minimal sedation techniques.
 - (m) Description, maintenance and use of inhalation sedation equipment.
 - (n) Introduction to potential health hazards of trace anesthetics and proposed techniques for limiting occupational exposure.
 - (o) Discussion of abuse potential.
- (2) Board approved education program that provides comprehensive training for a Class 2 Permit shall consist of a minimum of 60 hours in administration and management of minimal sedation, including the following course content:
- (a) Historical, philosophical and psychological aspects of anxiety and pain control.
 - (b) Patient evaluation and selection through review of medical history taking, physical diagnosis and psychological profiling.
 - (c) Use of patient history and examination for ASA classification, risk assessment and pre-procedure fasting instruction.
 - (d) Definitions and descriptions of physiological and psychological aspects of anxiety and pain.
 - (e) Description of the sedation anesthesia continuum, with special emphasis on the distinction between the conscious and the unconscious state.
 - (f) Review of adult respiratory and circulatory physiology and related anatomy.
 - (g) Pharmacology of local anesthetics and agents used in moderate sedation, including drug interactions and contraindications.
 - (h) Indications and contraindications for use of moderate sedation
 - (i) Review of dental procedures possible under moderate sedation.
 - (j) Patient monitoring using observation, monitoring equipment, with particular attention to vital signs, ventilation, breathing and reflexes related to consciousness.

- (k) Maintaining proper records with accurate chart entries recording medical history, physical examination, informed consent, time oriented anesthesia record, including the names of all drugs administered, doses and monitored physiological parameters.
- (L) Prevention, recognition and management of complications and emergencies.
- (m) Description, maintenance and use of moderate sedation monitors and equipment.
- (n) Discussion of abuse potential.
- (o) Intravenous access anatomy, equipment and technique.
- (p) Prevention, recognition and management of complications of venipuncture and other parenteral techniques.
- (q) Description and rationale for the technique to be employed.
- (r) Prevention, recognition and management of systemic complications of moderate sedation, with particular attention to airway maintenance and support of the respiratory and cardiovascular systems.
- (s) 20 individually managed cases. A Class 2 – enteral requires 5 of the 20 individually managed cases to involve a live patient. A Class 2 – parenteral requires all 20 individually managed parenteral cases to involve a live patient.

DE 11.075 Continuing education. Each dentist with an anesthesia permit shall complete 2 hours of continuing education on the topic of anesthesia each biennium. The continuing education completed under this section shall count toward the continuing education requirement under DE 13.03.

DE 11.85 Auxiliary Personnel. (1) Auxiliary personnel shall be certified in basic life support for the health care provider.

(2) A dentist administering general anesthesia, deep sedation or moderate sedation shall have two additional individuals present during the procedure.

(3) If a dentist both administering general anesthesia, deep sedation or moderate sedation and performing the dental procedure, one of the two auxiliary personnel must be designated to only monitor the patient.

(3) A dentist administering minimal sedation shall have one individual present during the procedure who is not the administering dentist.

DE 11.09 Standards of Care. (1) GENERAL. A dentist administering anesthesia or sedation shall remain in the room to continuously monitor the patient until the patient meets the criteria for transfer to recovery and may not leave the dental office or facility until the patient meets the criteria for discharge and is discharged from the dental office or facility.

(2) PREOPERATIVE PREPARATION. Pre-operative preparation for the administration of anesthesia or sedation shall include all of the following:

(a) Determine the adequacy of the oxygen supply and equipment necessary to deliver oxygen under positive pressure.

(b) Take and record the patient record baseline vital signs, including blood pressure, respiratory rate and heart rate. For the administration of general anesthesia and deep and moderate sedation, baseline vital signs include weight, height, blood pressure, heart rate, respiratory rate, blood oxygen saturation by pulse oximetry, and body temperature when appropriate. The inability to take vital signs due to the patient's behavior or condition shall be documented in the patient record.

- (c) Complete medical history and a focused physical evaluation.
 - (d) Instruct the patient on specific dietary limitations based upon the sedative and anesthetic technique to be used and patient's physical status.
 - (e) Provide pre-operative instructions to the patient, or as appropriate, to the patient's parent or legal guardian.
 - (f) Notify and require a patient to arrive and leave with a vested escort.
 - (g) Establish and secure, where clinically indicated, an intravenous line throughout the procedure, except as provided for pediatric or special needs patients.
 - (h) Advise the patient of fasting requirements.
- (3) MONITORING AND EVALUATION OF GENERAL ANESTHESIA, DEEP SEDATION OR MODERATE SEDATION.** A dentist administering general anesthesia, deep sedation or moderate sedation shall continuously monitor and evaluate all of the following:
- (a) Level of consciousness.
 - (b) Oxygenation saturation by pulse oximetry.
 - (c) Chest excursions continually.
 - (d) Ventilation monitored by end-tidal carbon dioxide.
 - (e) Auscultation of breath sounds with precordial or pretracheal stethoscope.
 - (f) Respiration rate.
 - (g) Heart rate and rhythm via electrocardiogram (ECG).
 - (h) Blood pressure.
 - (i) Color of mucosa, skin or blood
 - (j) Body temperature whenever triggering agents associated with malignant hyperthermia are administered.
- (4) MONITORING AND EVALUATION OF MINIMAL SEDATION.** A dentist administering minimal sedation shall continuously monitor and evaluate all of the following:
- (a) Level of consciousness.
 - (b) Chest excursions.
 - (c) Ventilation by either auscultation of breath sounds or by verbal communication with the patient.
 - (d) Color of mucosa, skin or blood
 - (e) Blood pressure, heart rate, and oxygenation saturation by pulse oximetry pre-operatively and post-operative and intraoperatively.
- (5) RECOVERY AND DISCHARGE.** A dentist shall maintain and implement recovery and discharge procedures which include all of the following:
- (a) Immediate availability of oxygen and suction equipment.
 - (b) Monitor and document the patient's blood pressure, heart rate, oxygenation and level of consciousness during recovery.
 - (c) Determine and document that blood pressure, heart rate, level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge.
 - (d) Post-operative verbal and written instructions provided.
 - (e) If a reversal agent is administered before discharge criteria have been met, the patient must be monitored until recovery is assured.
- (6) EQUIPMENT.** A dentist administering anesthesia or sedation shall have immediately available and maintain equipment, appropriate for patients served, in good working order according to manufacturer's directions all the following equipment:
- (a) Alternative light source for use during power failure.

- (b) Automated external defibrillator
 - (c) Disposable syringes in assorted sizes.
 - (d) Oxygen in a portable cylinder E tank capable of administering positive pressure ventilation via a bag-valve-mask system.
 - (e) Sphygmomanometer and stethoscope for pediatric and adult patients.
 - (f) Suction and backup system.
 - (g) An operating chair capable of withstanding cardiopulmonary resuscitation or a back board.
 - (h) Emergency airway equipment including oral and nasal airway and advanced airway devices for appropriate patient populations being served.
- (7) **Drugs.** A dentist administering anesthesia or sedation shall be responsible to maintain and properly store drugs in current and unexpired condition and properly dispose of expired drugs. The following drugs shall be maintained in an emergency drug kit:
- (a) Non-enteric coated aspirin.
 - (b) Ammonia inhalants.
 - (c) Antihistamine.
 - (d) Antihypoglycemic agent.
 - (e) Bronchodilator.
 - (f) Epinephrine preloaded syringes for pediatric and adult.
 - (g) Oxygen.
 - (h) Nitroglycerin
 - (i) Reversal agents
 - (j) If Class 2 and Class 3, muscle relaxant.
- (8) **EMERGENCY MANAGEMENT.** A dentist administering anesthesia or sedation shall be responsible for the sedative or anesthetic management, diagnosis and treatment of emergencies related to the administration of anesthesia or sedation and for ensuring the equipment, drugs and protocols for patient rescue are immediately available.
- (9) **ANESTHESIA RECORD.** A dentist shall maintain an anesthesia record that documents all events related to the administration of the sedative or anesthetic agents, including all of the following:
- (a) Time-oriented anesthesia record that includes the date, names of all drugs administered, dosages, methods of administration and monitored physiological parameters.
 - (c) Heart rate, respiratory rate, blood pressure, pulse oximetry, and end-tidal carbon dioxide measurements shall be recorded in five-minute intervals for general anesthesia, deep and moderate sedation.
 - (d) Heart rate, respiratory rate, blood pressure, and pulse oximetry shall be recorded in fifteen-minute intervals for minimal sedation.
 - (e) The duration of the procedure
 - (f) The individuals present during the procedure.

DE 11.10 Reporting of adverse occurrences related to anesthesia administration. (1) A dentist shall report to the board any anesthesia or sedation related mortality which occurs during or as a result of treatment provided by the dentist within two business days of the dentist's notice of such mortality.

(2) A dentist shall report any morbidity which may result in permanent physical or mental injury as a result of the administration of anesthesia or sedation by the dentist to the Board within 30 days of the notice of the occurrence of any such morbidity.

1. Keep the number of permits at three.
 - Class 1 is enteral administration of moderate sedation.
 - Class 2 is parenteral administration of moderate sedation
 - Class 3 is administration of deep sedation or general anesthesia
2. State that minimal sedation does not require a permit.
3. Class 3 education should include successful completion of a board approved postdoctoral training program in the administration of deep sedation and general anesthesia or postdoctoral training program in anesthesiology that is approved by ACGME.
4. Class 1 education should be 24 hours. Eliminate all of the proposed course content and replace with content similar to the DOCS program content.
5. Keep the proposed continuing education requirement.
6. Each permit should have different requirements for auxiliary personnel and only the minimum necessary. The proposed requires the same number of people for moderate and deep/general anesthesia.
7. Each permit should have different requirements for standards of care and only the minimum necessary. (OK with sub. (7) Drugs and (8) Emergency Management).
8. Keep the proposed reporting of adverse occurrences.

Chapter DE 11

ANESTHESIA

DE 11.01	Authority and purpose.	DE 11.06	Requirements for conscious sedation–parenteral.
DE 11.02	Definitions.	DE 11.07	Requirements for deep sedation and general anesthesia.
DE 11.025	Permit to administer anesthesia.	DE 11.08	Office facilities and equipment.
DE 11.03	Requirements for nitrous oxide inhalation.	DE 11.09	Standards of care.
DE 11.04	Requirements for anxiolysis.	DE 11.10	Reporting of adverse occurrences related to anesthesia administration.
DE 11.05	Requirements for conscious sedation–enteral.		

DE 11.01 **Authority and purpose.** The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a) and 447.02 (2) (b), Stats., for the purpose of defining standards for the administration of anesthesia by dentists. The standards specified in this chapter shall apply equally to general anesthesia and sedation, regardless of the route of administration.

History: Cr. Register, August, 1985, No. 356, eff. 9-1-85; am. Register, October, 1988, No. 394, eff. 11-1-88; am. Register, August, 1991, No. 428, eff. 9-1-91.

DE 11.02 **Definitions.** In this chapter,

(1) “Analgesia” means the diminution or elimination of pain in a conscious patient.

(1m) “Anxiolysis” means the use of medication to relieve anxiety before or during a dental procedure which produces a minimally depressed level of consciousness, during which the patient’s eyes are open and the patient retains the ability to maintain an airway independently and to respond appropriately to physical and verbal command.

(1s) “Class I permit” means a sedation permit enabling a dentist to administer oral conscious sedation-enteral.

(1t) “Class II permit” means a sedation permit enabling a dentist to administer conscious sedation-parenteral and conscious sedation-enteral.

(1u) “Class III permit” means a sedation permit enabling a dentist to administer deep sedation, general anesthesia, conscious sedation-parenteral, and conscious sedation-enteral.

(2) “Conscious sedation” means a depressed level of consciousness during which the patient mimics physiological sleep, has vitals that are not different from that of sleep, has his or her eyes closed most of the time while still retaining the ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command, produced by a pharmacologic or non-pharmacologic method, or a combination of pharmacologic and non-pharmacologic methods.

(3) “Deep sedation” means a controlled state of depressed consciousness, accompanied by partial loss of protective reflexes, including the ability to independently and continuously maintain an airway and to respond purposefully to verbal command, produced by a pharmacologic or non-pharmacologic method, or a combination of pharmacologic and non-pharmacologic methods.

(4) “General anesthesia” means a controlled state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the ability to independently maintain an airway and respond purposefully to physical stimulation or verbal command, produced by a pharmacologic or non-pharmacologic method, or a combination of pharmacologic and non-pharmacologic methods.

(6) “Nitrous oxide inhalation” means analgesia by administration of a combination of nitrous oxide and oxygen in a patient.

(7) “Operative supervision” means the dentist is in the operatory performing procedures with the aid of qualified staff.

(8) “Qualified staff” means a person is certified in the administration of basic life support in compliance with the standards set forth by the American Heart Association, the American Red Cross, or other organization approved by the board, and has training in how to monitor vital signs, and how to use a pulse oximeter, blood pressure cuff, and a precordial or a pretracheal stethoscope. If the dentist is administering deep sedation and general anesthesia under s. DE 11.07, a person shall also be trained in how to use an EKG.

(9) “Routes of administration” include the following:

(a) “Enteral” means administration by which the agent is absorbed through the gastrointestinal tract or through the oral, rectal or nasal mucosa.

(b) “Inhalation” means administration by which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.

(c) “Parenteral” means administration by which the drug bypasses the gastrointestinal tract through either intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), or intraocular (IO) methods.

(d) “Transdermal or transmucosal” means administration by which the drug is administered by patch or iontophoresis.

(10) “Time-oriented anesthesia record” means documentation at appropriate intervals of drugs, doses and physiological data obtained during patient monitoring.

History: Cr. Register, August, 1985, No. 356, eff. 9-1-85; r. and recr. Register, October, 1988, No. 394, eff. 11-1-88; r. (4), renum. (1) to (3) to be (2) to (4) and am., cr. (1) and (5), Register, August, 1991, No. 428, eff. 9-1-91; CR 04-095: am. (1) to (4), cr. (1m) and (6) to (10), r. (5) Register August 2006 No. 608, eff. 1-1-07; CR 13-061: cr. (1s) to (1u) Register June 2014 No. 702, eff. 7-1-14.

DE 11.025 **Permit to administer anesthesia. (1)** Dentists shall submit an application to administer anesthesia as specified in this chapter on a form prepared for and approved by the board. Each application shall be specific to the sedation permit class.

Note: Copies of the Application For Dental Permit to Administer Conscious Sedation are accessible from the department’s webpage at: <http://dps.wi.gov/>.

(2) The board may grant a sedation permit and shall consider any of the following actions in developing their decision on an application:

(a) Defer a decision if the licensee has a pending investigation or has not met the conditions of a previous investigation.

(b) Defer a decision if any sedation permits held by the licensee have been temporally suspended.

(c) Defer a decision or recommend denial if any permits held by the licensee have been revoked or conditions of revocation have not been satisfactorily met.

(d) Recommend denial based on the severity of any investigations regarding noncompliance with ch. DE 5.

(e) Take any other action or actions necessary to maintain the health, welfare and safety of a patient or the public.

History: CR 13-061: cr. Register June 2014 No. 702, eff. 7-1-14.

DE 11.03 Requirements for nitrous oxide inhalation. (1) A dentist or a dental hygienist who holds a valid certificate under ch. DE 15 may use nitrous oxide inhalation on an outpatient basis for dental patients provided that he or she utilizes adequate equipment with failsafe features and a 25% minimum oxygen flow.

(2) A dentist utilizing nitrous oxide inhalation shall be trained and certified in administering basic life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, the American Red Cross, or other organization approved by the board.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07; CR 15-056: am. (1) Register February 2016 No. 722, eff. 3-1-16.

DE 11.04 Requirements for anxiolysis. A dentist utilizing anxiolysis shall be trained and certified in administering basic life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, the American Red Cross, or any other organization approved by the board.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07.

DE 11.05 Requirements for conscious sedation–enteral. (1) No dentist may administer conscious sedation via an enteral route without having first obtained a class I permit from the board, unless a dentist has been granted a permit under s. DE 11.06 or 11.07. A class I permit enables a dentist to utilize conscious sedation enterally. The board may grant a class I permit to administer conscious sedation enterally to a dentist who submits a completed application for this sedation permit class and does all of the following:

(a) Provides proof of one of the following:

1. A board approved training course which includes:

a. Eighteen hours of didactic instruction which addresses physical evaluation of patients, conscious sedation–enteral, emergency management, and conforms to the principles in part one or part 3 of the American Dental Association’s “Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry.”

b. Twenty clinical cases utilizing an enteral route of administration to achieve conscious sedation, which may include group observation.

2. Graduate level training approved by the board that, at a minimum, includes the requirements as set forth in subd. 1. a. and b.

(b) Provides proof of certification in basic cardiac life support for the health care provider and a board approved training program in airway management or a course in advanced cardiac life support. If the dentist is sedating patients age 14 or younger, the dentist shall provide proof of certification in pediatric advanced life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, the American Red Cross, or any other organization approved by the board.

(2) Any dentist who utilizes an enteral route of administration to achieve conscious sedation shall have qualified staff present throughout the dental procedure.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07; CR 13-061: am. (1) (intro.) Register June 2014 No. 702, eff. 7-1-14.

DE 11.06 Requirements for conscious sedation–parenteral. (1) No dentist may administer conscious sedation via a parenteral route without having first obtained a class II permit from the board, unless a dentist has been granted a permit under s. DE 11.07. A class II permit enables a dentist to utilize conscious sedation–enteral, and conscious sedation–parenteral. A dentist who holds a class II permit does not have to obtain a class I sedation permit. The board may grant a class II permit to administer conscious sedation–parenterally to a dentist who submits a completed application for this sedation permit class and does all the following:

(a) Provides proof of one of the following:

1. A board approved training course which includes:

a. A minimum of 60 hours of didactic instruction which addresses the physical evaluation of patients, IV sedation, and emergency management.

b. Twenty clinical cases of managing parenteral routes of administration.

2. Graduate level training approved by the board that, at a minimum, includes the requirements as set forth in subd. 1.

3. The utilization of conscious sedation administered parenterally on an outpatient basis for 5 years preceding January 1, 2007, by a dentist licensed under this chapter.

(b) Provides proof of certification in advanced cardiac life support. If the dentist is a pediatric specialist, the dentist is allowed to substitute certification in pediatric advanced life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, or any other organization approved by the board.

(2) Any dentist who utilizes a parenteral route of administration to achieve conscious sedation shall have qualified staff present throughout the dental procedure.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07; CR 13-061: am. (1) Register June 2014 No. 702, eff. 7-1-14.

DE 11.07 Requirements for deep sedation and general anesthesia. (1) No dentist may administer deep sedation or general anesthesia without having first obtained a class III permit from the board and submits a completed application for this sedation permit class. A class III permit enables a dentist to utilize conscious sedation–enteral, conscious sedation–parenteral, deep sedation, and general anesthesia. A dentist who holds class III sedation permit shall not have to obtain any other class of sedation permit. The board may grant a class III permit to administer deep sedation or general anesthesia to a dentist who does all of the following:

(a) Provides proof of one of the following:

1. Successful completion of a board approved postdoctoral training program in the administration of deep sedation and general anesthesia.

2. Successful completion of a postdoctoral training program in anesthesiology that is approved by the Accreditation Council for Graduate Medical Education.

3. Successful completion of a minimum of one year advanced clinical training in anesthesiology provided it meets the objectives set forth in part 2 of the American Dental

Association's "Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry."

4. Has been a licensed dentist under this chapter who has been utilizing general anesthesia for 5 years prior to January 1, 2007.

(b) Provides proof of certification in advanced cardiac life support. If the dentist is a pediatric specialist, the dentist is allowed to substitute certification in pediatric advanced life support. This certification shall be renewed in compliance with the standards set forth by the American Heart Association, or any other organization approved by the board.

(2) Any dentist who administers deep sedation or general anesthesia shall have qualified staff present throughout the dental procedure.

(3) Nothing in this section may be construed to prevent a dentist from employing or working in conjunction with a certified registered nurse anesthetist, or with a licensed physician or dentist who is a member of the anesthesiology staff of an accredited hospital, provided that the anesthesia personnel must remain on the premises of the dental facility until the patient under general anesthesia or deep sedation regains consciousness.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07; CR 13-061: am. (1) (intro.) Register June 2014 No. 702, eff. 7-1-14.

DE 11.08 Office facilities and equipment. (1) A dental office shall have all of the following if a dentist is administering conscious sedation-enteral, conscious sedation-parenteral, deep sedation, and general anesthesia:

(a) An operating room containing all of the following:

1. Oxygen and supplemental gas-delivery system capable of delivering positive pressure oxygen ventilation.
2. Suction and backup system.
3. Auxiliary lighting system.
4. Gas storage facilities.
5. An operating chair capable of withstanding cardiopulmonary resuscitation or a back board.
6. Emergency equipment including a defibrillator, cardiopulmonary pocket mask, and appropriate emergency medications.
7. Monitoring equipment including a pulse oximeter, blood pressure cuff, and precordial or pretracheal stethoscope.
8. An EKG if administering deep sedation or general anesthesia.

(b) A recovery room containing all of the following:

1. Oxygen and supplemental gas-delivery system capable of delivering positive pressure oxygen ventilation.
2. Suction and backup system.
3. Auxiliary lighting system.
4. Wheelchair.
5. An operating chair capable of withstanding cardiopulmonary resuscitation or a back board.
6. Emergency equipment including a defibrillator, cardiopulmonary pocket mask, and appropriate emergency medications.

(2) Nothing in this section shall be construed to prevent an operating room from also being used as a recovery room, nor shall it be construed to prevent the sharing of equipment between an operating room and a recovery room, provided all the required equipment is in the room being used.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07.

DE 11.09 Standards of care. (1) Before the administration of any type of sedation a complete written medical history shall be obtained from each patient. The

medical history shall identify any medications a patient is taking and any allergies to medication a patient has.

(2) The recording of a time-oriented anesthesia record including appropriate vital signs, blood pressure, pulse, and oxygen saturation q 5 minutes, is required for conscious sedation-enteral, conscious sedation-parenteral, deep sedation, and general anesthesia.

(3) During the anesthesia period for conscious sedation-enteral, conscious sedation-parenteral, deep sedation, or general anesthesia, the oxygenation, ventilation, and circulation of the patient shall be continually evaluated, and any medications that are administered shall be documented in writing, including the dosages, time intervals, and the route of administration.

(4) A patient shall be continually observed during the anesthesia period for conscious sedation-enteral, conscious sedation-parenteral, deep sedation, and general anesthesia either by the treating dentist or by qualified staff. No permit holder shall have more than one person in conscious sedation-enteral, conscious sedation-parenteral, deep sedation, or general anesthesia at one time, notwithstanding patients in recovery.

(5) Operative supervision is required for deep sedation and general anesthesia.

(6) Qualified staff shall continuously monitor post-treatment patients before final evaluation and discharge by the dentist. Written post-operative instructions shall be given to each patient or to a responsible adult who accompanies the patient for those individuals having undergone conscious sedation-enteral, conscious sedation-parenteral, deep sedation, or general anesthesia. Documentation of the post-operative instructions shall be noted in the patient's chart.

(8) Any dentist whose patient lapses into conscious sedation-enteral from anxiety shall meet the requirements found in s. DE 11.05 and shall follow any applicable requirements in s. DE 11.09.

(9) Unless a dentist holds a class 3 permit, he or she shall not administer any drug that has a narrow margin for maintaining consciousness including, but not limited to, ultra-short acting barbiturates, propofol, ketamine, or any other similarly acting drugs.

(10) Dentists shall maintain verifiable records of the successful completion of any and all training of staff.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07.

Note: Section DE 11.09 (7) dealing with titration, has been removed from the rule in compliance with statutory restraints based on the objections by the Senate Committee on Health and the Joint Committee for Review of Administrative Rules. The Wisconsin Dentistry Examining Board intends to promulgate s. DE 11.09 (7) upon resolution of those objections.

DE 11.10 Reporting of adverse occurrences related to anesthesia administration. Dentists shall submit a report within 30 days to the board of any mortality or other incident which results in temporary or permanent physical or mental injury requiring hospitalization of a patient during, or as a result of, anesthesia administration under this chapter. The report shall be on a form approved by the board and shall include, at the minimum, responses to all of the following:

- (1) A description of the dental procedures.
- (2) The names of all participants in the dental procedure and any witnesses to the adverse occurrence.
- (3) A description of the preoperative physical condition of the patient.
- (4) A list of drugs and dosage administered before and during the dental procedures.

(5) A detailed description of the techniques utilized in the administration of all drugs used during the dental procedure.

(6) A description of the adverse occurrence, including the symptoms of any complications, any treatment given to the patient, and any patient response to the treatment.

(7) A description of the patient's condition upon termination of any dental procedures undertaken.

Note: Forms are available at the office of the Dentistry Examining Board located at 1400 East Washington Avenue, P.O. Box 8935, Madison, WI 53708.

History: CR 04-095: cr. Register August 2006 No. 608, eff. 1-1-07.

AK Board of Dental Examiners (Proposed Rule Aug. 7): Amends CE requirements for advanced airway management or general anesthesia as it relates to pediatric patients. Amends licensure renewal requirements to specify the number of pediatric patients that must be treated for a pediatric designation. Specifies monitoring of pediatric patients. Comment Deadline: 09/10/18 (Source: *Alaska Administrative Journal*, 8/7/18).

AK Governor's Office (Final Rule March 17): Updates the state's permitting requirements and procedures for the administration of dental sedation and general anesthesia. Stipulates pediatric administration requirements. (Source: *Alaska Administrative Journal*, 03/17/2018).

AL Board of Dental Examiners (Final Rule July 26): Amends regulations related to requirements for inspections of facilities prior to the issuance of a general anesthesia or parenteral sedation permit. Adds the requirement of capnography monitoring for procedures performed in dental clinics under general anesthesia and/or parenteral sedation. Requires teams of no less than two qualified examiners be appointed by the Board and present at each inspection. (Source: *Alabama Administrative Monthly*, 08/31/18).

CA SB 501 (Sent to the Governor Sep. 6): Requires the Office of Oral Health to provide the legislature a report analyzing the effects on access to care for pediatric dental patients by 2022. Requires the dental board review all available data on all adverse events related general anesthesia and sedation and submit a report to the legislature by 2022. Establishes new requirements for the administration of general anesthesia or sedation, including educational, equipment and personnel requirements.

CA AB 2643 (Introduced Feb. 15): Revises the state's required written informed consent statement for minors to specify that it is required in the case of general anesthesia and hat it include a provision to encourage exploring nonsurgical treatment options.

Revises insurance laws related to coverage of anesthesia for dental services by removing language that currently limits coverage to procedures rendered in a hospital or surgery center.

CA AB 224 (Passed the Assembly and Sent to the Senate May 31): Amends sedation requirements. Requires the Dental Board to “contract with a nonprofit research organization for the purpose of obtaining high-quality pediatric sedation and anesthesia-related data.” Redefines deep sedation, general anesthesia and moderate sedation. Prohibits dentists from administering or ordering the administration of deep sedation or general anesthesia to patients under 13 years of age unless that dentist holds a pediatric endorsement for the general anesthesia permit. To secure the endorsement, for patients under 7 years of age, requires proof of csedation or general anesthesia to children, requires the dentist and at least one support staff member to be trained in Pediatric Advanced Life Support (PALS) and airway management, equivalent to the American Academy of Pediatrics and American Academy of Pediatric Dentistry (AAP-AAPD) Guidelines or as determined by the Board.

CA SB 392 (Passed the Senate and Sent to the Assembly May 31): On or before January 1, 2019, the Dental Board of California shall provide to the legislature a report and analysis of the effects on access to care for pediatric dental patients, specifically as it relates to requiring the addition of a 2nd general anesthesia permit holder to be present during the administration of general anesthesia on a patient 7 years of age or younger, if the provider is currently a general anesthesia permit holder.

CA SB 501 (Passed the Senate and Sent to the Assembly May 30): Amends the state's definition of general anesthesia in the Dental Practice Act to mirror ADA definitions. Requires dentists to have a pediatric endorsement of their general anesthesia permit and have completed a Commission on Dental Accreditation accredited or equivalent residency training program providing competency in the administration of deep sedation or general anesthesia to be eligible to administer these drugs to patients under 7 years of age. For any procedure involving deep sedation or general anesthesia for patients between seven and 13 years of age, the dentist and at least two support staff must be present and would require the dentist and at least one support staff to have advanced life support and airway management training. Requires at least three people to be present during procedures on children under seven years of age and would require the dentist and other attendees to hold specified certifications and have certain advanced life support and airway management training. Requires a study on the effects of access to care for pediatric dental patients specifically as it relates to requiring the addition of a second general anesthesia permit holder to be present during the administration of general anesthesia on a patient seven years of age or younger.

CA AB 2235 (Signed by the Governor Sep 23): Establishes a committee within the Board of Dentistry to investigate whether the current laws, regulations, and policies of the state are sufficient to guard against unnecessary use of anesthesia for young patients and potential injury or death. Requires a dentist to obtain written informed consent of the patient prior to administering general anesthesia or conscious sedation including notice that all sedation and anesthesia medications involve risks of complications. Makes it unprofessional conduct for a licensee to fail to report the death of a patient or removal to a hospital within a specified period and manner. Completion of at least 20 cases to establish competency, both at the time of initial application and at renewal. To administer deep

FL Board of Dentistry (Proposed Rule Aug. 1): Updates anesthesia definitions by replacing references to conscious sedation with moderate sedation. Replaces references to anxiolysis with minimal sedation. Comment Deadline: 08/21/17 (Source: *Florida Administrative Weekly*, Issue Vol. 43/No. 148, 08/01/2017).

HI HB 561 (Introduced Jan 20): Requires every dentist to post, in a conspicuous place, a notice containing contact information for the Consumer Resource Center of the Regulated Industries Complaints Office. Requires the Board of Dental Examiners to conduct on-site inspections of the facilities, equipment, and staffing of all applicants seeking written authorizations or permits for the administration of general anesthesia,

deep sedation, or moderate (conscious) sedation. Requires the adoption of a "Code Blue" or other emergency plan or protocol.

HI HB 561 (Signed by the Governor July 11): Requires every dentist to post, in a conspicuous place, a notice containing contact information for the Consumer Resource Center of the Regulated Industries Complaints Office. Requires dentists to adhere to ADA policies regarding the administration of general anesthesia and sedation, except when treating pediatric patients, AAPD policies will be followed. Establishes sedation permit requirements. Requires inspection of a dentist's facilities, equipment and personnel prior to the issuance or renewal of a written authorization or permit to administer anesthesia or sedation.

IA Dental Board (Final Rule Dec. 6): Requires a pretracheal or precordial stethoscope to be maintained in offices where deep sedation/general anesthesia is being administered, in addition to a capnograph. Clarifies certification in ACLS. Adds a new definition of "hospitalization" to clarify adverse occurrence reporting. Requires those seeking a moderate sedation permit to successfully complete "a training program that includes rescuing patients from a deeper level of sedation than intended." Clarifies that a capnograph must be utilized on patients receiving moderate sedation unless invalidated by the nature of the patient, procedure or equipment. Requires all general anesthesia/deep sedation permit holders to utilize a pretracheal or precordial stethoscope to monitor continually auscultation of breath sounds beginning Jan. 1, 2018. Effective: 01/10/18 (Source: *Iowa Administrative Bulletin*, Volume XL Number 12, 12/06/2017).

ID HCR 46 (Introduced Feb. 15): Seeks to reject rules passed by the Idaho Dental Board that deleted the ADA's sedation-related documents that were incorporated by reference and revised the state's sedation guidelines.

ID HCR 46 (Passed the Legislature March 9): Seeks to reject rules passed by the Idaho Dental Board that deleted the ADA's sedation-related documents that were incorporated by reference and revised the state's sedation guidelines.

ID State Board of Dentistry (Proposed Rule Aug. 1): Proposes to eliminate the option of supplemental dosing when providing minimal sedation for patients. Comment Deadline: 09/26/18 (Source: *Idaho Administrative Bulletin*, 18-9, 09/05/18).

ID State Board of Dentistry (Proposed Rule Temporary Rule Adoption March 7): Amends education requirements for moderate sedation permits. For a moderate enteral sedation permit, requires completion of 24 hours of instruction plus management of at least 10 adult cases. For a moderate parenteral sedation permit, requires 60 hours of instruction plus management of at least 20 patients by IV route. Effective: 03/30/18 (Source: *Idaho Administrative Bulletin*, Volume 18-3, 03/07/2018).

LA Board of Dentistry (Final Rule June 20): Requires that every dentist who performs moderate or greater sedation must now have adequate equipment for the establishment of an intravenous infusion, regardless of the route of administration of the sedation. (Source: *Louisiana Register*, June 2018).

LA Department of Health (Notice of Intent Oct 21): Requires any dentist in a room where a child is being sedated to have PALS certification, regardless if they are the one administering the sedation. Comment Deadline: 11/16/16 (Source: *Louisiana Register*, Vol. 42, No. 10, 10/21/2016).

LA Department of Health (Finale Rule May 20): Removes from regulations references to anesthesia/sedation delivery route and amends educational requirements. Defines pediatric as children under 13 years of age. (Source: *Louisiana Register*, Vol.43, No.05, 05/20/2017).

ME Board of Dental Examiners (Proposed Rule Jan. 18): Revises the state's dental anesthesia regulations. Eliminates site permits and board-required inspection prior to issuing permits. Requires dentist applicants to self-certify compliance with the sedation rule. Requires capnography to be used by 2018. Comment Deadline: 03/13/17 (Source: *Maine Weekly Notice*, 01/18/2017).

ME Board of Dental Examiners (Proposed Rule May 11): Requires dentists to use an electrocardiograph if providing moderate sedation services to patients with ASA III or higher. Comment Deadline: 06/03/17 (Source: *Maine Government Register*, 05/03/2017).

ME Department of Professional and Financial Regulation (Final Rule Aug. 23): Eliminates site permits and a Board-required inspection prior to issuing permits. Establishes a new permit for itinerate dental sedation. Requires dentists to self-certify compliance with the sedation rule. Effective: 08/27/17 (Source: *Maine Government Register*, 08/23/2017).

MT Labor and Industry (Final Rule Feb 6): Modifies office inspection regulations to allow a single qualified inspector to perform moderate sedation or deep sedation/general anesthesia facility inspections in an effort to address a backlog of initial inspections. (Source: *Montana Administrative Register*, Issue 4, 02/17/2017).

NC Occupational Licensing Boards and Commissions (Proposed Rule Feb. 15): Establishes permits for itinerant moderate conscious sedation and itinerant moderate pediatric conscious sedation and sets forth the requirements for each of these permits. Generally amends equipment and drug requirements for general anesthesia and moderate conscious sedation. Comment Deadline: 04/16/18 (Source: *North Carolina Register*, Volume 32, Issue 16, 02/15/2018).

NC Board of Dental Examiners (Proposed Rule Sept. 17): Establishes procedures for administering written examinations in connection with the applications for sedation and anesthesia permits. Amends requirements for obtaining a minimal sedation permit and requires all such permits holders to have ACLS. Requires dentists seeking a permit to administer moderate pediatric sedation to hold PALS. Comment Deadline: 11/16/18 (Source: *North Carolina Register*, 33/06, 09/17/2018).

NC Occupational Licensing Boards and Commissions (Proposed Rule Jan. 17): Increases training requirements for general anesthesia and moderate sedation permit holders. Clarifies equipment to be maintained in an office. Requires two BLS-certified auxiliaries to be present during all general anesthesia procedures. Adopts new

category of itinerant general anesthesia providers. Requires a dentist to hold an appropriate anesthesia permit to allow a CRNA to administer anesthesia. Requires a precordial stethoscope or capnograph. Comment Deadline: 03/20/17 (Source: *North Carolina Register*, Volume 31, Issue 14, 01/17/2017).

NC Occupational Licensing Boards and Commissions (Final Rule July 3): Clarifies anesthesia terms and definitions. Requires a dentist to hold a general anesthesia permit prior to allowing a CRNA to administer deep sedation or general anesthesia. Requires a dentist to have two years of advanced training in anesthesiology to secure a general anesthesia permit rather than a minimum of one year. OMS residency and ABOMS diplomate status also qualify a dentist to secure a general anesthesia permit. Requires each facility where general anesthesia will be performed to pass an inspection. Amends facility requirements including requiring a precordial stethoscope or capnograph for the delivery of general anesthesia, deep sedation and moderate conscious sedation. Requires patient medical and consent records be maintained for 10 years. Stipulates the requirements of the anesthesia record. Stipulates itinerant general anesthesia permit requirements. Stipulates requirements for the delivery of and permitting for moderate pediatric conscious sedation. Effective: 06/01/17 (Source: *North Carolina Register*, Volume 32, Issue 1, 07/03/2017).

NH HB 1577 (Signed by the Governor June 8): Requires a dentist, anesthesiologist or CRNA to be present while general anesthesia, deep sedation or moderate sedation “is in effect.” Requires completion of a CODA residency to administer general anesthesia or deep sedation. Requires a dedicated anesthesia provider when treating patients under the age of 13, but exempts board-eligible OMSs or dental anesthesiologists from this requirement. Requires both the treating dentist and separate anesthesia provider to both be PALS certified when treating these patients. Requires informed consent that the procedure may be performed in a hospital setting. Requires dentists to report adverse events in a specified manner.

NV Dentists (Proposed Rule Feb 13): Revises anesthesia definitions to remove the term "conscious sedation" and replace with "moderate sedation." Develops a pediatric moderate sedation permit and defines pediatric as 12 years and under. Specifies requirements to secure a pediatric permit, including completion of 60 hours of training dedicated exclusively to the administration of pediatric moderate sedation and 25 pediatric patients or completion of a pediatric training residency. Allows completion of a dental anesthesiology residency as a pathway to secure a general anesthesia permit. Allows a general anesthesia permit holder to administer all levels of sedation, including pediatric moderate sedation. Requires general anesthesia permit holders to have a capnography monitor. Requires pediatric-sized equipment and specified drugs to be available if administering sedation or anesthesia to a pediatric patient. Revises office inspection requirements. (Source: *Nevada Register of Administrative Regulations*, Vol. 232, 02/13/2017).

NV Board of Dental Examiners (Proposed Rule Aug. 23): Replaces the term “conscious sedation” with “moderate sedation” and “pediatric moderate sedation.” Defines pediatric as a patient 12 years of age or younger. Requires a separate

certificate of site permit for each location where sedation or general anesthesia, deep sedation or moderate sedation is being administered. Clarifies educational requirements for sedation permits. Establishes requirements for a pediatric moderate sedation permit. Allows the educational requirements of a dental anesthetist to qualify for securing a general anesthesia permit. Requires the use of capnography for the administration of general anesthesia, deep sedation and moderate sedation. Specifies equipment and drugs required to deliver anesthesia to pediatric patients. Provides for the inspection of offices. (Source: *Nevada Register of Administrative Regulations*, Vol. 236, 08/23/2017).

NY Education Department (Final Rule Dec 13): Amends dental anesthesia definitions to reflect ADA standards. Incorporates the ASA Patient Physical Status Classification. Institutes a pediatric dental parenteral conscious (moderate) sedation permit. Requires dentists to maintain time-oriented anesthesia records. Requires dentists administering general anesthesia to pediatric patients to have PALS certification. Stipulates requirements for securing a dental parenteral conscious (moderate) sedation permit. Stipulates practice requirements including utilizing end-tidal CO₂ monitors for intubated patients and possibly for non-intubated patients receiving general anesthesia. Effective 7/1/17 and 1/1/18 (Source: *New York Register*, Volume XXXVIII, Issue 52, 12/28/2016)

NY Education Department (Proposed Rule Sep 28): Revises the state's dental anesthesia regulations and responds to comments received related to the regulations from outside groups. Comment Deadline: 10/27/16 (Source: *New York Register*, Volume XXXVIII, Issue 39, 09/28/2016).

PA HB 789 (Introduced March 10): Stipulates that anesthesia shall be administered in a hospital by an anesthesiologist, a qualified physician, a physician enrolled in a residency program in anesthesia or oral surgery, a dentist anesthetist or a nurse anesthetist

PA Governor's Office (Notice Aug. 19): Provides notice that the State Board of Dentistry will be undergoing proposed rulemaking this fall to “update the standards for the administration of general anesthesia, deep sedation, moderate sedation, minimal sedation and nitrous oxide/oxygen analgesia in dental offices to conform to and adopt the current standards used by the dental profession.” (Source: *Pennsylvania Bulletin*, Volume 47, Number 33, 08/19/2017).

PA SB 960 (Introduced Nov. 29): Puts into statutes current Department of Health regulations that require a physician or appropriately trained dentist to supervise the administration of anesthesia. Stipulates anesthesia care provided in a hospital shall be delivered only by an anesthesiologist, qualified physician, physician enrolled in and anesthesiology or oral surgery residency program, a dental anesthesiologist or a CRNA with appropriate supervision or a nursing student with appropriate supervision.

TX State Board of Dental Examiners (Proposed Rule Feb. 26): Seeks to reconsider amendments to the state's anesthesia portability regulations after it was determined

that the revision was improperly adopted. Comment Deadline: 04/08/18 (Source: *Texas Register*, Volume 43 Number 10, 03/09/2018).

TX State Board of Dental Examiners (Proposed Rule Feb. 26): Requires dentists who provide anesthesia services in multiple locations to attest to that fact on their permit applications. Comment Deadline: 04/08/18 (Source: *Texas Register*, Volume 43 Number 10, 03/09/2018).

TX State Board of Dental Examiners (Proposed Rule Feb. 26): Requires dentists to undergo additional didactic and clinical training prior to providing levels 2, 3, or 4 sedation/anesthesia to high-risk patients. Comment Deadline: 04/08/18 (Source: *Texas Register*, Volume 43 Number 10, 03/09/2018).

TX State Board of Dental Examiners (Proposed Rule Feb. 26): Requires dentists to undergo additional didactic and clinical training prior to providing levels 2, 3, or 4 sedation/anesthesia to pediatric patients. Comment Deadline: 04/08/18 (Source: *Texas Register*, Volume 43 Number 10, 03/09/2018).

TX State Board of Dental Examiners (Final Rule Jan. 18): Establishes the Dental Board's Anesthesia Advisory Committee. (Source: *Texas Register*, Volume 43 Number 5, 02/02/2018).

TX State Board of Dental Examiners (Final Rule Jan. 18): Requires a dentist who applies for a sedation/anesthesia permit to include in the application a statement indicating whether the dentist provides or will provide sedation/anesthesia in more than one location. Specifies that dentists providing sedation/anesthesia services in more than one location are responsible for providing these services in compliance with state laws and that the dentists shall ascertain that the location is supplied and staffed in a condition that meets the standard of care. Effective: 02/07/18 (Source: *Texas Register*, Volume 43 Number 5, 02/02/2018).

TX State Board of Dental Examiners (Proposed Rule Jan. 18): Establishes the requirements of a preoperative checklist for all levels of sedation/anesthesia as required by SB 313. Comment Deadline: 03/04/18 (Source: *Texas Register*, Volume 43 Number 5, 02/02/2018).

TX State Board of Dental Examiners (Proposed Rule Jan. 18): Establishes the requirements of emergency preparedness for all levels of sedation/anesthesia as required by SB 313. Comment Deadline: 03/04/18 (Source: *Texas Register*, Volume 43 Number 5, 02/02/2018).

TX State Board of Dental Examiners (Proposed Rule Sept. 29): Establishes an advisory committee on dental anesthesia within the dental board. Comment Deadline: 11/12/17 (Source: *Texas Register*, Volume 42 Number 41, 10/13/2017).

TX State Board of Dental Examiners (Proposed Rule Sept. 29): Requires dentists applying or renewing a sedation permit to include a statement indicating whether the dentists provides or will provide sedation in more than one location and the physical address of each location. Comment Deadline: 11/12/17 (Source: *Texas Register*, Volume 42 Number 41, 10/13/2017).

TX State Board of Dental Examiners (Proposed Rule Sept. 29): Requires dentists delivering sedation or anesthesia to create and maintain in the patient's records a preoperative sedation checklist. Specifies the minimum requirements for the

checklist. Comment Deadline: 11/12/17 (Source: *Texas Register*, Volume 42 Number 41, 10/13/2017).

TX State Board of Dental Examiners (Proposed Rule Sept. 29): Requires anesthesia permit holders to develop written emergency preparedness policies and procedures. Specifies minimum requirements. Comment Deadline: 11/12/17 (Source: *Texas Register*, Volume 42 Number 41, 10/13/2017).

TX State Board of Dental Examiners (Proposed Rule Sept. 29): Stipulates minimum drugs and equipment that must be present in any office delivering sedation or anesthesia. Comment Deadline: 11/12/17 (Source: *Texas Register*, Volume 42 Number 41, 10/13/2017).

TX State Board of Dental Examiners (Proposed Rule Dec 5): Amends dental sedation regulations, including definitions, permitting processes and procedures, educational requirements, monitoring, and requirements for the treatment of pediatric patients. Comment Deadline: 1/31/17 (Source: *Texas Register*, Volume 41 Number 51, 12/16/2016).

TX State Board of Dental Examiners (Proposed Rule Sep 1): Establishes the blue ribbon panel on dental sedation/anesthesia safety and sets out its procedures and limitations. Comment Deadline: 10/16/16 (Source: *Texas Register*, Volume 41 Number 38, 09/16/2016).

TX State Board of Dental Examiners (Proposed Rule July 28): Establishes the Advisory Committee on Dental Anesthesia and specifies its duties and the appointment of its members. Comment Deadline: 09/10/17 (Source: *Texas Register*, Volume 42 Number 32, 08/11/2017).

TN HB 522/SB 613 (Introduced Feb. 8): Requires sedation permits to be prominently displayed at all times.

UT HB 142 (Signed by the Governor March 21): Beginning January 1, 2018, requires the Division of Occupation and Professional Licensing to create a database of deaths and adverse events from the administration of sedation or general anesthesia in outpatient settings. Incorporates reports submitted to the Dental Board, among other licensing boards, into this database. Specifies information that must be submitted. Requires a healthcare provider (including a dentist) who administers sedation intravenously to a patient in an outpatient setting to obtain informed consent from the patient. Requires practitioners administering IV sedation to have access to an advanced cardiac life support crash cart.

VA Board of Dentistry (Final Rule Jan 12): Eliminates some requirements that are not necessary for patient safety with the administration of only nitrous oxide. Comment Deadline: 01/25/17; Effective: 02/10/17 (Source: *Virginia Register of Regulations*, 33:09 VA.R, 12/26/2016).

VA Board of Dentistry (Final Rule April 17): Requires that a dentist who administers conscious/moderate sedation, deep sedation or general anesthesia maintain an end-tidal carbon dioxide monitor (capnograph) in working order and immediately available to areas where patients will be sedated and recover from sedation and monitor end-

tidal carbon dioxide in a patient during administration of conscious/moderate sedation or deep sedation or general anesthesia. Effective: 06/14/17 (Source: *Virginia Register of Regulations*, 33:19 VA.R, 05/15/2017).

VA Board of Dentistry (Proposed Rule Dec. 4): For consistency with the revised ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students, amends the use of the term conscious/moderate sedation throughout the chapters to refer to moderate sedation. Changes the name of the guidelines consistent with the 2016 title. Eliminates the training for dentists to administer moderate sedation by the enteral method only as the guidelines no longer make a distinction for enteral administration and specify the same training for all who administer moderate sedation. Comment Deadline: 02/23/18 (Source: *Virginia Register of Regulations*, 34:09 VA.R, 12/26/2017).

WA Department of Health (Proposed Rule Dec 6): Updates monitoring and equipment requirements for moderate sedation with parenteral agents regulations to align with the ADA, AAPD, AAOMS, and ASA standards. Specifies if treating a minor the dentist must have training in pediatric sedation and PALS. If treating an adult, the dentist must have appropriate training and ACLS. Requires expired CO2 monitoring. Provides for exceptions that must be documented. Provides requirements for the immobilization devices used on pediatric patients. Comment Deadline: 01/20/17 (Source: *Washington State Register*, 16-24, 01/10/2017).

WA Department of Health (Final Rule April 14): Specifies that dentists administering sedation or anesthesia on adults must have training in adult sedation and those administering to a minor must have training in pediatric sedation. Requires ACLS for treating adults and PALS for treating minors. Requires monitoring of expired carbon dioxide. Provides exceptions for specific pediatric cases. Effective: 04/08/17 (Source: *Washington State Register*, WSR 17-07, 04/25/2017).

WY Board of Dental Examiners (Emergency Rule Dec 5): Requires licensees to provide information regarding the status of their BLS and ACLS certification annually to the Dental Board. (Source: *Wyoming Government Register*, 12/05/2016)

Senate Bill No. 501

CHAPTER 929

An act to amend Sections 1601.4 and 2827 of, to amend, repeal, and add Sections 1682, 1724, and 1750.5 of, to add Sections 1601.8, 1646.10, 1647.9.5, and 1647.17.5 to, to add Article 2.75 (commencing with Section 1646), Article 2.84 (commencing with Section 1647), and Article 2.87 (commencing with Section 1647.30) to Chapter 4 of Division 2 of, to add and repeal Section 1601.7 of, and to repeal Article 2.7 (commencing with Section 1646), Article 2.85 (commencing with Section 1647.10), and Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of, the Business and Professions Code, relating to dentistry.

[Approved by Governor September 29, 2018. Filed with
Secretary of State September 29, 2018.]

LEGISLATIVE COUNSEL'S DIGEST

SB 501, Glazer. Dentistry: anesthesia and sedation: report.

Existing law imposes various functions and duties on the State Department of Public Health with respect to the administration and oversight of various health programs and facilities relating to the prevention of disease and the promotion of health.

This bill, on or before January 1, 2022, and upon appropriation from the Legislature, would require the Office of Oral Health in the State Department of Public Health to provide to the Legislature a report analyzing the effects on access to care for pediatric dental patients, as specified.

The Dental Practice Act provides for the licensure and regulation of dentists by the Dental Board of California within the Department of Consumer Affairs. The act governs the use of general anesthesia, conscious sedation, and oral conscious sedation for pediatric and adult patients. The act makes it unprofessional conduct for a dentist to engage in certain conduct, including failing to obtain written consent prior to administering general anesthesia or conscious sedation. The act also makes a willful violation of its provisions, including practicing without a valid certificate or license, a crime, and defines various terms relating to anesthesia and sedation.

This bill would require the board to review available data on all adverse events related to general anesthesia and deep sedation, moderate sedation, and minimal sedation in dentistry and relevant professional guidelines, recommendations, or best practices for the provision of dental anesthesia and sedation care in dentistry. By January 1, 2022, the bill would require the board to provide a report to the Legislature regarding any findings relevant to inform standards of dental anesthesia and sedation. The bill would also require the board to retain available data on all adverse events

related to general anesthesia and deep sedation, moderate sedation, and minimal sedation in dentistry for not less than 15 years.

This bill, beginning January 1, 2022, would establish new provisions governing the use of deep sedation and general anesthesia for dental patients. Among other requirements, the bill would require a dentist to possess either a current license in good standing and a general anesthesia permit, or other specified credentials in order to administer or order the administration of deep sedation or general anesthesia on an outpatient basis. The bill would require dentists to possess a pediatric endorsement of their general anesthesia permit to administer or order the administration of deep sedation or general anesthesia to patients under 7 years of age and would require dentists to be present within the dental office during the ordering and administration of general anesthesia or deep sedation. The bill would also require the presence of the operating dentist and at least 2 additional personnel for patients under 13 years of age for procedures involving deep sedation or general anesthesia and would require that certain personnel be present throughout the procedure and to maintain current certification in pediatric life support and airway management, as specified. The bill would require a dentist applying for a pediatric endorsement for the general anesthesia permit to provide proof of successful completion of an accredited or equivalent residency training program, and a certain number of cases of deep sedation or general anesthesia for patients under 7 years of age, along with current certification in specific life support training. Additionally, the bill would permit the board to require onsite inspections and evaluations of licensees and to contract with organizations or individuals to perform onsite inspections and evaluations. The bill would make a violation of these provisions unprofessional conduct and grounds for revocation or suspension of a dentist's permit or license, or both. The bill would also authorize a licensed physician and surgeon to administer deep sedation or general anesthesia if that physician and surgeon meets certain requirements, including holding a valid general anesthesia permit.

The Dental Practice Act prohibits a dentist from administering or ordering the administration of conscious sedation, as defined, on an outpatient basis unless the dentist meets certain licensing criteria.

This bill, effective January 1, 2022, would repeal existing provisions relating to the use of conscious sedation. The bill would replace the term "conscious sedation" with "moderate sedation," meaning a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands and meets other criteria. The bill would authorize a dentist to administer or order the administration of moderate sedation on an outpatient basis to a dental patient if the dentist meets specified licensing criteria and has applied to the board, submitted an application fee, and shown successful completion of training in moderate sedation. The bill would require a dentist who orders the administration of moderate sedation to be physically present in the treatment facility while the patient is sedated and would require the presence of additional specified personnel for sedation of patients 13 years of age or younger. The bill would specify that training

in the administration of moderate sedation is acceptable if it consists of a certain number of instructional hours and completion of cases and complies with certain guidelines for teaching pain control and sedation. The bill would require a dentist to obtain a pediatric endorsement on the moderate sedation permit prior to administering moderate sedation to a patient under 13 years of age, except as specified, and would require a dentist to obtain specified training to receive a pediatric endorsement. The bill also would require for patients under 13 years of age that there be at least 2 support personnel in addition to the operating dentist present at all times during the procedure, that the operating dentist and one of the additional personnel maintain certification in pediatric life support and airway management, as specified, and that one additional personnel with the certification in pediatric life support and airway management be dedicated to monitoring the patient during the procedure.

The bill, beginning January 1, 2022, also would establish new requirements for dentists administering or ordering the administration of minimal sedation, defined as a drug-induced state during which patients respond normally to verbal commands. The bill would authorize a dentist to administer or order the administration of minimal sedation on pediatric patients under 13 years of age if the dentist possesses specified licensing credentials and follows certain procedures. The bill would require any dentist who desires to administer or order the administration of minimal sedation to apply to the board, as specified, and to submit an application fee. The bill would make a violation of these provisions governing minimal sedation unprofessional conduct, constituting grounds for the revocation or suspension of the dentist's permit, or both. Additionally, by expanding the scope of an existing crime for violations of the Dental Practice Act, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 1601.4 of the Business and Professions Code is amended to read:

1601.4. (a) (1) The board shall review both of the following:

(A) Available data on all adverse events related to general anesthesia and deep sedation, moderate sedation, and minimal sedation in dentistry.

(B) Relevant professional guidelines, recommendations, or best practices for the provision of dental anesthesia and sedation care.

(2) By January 1, 2022, the board shall report to the Legislature any findings pursuant to this subdivision that are relevant to inform dental anesthesia and sedation standards.

(3) A report to be submitted pursuant to this subdivision shall be submitted in compliance with Section 9795 of the Government Code.

(b) The board shall provide a report on pediatric deaths related to general anesthesia and deep sedation in dentistry at the time of its sunset review pursuant to subdivision (d) of Section 1601.1.

(c) The board shall retain available data on all adverse events related to general anesthesia and deep sedation, moderate sedation, and minimal sedation in dentistry for not less than 15 years.

SEC. 2. Section 1601.7 is added to the Business and Professions Code, to read:

1601.7. (a) On or before January 1, 2022, and upon appropriation from the Legislature, the Office of Oral Health in the State Department of Public Health shall provide to the Legislature a report and analysis that addresses all of the following issues related to access to dental anesthesia care:

(1) An analysis of the costs of anesthesia and a discussion of payer sources for anesthesia services, including, but not limited to, an analysis of any difference in patient charges, patient payments, and public and private third-party reimbursement between both of the following:

(A) Dental anesthesia provided by a single dentist or anesthesia provider.

(B) Dental anesthesia provided by a dentist and a separate anesthesia provider.

(2) An analysis of the overall capacity of the state's dental anesthesia delivery systems, including, but not limited to, a separate analysis of capacity for care provided by a single dental surgeon or anesthesia provider and dental anesthesia provided by a dental surgeon and a separate anesthesia provider.

(3) An analysis of barriers to access of needed dental anesthesia care including, but not limited to, cost, delivery system capacity, and any other barriers identified in the current system. The analysis shall also include information regarding if provider requirements were to change and, if appropriate, recommendations to address such barriers to improve access.

(4) To the extent data is available, an analysis of disparities to access of needed dental anesthesia care by racial or ethnic background, insurance status, geographic area, or other relevant categories.

(5) The role of pediatric dental anesthesia in meeting the state's overall dental health goals as expressed in the California Oral Health Plan created by the State Department of Public Health.

(b) The Office of Oral Health may use a contract, grant, or other means to engage an agency appropriate for the type of analysis needed to create the report in subdivision (a), and public or private funds, upon appropriation, may be used. The report shall be made public on the State Department of Public Health's Internet Web site.

(c) (1) A report to be submitted pursuant to subdivision (a) shall be submitted in compliance with Section 9795 of the Government Code.

(2) Pursuant to Section 10231.5 of the Government Code, this section is repealed on January 1, 2025.

SEC. 3. Section 1601.8 is added to the Business and Professions Code, to read:

1601.8. For purposes of training standards for general anesthesia, deep sedation, and moderate sedation, the board may approve a training standard in lieu of Pediatric Advanced Life Support (PALS) certification if the training standard is an equivalent or higher level of training for pediatric dental anesthesia-related emergencies than PALS certification that includes, but is not limited to, pediatric life support and airway management.

SEC. 4. Article 2.75 (commencing with Section 1646) is added to Chapter 4 of Division 2 of the Business and Professions Code, to read:

Article 2.75. Use of Deep Sedation and General Anesthesia

1646. As used in this article, the following definitions apply:

(a) “Deep sedation” means 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.

(b) “General anesthesia” means 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.

1646.1. (a) A dentist shall possess either a current license in good standing and a general anesthesia permit issued by the board or a permit under Section 1638 or 1640 and a general anesthesia permit issued by the board in order to administer or order the administration of deep sedation or general anesthesia on an outpatient basis for dental patients.

(b) A dentist shall possess a pediatric endorsement of their general anesthesia permit to administer or order the administration of deep sedation or general anesthesia to patients under seven years of age.

(c) A dentist shall be physically within the dental office at the time of ordering, and during the administration of, general anesthesia or deep sedation.

(d) For patients under 13 years of age, all of the following shall apply:

(1) The operating dentist and at least two additional personnel shall be present throughout the procedure involving deep sedation or general anesthesia.

(2) If the operating dentist is the permitted anesthesia provider, then both of the following shall apply:

(A) The operating dentist and at least one of the additional personnel shall maintain current certification in Pediatric Advanced Life Support

(PALS) or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8. The additional personnel who is certified in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management shall be solely dedicated to monitoring the patient and shall be trained to read and respond to monitoring equipment including, but not limited to, pulse oximeter, cardiac monitor, blood pressure, pulse, capnograph, and respiration monitoring devices.

(B) The operating dentist shall be responsible for initiating and administering any necessary emergency response.

(3) If a dedicated permitted anesthesia provider is monitoring the patient and administering deep sedation or general anesthesia, both of the following shall apply:

(A) The anesthesia provider and the operating dentist, or one other trained personnel, shall be present throughout the procedure and shall maintain current certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8.

(B) The anesthesia provider shall be responsible for initiating and administering any necessary emergency response and the operating dentist, or other trained and designated personnel, shall assist the anesthesia provider in emergency response.

(e) This article does not apply to the administration of local anesthesia, minimal sedation, or moderate sedation.

1646.2. (a) A dentist who desires to administer or order the administration of deep sedation or general anesthesia shall apply to the board on an application form prescribed by the board. The dentist must submit an application fee and produce evidence showing that he or she has successfully completed a minimum of one year of advanced training in anesthesiology and related academic subjects approved by the board, or equivalent training or experience approved by the board, beyond the undergraduate school level.

(b) The application for a permit shall include documentation that equipment and drugs required by the board are on the premises.

(c) A dentist may apply for a pediatric endorsement for the general anesthesia permit by providing proof of successful completion of all of the following:

(1) A Commission on Dental Accreditation (CODA)-accredited or equivalent residency training program that provides competency in the administration of deep sedation and general anesthesia on pediatric patients.

(2) At least 20 cases of deep sedation or general anesthesia to patients under seven years of age in the 24-month time period directly preceding application for a pediatric endorsement to establish competency, both at the time of initial application and at renewal. The applicant or permitholder shall maintain and be able to provide proof of these cases upon request by the board for up to three permit renewal periods.

(3) Current certification in Advanced Cardiac Life Support (ACLS) and Pediatric Advanced Life Support (PALS) or other board-approved training in pediatric life support and airway management, pursuant to Section 1601.8, for the duration of the permit.

(d) Applicants for a pediatric endorsement who otherwise qualify for the pediatric endorsement but lack sufficient cases of pediatric sedation to patients under seven years of age may administer deep sedation and general anesthesia to patients under seven years of age under the direct supervision of a general anesthesia permitholder with a pediatric endorsement. The applicant may count these cases toward the 20 cases required to qualify for the applicant's pediatric endorsement.

1646.3. (a) A physical evaluation and medical history shall be taken before the administration of deep sedation or general anesthesia.

(b) Any dentist holding a permit shall maintain medical history, physical evaluation, deep sedation, and general anesthesia records as required by board regulations.

1646.4. (a) Prior to the issuance or renewal of a permit for the use of deep sedation or general anesthesia, the board may, at its discretion, require an onsite inspection and evaluation of the licensee and the facility, equipment, personnel, and procedures utilized by the licensee. The permit of any dentist who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the dentist of the failure, unless within that time period the dentist has retaken and passed an onsite inspection and evaluation. Every dentist issued a permit under this article shall have an onsite inspection and evaluation at least once every five years. Refusal to submit to an inspection shall result in automatic denial or revocation of the permit.

(b) The board may contract with public or private organizations or individuals expert in dental outpatient general anesthesia to perform onsite inspections and evaluations. The board may not, however, delegate its authority to issue permits or to determine the persons or facilities to be inspected.

(c) It is the intent of the Legislature that the board hire sufficient staff to administer the program and that the fees established pursuant to this section be equivalent to administration and enforcement costs incurred by the board in carrying out this article.

1646.5. A permittee shall be required to complete 24 hours of approved courses of study related to deep sedation or general anesthesia as a condition of renewal of a permit. Those courses of study shall be credited toward the total continuing education hours required by the board pursuant to Section 1645.

1646.6. (a) The application fee for a permit or renewal under this article shall not exceed the amount prescribed in Section 1724.

(b) The fee for an onsite inspection shall not exceed the amount prescribed in Section 1724.

(c) It is the intent of the Legislature that fees established pursuant to this section be equivalent to administrative and enforcement costs incurred by the board in carrying out this article.

(d) At the discretion of the board, the fee for onsite inspection may be collected and retained by a contractor engaged pursuant to subdivision (b) of Section 1646.4.

1646.7. (a) A violation of this article constitutes unprofessional conduct and is grounds for the revocation or suspension of the dentist's permit or license, or both. The board shall issue probationary terms only for violations that do not result in bodily harm.

(b) A violation of any provision of this article or Section 1682 is grounds for suspension or revocation of the physician and surgeon's permit issued pursuant to this article by the board. The exclusive enforcement authority against a physician and surgeon by the board shall be to suspend or revoke the permit issued pursuant to this article. The board shall refer a violation of this article by a physician and surgeon to the Medical Board of California for its consideration as unprofessional conduct and further action, if deemed necessary by the Medical Board of California, pursuant to Chapter 5 (commencing with Section 2000). A suspension or revocation of a physician and surgeon's permit by the board pursuant to this article shall not constitute a disciplinary proceeding or action for any purpose except to permit the initiation of an investigation or disciplinary action by the Medical Board of California, as authorized by Section 2220.5.

(c) The proceedings under this section shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted therein.

1646.8. Nothing in this chapter shall be construed to authorize a dentist to administer or directly supervise the administration of general anesthesia or deep sedation for reasons other than dental treatment, as defined in Section 1625.

1646.9. (a) A physician and surgeon licensed pursuant to Chapter 5 (commencing with Section 2000) may administer deep sedation or general anesthesia in the office of a licensed dentist for dental patients, without regard to whether the dentist possesses a permit issued pursuant to this article, if all of the following conditions are met:

(1) The physician and surgeon possesses a current license in good standing to practice medicine in this state.

(2) The physician and surgeon holds a valid general anesthesia permit issued by the Dental Board of California pursuant to subdivision (b).

(3) The physician and surgeon meets the requirements of subdivision (d) of Section 1646.1.

(b) A physician and surgeon who desires to administer deep sedation or general anesthesia as set forth in subdivision (a) shall apply to the board on an application form prescribed by the board and shall submit all of the following:

(1) The payment of an application fee prescribed by this article.

(2) Evidence satisfactory to the Medical Board of California showing that the applicant has successfully completed a postgraduate residency training program in anesthesiology that is recognized by the American Council on Graduate Medical Education, as set forth in Section 2079.

(3) Documentation demonstrating that all equipment and drugs required by the board are on the premises for use in any dental office in which he or she administers deep sedation or general anesthesia.

(4) Information relative to the current membership of the applicant on hospital medical staffs.

(c) Prior to issuance or renewal of a permit pursuant to this section, the board may, at its discretion, require an onsite inspection and evaluation of the facility, equipment, personnel, including, but not limited to, the physician and surgeon, and procedures utilized. At least one of the persons evaluating the procedures utilized by the physician and surgeon shall be a licensed physician and surgeon expert in outpatient deep sedation or general anesthesia who has been authorized or retained under contract by the board for this purpose.

(d) The permit of a physician and surgeon who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the physician and surgeon of the failure unless within that time period the physician and surgeon has retaken and passed an onsite inspection and evaluation. Every physician and surgeon issued a permit under this article shall have an onsite inspection and evaluation at least once every five years. Refusal to submit to an inspection shall result in automatic denial or revocation of the permit.

(e) A physician and surgeon who additionally meets the requirements of paragraphs (2) and (3) of subdivision (c) of Section 1646.2 may apply to the board for a pediatric endorsement to provide deep sedation or general anesthesia to a child under seven years of age. A physician and surgeon without sufficient cases to obtain a pediatric endorsement may qualify for the endorsement pursuant to the requirements of subdivision (d) of Section 1646.2.

1646.10. A general anesthesia permit shall expire on the date provided in Section 1715 that next occurs after its issuance, unless it is renewed as provided in this article.

1646.11. A general anesthesia permitholder who has a permit that was issued before January 1, 2022, may follow the terms of that existing permit until it expires. Any permit issued or renewed pursuant to this article on or after January 1, 2022, shall require the permitholder to follow the new requirements of this article.

1646.13. This article shall become operative on January 1, 2022.

SEC. 5. Section 1646.10 is added to Article 2.7 of Chapter 4 of Division 2 of the Business and Professions Code, immediately following Section 1646.9, to read:

1646.10. This article shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 6. Article 2.84 (commencing with Section 1647) is added to Chapter 4 of Division 2 of the Business and Professions Code, to read:

Article 2.84. Use of Moderate Sedation

1647. (a) The Legislature finds and declares that a commendable patient safety record has been maintained in the past by dentists and those other qualified providers of anesthesia services who, pursuant to a dentist's authorization, administer patient sedation, and that the increasing number of pharmaceuticals and techniques used to administer them for patient sedation require additional regulation to maintain patient safety in the future.

(b) The Legislature further finds and declares all of the following:

(1) That previous laws enacted in 1980 contained separate and distinct definitions for general anesthesia and the state of consciousness.

(2) That in dental practice, there is a continuum of sedation used which cannot be adequately defined in terms of consciousness and general anesthesia.

(3) That the administration of sedation through this continuum results in different states of consciousness that may or may not be predictable in every instance.

(4) That in most instances, the level of sedation will result in a predictable level of consciousness during the entire time of sedation.

(c) The Legislature further finds and declares that the educational standards presently required for deep sedation and general anesthesia should be required when the degree of sedation in the continuum of sedation is such that there is a reasonable possibility that loss of consciousness may result, even if unintended. However, achieving the degree of moderate sedation, where a margin of safety exists wide enough to render unintended loss of consciousness unlikely, requires educational standards appropriate to the administration of the resulting predictable level of consciousness.

1647.1. (a) As used in this article, "moderate sedation" means a drug-induced depression of consciousness during which a patient responds purposefully to verbal commands, either alone or accompanied by light tactile stimulation, no interventions are required to maintain a patient's airway, spontaneous ventilation is adequate, and cardiovascular function is usually maintained.

(b) The drugs and techniques used in moderate sedation shall have a margin of safety wide enough to render unintended loss of consciousness unlikely. Further, patients whose only response is reflex withdrawal from painful stimuli shall not be considered to be in a state of moderate sedation.

1647.2. (a) A dentist may administer or order the administration of moderate sedation on an outpatient basis for a dental patient if one of the following conditions is met:

(1) The dentist possesses a current license in good standing and either holds a valid general anesthesia permit or obtains a moderate sedation permit.

(2) The dentist possesses a current permit under Section 1638 or 1640 and either holds a valid general anesthesia permit or obtains a moderate sedation permit.

(b) A dentist shall obtain a pediatric endorsement on the moderate sedation permit prior to administering moderate sedation to a patient under 13 years of age.

(c) (1) A dentist who orders the administration of moderate sedation shall be physically present in the treatment facility while the patient is sedated.

(2) For patients under 13 years of age, there shall be at least two support personnel in addition to the operating dentist present at all times during the procedure involving moderate sedation. The operating dentist and one personnel member shall maintain current certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8. The personnel member with current certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management shall be dedicated to monitoring the patient during the procedure involving moderate sedation and may assist with interruptible patient-related tasks of short duration, such as holding an instrument.

(d) A dentist with a moderate sedation permit or a moderate sedation permit with a pediatric endorsement shall possess the training, equipment, and supplies to rescue a patient from an unintended deeper level of sedation.

(e) This article shall not apply to the administration of local anesthesia, minimal sedation, deep sedation, or general anesthesia.

1647.3. (a) A dentist who desires to administer or to order the administration of moderate sedation shall apply to the board on an application form prescribed by the board. The dentist shall submit an application fee and produce evidence showing that he or she has successfully completed training in moderate sedation that meets the requirements of subdivision (c).

(b) The application for a permit shall include documentation that equipment and drugs required by the board are on the premises.

(c) Training in the administration of moderate sedation shall be acceptable if it meets all of the following as approved by the board:

(1) Consists of at least 60 hours of instruction.

(2) Requires satisfactory completion of at least 20 cases of administration of moderate sedation for a variety of dental procedures.

(3) Complies with the requirements of the Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students of the American Dental Association, including, but not limited to, certification of competence in rescuing patients from a deeper level of sedation than intended, and managing the airway, intravascular or intraosseous access, and reversal medications.

(d) A dentist may apply for a pediatric endorsement for a moderate sedation permit by confirming all of the following:

(1) Successful completion of residency in pediatric dentistry accredited by the Commission on Dental Accreditation (CODA) or the equivalent training in pediatric moderate sedation, as determined by the board.

(2) Successful completion of at least 20 cases of moderate sedation to patients under 13 years of age to establish competency in pediatric moderate sedation, both at the time of the initial application and at renewal. The applicant or permit holder shall maintain and shall provide proof of these cases upon request by the board for up to three permit renewal periods.

(3) In order to provide moderate sedation to children under seven years of age, a dentist shall establish and maintain current competency for this pediatric population by completing 20 cases of moderate sedation for children under seven years of age in the 24-month period immediately preceding application for the pediatric endorsement and for each permit renewal period.

(4) Current certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8.

(e) A permit holder shall maintain current and continuous certification in Pediatric Advanced Life Support (PALS) and airway management or other board-approved training in pediatric life support and airway management, adopted pursuant to Section 1601.8, for the duration of the permit.

(f) Applicants for a pediatric endorsement who otherwise qualify for the pediatric endorsement but lack sufficient cases of moderate sedation to patients under 13 years of age may administer moderate sedation to patients under 13 years of age under the direct supervision of a general anesthesia or moderate sedation permit holder with a pediatric endorsement. The applicant may count these cases toward the 20 required in order to qualify for the applicant's pediatric endorsement.

(g) Moderate sedation permit holders with a pediatric endorsement seeking to provide moderate sedation to children under seven years of age, but who lack sufficient cases of moderate sedation to patients under seven years of age pursuant to paragraph (3) of subdivision (d), may administer moderate sedation to patients under seven years of age under the direct supervision of a permit holder who meets those qualifications.

1647.4. A moderate sedation permit shall expire on the date specified in Section 1715 that next occurs after its issuance, unless it is renewed as provided in this article.

1647.5. A permittee shall be required to complete 15 hours of approved courses of study related to moderate sedation as a condition of renewal of a permit. Those courses of study shall be credited toward the total continuing education required by the board pursuant to Section 1645.

1647.6. (a) A physical evaluation and medical history shall be taken before the administration of moderate sedation.

(b) Any dentist holding a permit shall maintain records of the physical evaluation, medical history, and moderate sedation procedures used as required by board regulations.

1647.7. (a) Prior to the issuance or renewal of a permit to administer moderate sedation, the board may, at its discretion, require an onsite inspection and evaluation of the licensee and the facility, equipment, personnel, and procedures utilized by the licensee. The permit of any dentist who has failed an onsite inspection and evaluation shall be automatically suspended 30 days after the date on which the board notifies the dentist of the failure unless, within that time period, the dentist has retaken and passed an onsite inspection and evaluation. Every dentist issued a permit under this article shall have an onsite inspection and evaluation at least once in every six years. Refusal to submit to an inspection shall result in automatic denial or revocation of the permit.

(b) An applicant who has successfully completed the course required by Section 1647.3 may be granted a one-year temporary permit by the board prior to the onsite inspection and evaluation. Failure to pass the inspection and evaluation shall result in the immediate and automatic termination of the temporary permit.

(c) The board may contract with public or private organizations or individuals expert in dental outpatient moderate sedation to perform onsite inspections and evaluations. The board may not, however, delegate its authority to issue permits or to determine the persons or facilities to be inspected.

1647.8. (a) The application fee for a permit or renewal under this article shall not exceed the amount prescribed in Section 1724.

(b) The fee for an onsite inspection shall not exceed the amount prescribed in Section 1724.

(c) It is the intent of the Legislature that the board hire sufficient staff to administer the program and that the fees established pursuant to this section be equivalent to administration and enforcement costs incurred by the board in carrying out this article.

1647.9. A violation of this article constitutes unprofessional conduct and is grounds for the revocation or suspension of the dentist's permit or license, or both. The board shall issue probationary terms only for violations that do not result in bodily harm. The proceedings under this section shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted therein.

1647.10. A conscious sedation permitholder who has a permit that was issued before January 1, 2022, may follow the terms of that existing permit until it expires. Any permit issued or renewed pursuant to this article on or after January 1, 2022, shall require the permitholder to follow the requirements of this article.

1647.12. This article shall become operative on January 1, 2022.

SEC. 7. Section 1647.9.5 is added to Article 2.8 of Chapter 4 of Division 2 of the Business and Professions Code, immediately following Section 1647.9, to read:

1647.9.5. This article shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 8. Section 1647.17.5 is added to Article 2.85 of Chapter 4 of Division 2 of the Business and Professions Code, immediately following Section 1647.17, to read:

1647.17.5. This article shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 9. Article 2.87 (commencing with Section 1647.30) is added to Chapter 4 of Division 2 of the Business and Professions Code, to read:

Article 2.87. Use of Pediatric Minimal Sedation

1647.30. (a) As used in this article, “minimal sedation” means a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, airway reflexes, ventilatory, and cardiovascular functions are unaffected.

(b) The drugs and techniques used in minimal sedation shall have a margin of safety wide enough to render unintended loss of consciousness unlikely. Further, patients who require tactile stimulation to elicit a response to verbal commands shall not be considered to be in a state of minimal sedation.

(c) For the very young or developmentally delayed individual, incapable of the usually expected verbal response, a minimally depressed level of consciousness should be maintained.

1647.31. (a) A dentist may administer or order the administration of pediatric minimal sedation on an outpatient basis for pediatric dental patients under 13 years of age, if one of the following conditions is met:

(1) The dentist holds a current permit for deep sedation and general anesthesia, or holds a current permit for moderate sedation with a pediatric endorsement, or obtains a pediatric minimal sedation permit.

(2) The dentist possesses a current permit under Section 1638 or 1640 and holds a valid deep sedation and general anesthesia permit, a moderate sedation permit with a pediatric endorsement, or obtains a pediatric minimal sedation permit.

(b) A dentist who administers or orders the administration of pediatric minimal sedation shall be physically present in the treatment facility while the patient is sedated.

(c) A dentist with a pediatric minimal sedation permit shall possess the training, equipment, and supplies to rescue a patient from an unintended deeper level of sedation.

(d) This article does not apply to the administration of local anesthesia, moderate sedation, deep sedation, or general anesthesia.

1647.32. (a) A dentist who desires to administer or order the administration of pediatric minimal sedation shall apply to the board on an application form prescribed by the board. The dentist shall possess a current license in good standing, submit an application fee, and produce evidence showing that he or she has successfully completed training in pediatric minimal sedation that meets the requirements of subdivision (c).

(b) The application for a permit shall include documentation that equipment and drugs required by the board are on the premises.

(c) Training in the administration of pediatric minimal sedation shall be acceptable if it meets either of the following as approved by the board:

(1) Consists of at least 24 hours of pediatric minimal sedation instruction in addition to one clinical case. The pediatric minimal sedation instruction shall include training in pediatric monitoring, airway management, and resuscitation and patient rescue from moderate sedation.

(2) Completion of a CODA-approved residency in pediatric dentistry.

(d) A dentist shall be limited to administering a single drug whose primary purpose is sedative via the oral route, either singly or in divided doses, not to exceed the manufacturer's maximum recommended dose, plus a mix of nitrous oxide and oxygen and adjunctive agents such that the drugs either singly or in combination are unlikely to produce a state of unintended moderate sedation. This section shall not be construed to restrict the administration of adjunctive medication intended to relieve pain, affect the onset or duration of the primary sedative agent, or to reduce the side effects of sedation, including nausea or emesis.

(e) The operating dentist and a minimum of one additional personnel who are both trained in the monitoring and resuscitation of pediatric patients, as approved by the board, shall be present during the administration of minimal sedation.

1647.33. (a) The application fee for a pediatric minimal sedation permit or renewal under this article shall not exceed the amount prescribed in Section 1724.

(b) It is the intent of the Legislature that the board hire sufficient staff to administer the program and that the fees established pursuant to this section be equivalent to administration and enforcement costs incurred by the board in carrying out this article.

1647.34. A violation of any provision of this article constitutes unprofessional conduct and is grounds for the revocation or suspension of the dentist's permit or license, or both. The proceedings under this section shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted therein.

1647.35. A permitholder who has a permit that was issued before January 1, 2022, that authorized the permitholder to administer or order the administration of oral conscious sedation for minor patients under prior Article 2.85 (commencing with Section 1647.10) may follow the terms of that existing permit until it expires. Any permit issued or renewed pursuant to this article on or after January 1, 2022, shall require the permitholder to follow the requirements of this article.

1647.36. This article shall become operative on January 1, 2022.

SEC. 10. Section 1682 of the Business and Professions Code is amended to read:

1682. In addition to other acts constituting unprofessional conduct under this chapter, it is unprofessional conduct for:

(a) Any dentist performing dental procedures to have more than one patient undergoing conscious sedation or general anesthesia on an outpatient basis at any given time unless each patient is being continuously monitored on a one-to-one ratio while sedated by either the dentist or another licensed health professional authorized by law to administer conscious sedation or general anesthesia.

(b) Any dentist with patients recovering from conscious sedation or general anesthesia to fail to have the patients closely monitored by licensed health professionals experienced in the care and resuscitation of patients recovering from conscious sedation or general anesthesia. If one licensed professional is responsible for the recovery care of more than one patient at a time, all of the patients shall be physically in the same room to allow continuous visual contact with all patients and the patient to recovery staff ratio should not exceed three to one.

(c) Any dentist with patients who are undergoing conscious sedation to fail to have these patients continuously monitored during the dental procedure with a pulse oximeter or similar or superior monitoring equipment required by the board.

(d) Any dentist with patients who are undergoing conscious sedation to have dental office personnel directly involved with the care of those patients who are not certified in basic cardiac life support (CPR) and recertified biennially.

(e) (1) Any dentist to fail to obtain the written informed consent of a patient prior to administering general anesthesia or conscious sedation. In the case of a minor, the consent shall be obtained from the child's parent or guardian.

(2) The written informed consent, in the case of a minor, shall include, but not be limited to, the following information:

"The administration and monitoring of general anesthesia may vary depending on the type of procedure, the type of practitioner, the age and health of the patient, and the setting in which anesthesia is provided. Risks may vary with each specific situation. You are encouraged to explore all the options available for your child's anesthesia for his or her dental treatment, and consult with your dentist or pediatrician as needed."

(3) Nothing in this subdivision shall be construed to establish the reasonable standard of care for administering or monitoring oral conscious sedation, conscious sedation, or general anesthesia.

(f) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 11. Section 1682 is added to the Business and Professions Code, to read:

1682. In addition to other acts constituting unprofessional conduct under this chapter, it is unprofessional conduct for:

(a) Any dentist performing dental procedures to have more than one patient undergoing moderate sedation, deep sedation, or general anesthesia on an outpatient basis at any given time unless each patient is being continuously monitored on a one-to-one ratio while sedated by either the

dentist or another licensed health professional authorized by law to administer moderate sedation, deep sedation, or general anesthesia.

(b) Any dentist with patients recovering from moderate sedation, deep sedation, or general anesthesia to fail to have the patients closely monitored by licensed health professionals experienced in the care and resuscitation of patients recovering from moderate sedation, deep sedation, or general anesthesia. If one licensed professional is responsible for the recovery care of more than one patient at a time, all of the patients shall be physically in the same room to allow continuous visual contact with all patients and the patient to recovery staff ratio should not exceed three to one.

(c) Any dentist with patients who are undergoing deep sedation, general anesthesia, or moderate sedation to fail to have these patients continuously monitored during the dental procedure with a pulse oximeter or similar or superior monitoring equipment and ventilation continuously monitored using at least two of the three following methods:

(1) Auscultation of breath sounds using a precordial stethoscope.

(2) Monitoring for the presence of exhaled carbon dioxide with capnography.

(3) Verbal communication with a patient under moderate sedation. This method shall not be used for a patient under deep sedation or general anesthesia.

(d) Any dentist with patients who are undergoing moderate sedation to have dental office personnel directly involved with the care of those patients who are not certified in basic cardiac life support (CPR) and recertified biennially.

(e) (1) Any dentist to fail to obtain the written informed consent of a patient prior to administering moderate sedation, deep sedation, or general anesthesia. In the case of a minor, the consent shall be obtained from the child’s parent or guardian.

(2) The written informed consent for general anesthesia, in the case of a minor, shall include, but not be limited to, the following information:

“The administration and monitoring of deep sedation or general anesthesia may vary depending on the type of procedure, the type of practitioner, the age and health of the patient, and the setting in which anesthesia is provided. Risks may vary with each specific situation. You are encouraged to explore all the options available for your child’s anesthesia for his or her dental treatment, and consult with your dentist or pediatrician as needed.”

(3) Nothing in this subdivision shall be construed to establish the reasonable standard of care for administering or monitoring oral moderate sedation, moderate sedation, deep sedation, or general anesthesia.

(f) This section shall become operative on January 1, 2022.

SEC. 12. Section 1724 of the Business and Professions Code is amended to read:

1724. The amount of charges and fees for dentists licensed pursuant to this chapter shall be established by the board as is necessary for the purpose of carrying out the responsibilities required by this chapter as it relates to dentists, subject to the following limitations:

(a) The fee for an application for licensure qualifying pursuant to paragraph (1) of subdivision (c) of Section 1632 shall not exceed one thousand five hundred dollars (\$1,500). The fee for an application for licensure qualifying pursuant to paragraph (2) of subdivision (c) of Section 1632 shall not exceed one thousand dollars (\$1,000).

(b) The fee for an application for licensure qualifying pursuant to Section 1634.1 shall not exceed one thousand dollars (\$1,000).

(c) The fee for an application for licensure qualifying pursuant to Section 1635.5 shall not exceed one thousand dollars (\$1,000).

(d) The fee for an initial license and for the renewal of a license is five hundred twenty-five dollars (\$525). On and after January 1, 2016, the fee for an initial license shall not exceed six hundred fifty dollars (\$650), and the fee for the renewal of a license shall not exceed six hundred fifty dollars (\$650). On and after January 1, 2018, the fee for an initial license shall not exceed eight hundred dollars (\$800), and the fee for the renewal of a license shall not exceed eight hundred dollars (\$800).

(e) The fee for an application for a special permit shall not exceed one thousand dollars (\$1,000), and the renewal fee for a special permit shall not exceed six hundred dollars (\$600).

(f) The delinquency fee shall be 50 percent of the renewal fee for such a license or permit in effect on the date of the renewal of the license or permit.

(g) The penalty for late registration of change of place of practice shall not exceed seventy-five dollars (\$75).

(h) The fee for an application for an additional office permit shall not exceed seven hundred fifty dollars (\$750), and the fee for the renewal of an additional office permit shall not exceed three hundred seventy-five dollars (\$375).

(i) The fee for issuance of a replacement pocket license, replacement wall certificate, or replacement engraved certificate shall not exceed one hundred twenty-five dollars (\$125).

(j) The fee for a provider of continuing education shall not exceed five hundred dollars (\$500) per year.

(k) The fee for application for a referral service permit and for renewal of that permit shall not exceed twenty-five dollars (\$25).

(l) The fee for application for an extramural facility permit and for the renewal of a permit shall not exceed twenty-five dollars (\$25).

(m) The fee for an application for an elective facial cosmetic surgery permit shall not exceed four thousand dollars (\$4,000), and the fee for the renewal of an elective facial cosmetic surgery permit shall not exceed eight hundred dollars (\$800).

(n) The fee for an application for an oral and maxillofacial surgery permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of an oral and maxillofacial surgery permit shall not exceed one thousand two hundred dollars (\$1,200).

(o) The fee for an application for a general anesthesia permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of a general anesthesia permit shall not exceed six hundred dollars (\$600).

(p) The fee for an onsite inspection and evaluation related to a general anesthesia or conscious sedation permit shall not exceed four thousand five hundred dollars (\$4,500).

(q) The fee for an application for a conscious sedation permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of a conscious sedation permit shall not exceed six hundred dollars (\$600).

(r) The fee for an application for an oral conscious sedation permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of an oral conscious sedation permit shall not exceed six hundred dollars (\$600).

(s) The fee for a certification of licensure shall not exceed one hundred twenty-five dollars (\$125).

(t) The fee for an application for the law and ethics examination shall not exceed two hundred fifty dollars (\$250).

The board shall report to the appropriate fiscal committees of each house of the Legislature whenever the board increases any fee pursuant to this section and shall specify the rationale and justification for that increase.

(u) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 13. Section 1724 is added to the Business and Professions Code, to read:

1724. The amount of charges and fees for dentists licensed pursuant to this chapter shall be established by the board as is necessary for the purpose of carrying out the responsibilities required by this chapter as it relates to dentists, subject to the following limitations:

(a) The fee for an application for licensure qualifying pursuant to paragraph (1) of subdivision (c) of Section 1632 shall not exceed one thousand five hundred dollars (\$1,500). The fee for an application for licensure qualifying pursuant to paragraph (2) of subdivision (c) of Section 1632 shall not exceed one thousand dollars (\$1,000).

(b) The fee for an application for licensure qualifying pursuant to Section 1634.1 shall not exceed one thousand dollars (\$1,000).

(c) The fee for an application for licensure qualifying pursuant to Section 1635.5 shall not exceed one thousand dollars (\$1,000).

(d) The fee for an initial license and for the renewal of a license is five hundred twenty-five dollars (\$525). On and after January 1, 2016, the fee for an initial license shall not exceed six hundred fifty dollars (\$650), and the fee for the renewal of a license shall not exceed six hundred fifty dollars (\$650). On and after January 1, 2018, the fee for an initial license shall not exceed eight hundred dollars (\$800), and the fee for the renewal of a license shall not exceed eight hundred dollars (\$800).

(e) The fee for an application for a special permit shall not exceed one thousand dollars (\$1,000), and the renewal fee for a special permit shall not exceed six hundred dollars (\$600).

(f) The delinquency fee shall be 50 percent of the renewal fee for such a license or permit in effect on the date of the renewal of the license or permit.

(g) The penalty for late registration of change of place of practice shall not exceed seventy-five dollars (\$75).

(h) The fee for an application for an additional office permit shall not exceed seven hundred fifty dollars (\$750), and the fee for the renewal of an additional office permit shall not exceed three hundred seventy-five dollars (\$375).

(i) The fee for issuance of a replacement pocket license, replacement wall certificate, or replacement engraved certificate shall not exceed one hundred twenty-five dollars (\$125).

(j) The fee for a provider of continuing education shall not exceed five hundred dollars (\$500) per year.

(k) The fee for application for a referral service permit and for renewal of that permit shall not exceed twenty-five dollars (\$25).

(l) The fee for application for an extramural facility permit and for the renewal of a permit shall not exceed twenty-five dollars (\$25).

(m) The fee for an application for an elective facial cosmetic surgery permit shall not exceed four thousand dollars (\$4,000), and the fee for the renewal of an elective facial cosmetic surgery permit shall not exceed eight hundred dollars (\$800).

(n) The fee for an application for an oral and maxillofacial surgery permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of an oral and maxillofacial surgery permit shall not exceed one thousand two hundred dollars (\$1,200).

(o) The fee for an application for a general anesthesia permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of a general anesthesia permit shall not exceed six hundred dollars (\$600).

(p) The fee for an onsite inspection and evaluation related to a general anesthesia or moderate sedation permit shall not exceed four thousand five hundred dollars (\$4,500).

(q) The fee for an application for a moderate sedation permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of a conscious sedation permit shall not exceed six hundred dollars (\$600).

(r) The fee for an application for an oral conscious sedation permit shall not exceed one thousand dollars (\$1,000), and the fee for the renewal of an oral conscious sedation permit shall not exceed six hundred dollars (\$600).

(s) The fee for a certification of licensure shall not exceed one hundred twenty-five dollars (\$125).

(t) The fee for an application for the law and ethics examination shall not exceed two hundred fifty dollars (\$250).

(u) This section shall become operative on January 1, 2022.

SEC. 14. Section 1750.5 of the Business and Professions Code is amended to read:

1750.5. A person holding a dental sedation assistant permit pursuant to Section 1750.4 may perform the following duties under the direct supervision

of a licensed dentist or other licensed health care professional authorized to administer conscious sedation or general anesthesia in the dental office:

(a) All duties that a dental assistant is allowed to perform.

(b) Monitor patients undergoing conscious sedation or general anesthesia utilizing data from noninvasive instrumentation such as pulse oximeters, electrocardiograms, capnography, blood pressure, pulse, and respiration rate monitoring devices. Evaluation of the condition of a sedated patient shall remain the responsibility of the dentist or other licensed health care professional authorized to administer conscious sedation or general anesthesia, who shall be at the patient's chairside while conscious sedation or general anesthesia is being administered.

(c) Drug identification and draw, limited to identification of appropriate medications, ampule and vial preparation, and withdrawing drugs of correct amount as verified by the supervising licensed dentist.

(d) Add drugs, medications, and fluids to intravenous lines using a syringe, provided that a supervising licensed dentist is present at the patient's chairside, limited to determining patency of intravenous line, selection of injection port, syringe insertion into injection port, occlusion of intravenous line and blood aspiration, line release and injection of drugs for appropriate time interval. The exception to this duty is that the initial dose of a drug or medication shall be administered by the supervising licensed dentist.

(e) Removal of intravenous lines.

(f) Any additional duties that the board may prescribe by regulation.

(g) The duties listed in subdivisions (b) to (e), inclusive, may not be performed in any setting other than a dental office or dental clinic.

(h) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 15. Section 1750.5 is added to the Business and Professions Code, to read:

1750.5. (a) A person holding a dental sedation assistant permit pursuant to Section 1750.4 may perform the following duties under the direct supervision of a licensed dentist or other licensed health care professional authorized to administer moderate sedation, deep sedation, or general anesthesia in the dental office:

(1) All duties that a dental assistant is allowed to perform.

(2) Monitor patients undergoing moderate sedation, deep sedation, or general anesthesia utilizing data from noninvasive instrumentation such as pulse oximeters, electrocardiograms, capnography, blood pressure, pulse, and respiration rate monitoring devices. Evaluation of the condition of a sedated patient shall remain the responsibility of the dentist or other licensed health care professional authorized to administer moderate sedation, deep sedation, or general anesthesia, who shall be at the patient's chairside while moderate sedation, deep sedation, or general anesthesia is being administered.

(3) Drug identification and draw, limited to identification of appropriate medications, ampule and vial preparation, and withdrawing drugs of correct amount as verified by the supervising licensed dentist.

(4) Add drugs, medications, and fluids to intravenous lines using a syringe, provided that a supervising licensed dentist is present at the patient’s chairside, limited to determining patency of intravenous line, selection of injection port, syringe insertion into injection port, occlusion of intravenous line and blood aspiration, line release, and injection of drugs for appropriate time interval. The exception to this duty is that the initial dose of a drug or medication shall be administered by the supervising licensed dentist.

(5) Removal of intravenous lines.

(6) Any additional duties that the board may prescribe by regulation.

(7) The duties listed in paragraphs (2) to (5), inclusive, may not be performed in any setting other than a dental office or dental clinic.

(b) This section shall become operative on January 1, 2022.

SEC. 16. Section 2827 of the Business and Professions Code is amended to read:

2827. The utilization of a nurse anesthetist to provide anesthesia services in an acute care facility shall be approved by the acute care facility administration and the appropriate committee, and at the discretion of the physician, dentist or podiatrist. If a general anesthetic agent is administered in a dental office, the dentist shall hold a permit authorized by Article 2.7 (commencing with Section 1646) of Chapter 4 or, commencing January 1, 2022, Article 2.75 (commencing with Section 1646) of Chapter 4.

SEC. 17. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.



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

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Appendices

Appendix 1 – Texas Administrative Code

Appendix 2 – De-identified Data Methodology

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

§110.1 Definitions
§110.2 Sedation/Anesthesia Permit
§110.3 Nitrous Oxide/Oxygen Inhalation Sedation
§110.4 Minimal Sedation
§110.5 Moderate Sedation
§110.6 Deep Sedation or General Anesthesia
§110.7 Portability
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§110.9 Anesthesia Permit Renewal
§110.10 Use of General Anesthetic Agents

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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

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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

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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

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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

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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 caregiver.

(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

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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

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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

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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

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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 remifentanyl, alfentanil, and sufentanyl;
- (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	○ Over sedated
○ Sedation	○ Over sedation
○ Anesthesia	○ Enteral
○ N2O	○ Parenteral
○ IV	○ Intravenous
○ Halcion	○ Anaphylaxis
○ Overdose	○ Allergic
○ Sedate	○ Allergy
○ Sedated	○ 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