

(17) Average number of days to investigate a complaint from complaint received to investigation completed, for all complaints received; and

(18) Average number of days to resolve a complaint from complaint received to final order issued, for all complaints received.

(c) In addition, the agency shall publish on its website aggregate data related to the preceding fiscal year that addresses adverse outcomes and complaints involving anesthesia. This aggregate data shall include, at a minimum, the following data points related to the preceding fiscal year:

(1) Number of jurisdictional, filed complaints involving mortality and morbidity. Morbidity is defined as life-threatening complications following a dental procedure or treatment;

(2) Total number of jurisdictional complaints against dentists related to the standard of care in anesthesia, by level of sedation/anesthesia permit held by the dentist, that were filed by the Board in the preceding fiscal year; and

(3) For all anesthesia-related jurisdictional, filed complaints identified in paragraph (2) of this subsection, the level of sedation/anesthesia permit held by the dentist, the anesthesia-related complication identified in the Board's investigation (if any), and the resolution of each complaint:

- (A) Nonjurisdictional;
- (B) Jurisdictional, Not Filed;
- (C) Dismissed by Agency;
- (D) Dismissed by Board Vote;
- (E) Closed by Administrative Citation;
- (F) Closed by Remedial Plan;
- (G) Warning;
- (H) Reprimand;
- (I) Probation;
- (J) Suspension; or
- (K) Revocation.

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

Filed with the Office of the Secretary of State on December 5, 2016.

TRD-201606157

Kelly Parker

Executive Director

State Board of Dental Examiners

Earliest possible date of adoption: January 15, 2017

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



CHAPTER 110. SEDATION AND ANESTHESIA

22 TAC §§110.1 - 110.6, 110.9, 110.11

The State Board of Dental Examiners (Board) proposes amended rules §110.1, concerning definitions; §110.2, concerning sedation/anesthesia permits; §110.3, concerning nitrous

sedation; §110.4, concerning minimal sedation; §110.5, concerning moderate sedation; §110.6, concerning deep sedation; §110.9, concerning permit renewal; and new rule §110.11, concerning pediatric patients. The proposed rules establish new guidelines and permits for providing sedation and anesthesia.

Kelly Parker, Executive Director, has determined that for the first five-year period the proposed rules are in effect, there will not be any fiscal implications for state or local government as a result of enforcing or administering the amendments to the rule.

Ms. Parker has also determined that for the first five-year period the proposed rules are in effect, the public benefit anticipated as a result of administering these rules will be to ensure licensees are qualified and competent to sedate and anesthetize patients. Ms. Parker has determined that for the first five-year period the proposed rules are in effect, costs to persons or small businesses will be minimal. There is no foreseeable impact on employment in any regional area where the rules are enforced or administered.

Comments on the proposed rules may be submitted to Tyler Vance, General Counsel, 333 Guadalupe, Suite 3-800, Austin, Texas 78732, Fax (512) 475-0977, rulecomments@tsbde.texas.gov no later than January 31, 2017.

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

No statutes are affected by these proposal.

§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) Anxiolytic--a dangerous drug or controlled substance used to provide sedation and/or treat episodes of anxiety.

(3) [(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.

(4) [(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.

(5) [(4)] Child/children--a patient under the age of thirteen (13) at the time of a dental treatment or procedure. [twelve (12) years of age or younger.]

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

(7) [(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.

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

(9) [(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).

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

(11) [(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.

(12) [(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.

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

(14) [(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).

(15) [(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.

(16) [(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.

(17) [(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 under the age of thirteen (13) [aged twelve (12) or younger] should be avoided due to the risk of unobserved respiratory obstruction during the transport by untrained individuals.

(18) [(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.

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

(20) [(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).

(21) Pediatric patient--a patient who is under the age of 13 at the time of a dental treatment or procedure.

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

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

(24) [(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.]

(25) [(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.

(26) [(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.

§110.2. Sedation/General Anesthesia Permit.

(a) A dentist licensed under Chapter 101 of this title shall obtain a sedation/general [an] anesthesia permit for the following

sedation/general 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 sedation/general anesthesia 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) A dentist applying for a sedation/general anesthesia permit must meet the requirements of the highest permit level sought and all permit levels below the highest permit level sought.

(4) ~~[(3)]~~ Prior to issuance of a sedation/general 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.

(5) ~~[(4)]~~ An applicant for a sedation/general 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 shall not be approved.

§110.3. Nitrous Oxide/Oxygen Inhalation Sedation.

(a) Initial Application for Nitrous Oxide/Oxygen Inhalation/Sedation. ~~[Education and Professional Requirements.]~~ A dentist applying for a nitrous oxide/oxygen inhalation sedation permit shall demonstrate the following: ~~[meet one of the following educational/professional criteria:]~~

(1) current certification in Basic Life Support (BLS) for Healthcare Providers; and

(2) ~~[(4)]~~ satisfactory completion of one of the following education programs:

(A) an American Dental Association (ADA) Commission on Dental Accreditation (CODA) approved or recognized pre-doctoral dental or postdoctoral dental training program that affords comprehensive training administering and managing nitrous oxide/oxygen inhalation sedation, commensurate with the ADA's Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students; or

(B) 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 of at least four hours of in-person clinical experience in the administration and management of nitrous oxide, during which competency in inhalation sedation technique is achieved. Acceptable courses include those obtained from academic programs of instruction recognized by the 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). ~~[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) Maintenance of Permit. A dentist must comply with the requirements of rule 110.9 to qualify for annual renewal of a nitrous oxide/oxygen inhalation sedation permit.

(c) Administration of Nitrous Oxide/Oxygen Inhalation Sedation to Pediatric Patients. A dentist shall comply with all requirements regarding the treatment of pediatric patients, including those described in rule 110.11. Additionally, 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) Delegation and Supervision Requirements. A dentist performing nitrous oxide/oxygen inhalation sedation must maintain the minimum standard of care, including, but not limited to the requirements outlined in (e) below, and in addition, shall:

(1) 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;

(2) 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

(3) not supervise a Certified Registered Nurse Anesthetist (CRNA) any level of sedation unless the dentist holds a permit issued by the board for the level of sedation to be administered during the dental procedure being performed.

(e) Standard of Care and Clinical Requirements. A dentist must maintain the minimum standard of care in the administration of sedation/anesthesia in accordance with rule 108.7, including but not limited to the following requirements:

(1) Administration of Nitrous Oxide Following Anxiolysis or Analgesia. A dentist, who does not hold a Level 1 Minimal Sedation permit or higher, shall not administer nitrous oxide to a patient if the patient was treated with anxiolysis or analgesia administered by the dentist within the twelve hours prior to the dental treatment at which nitrous oxide will be administered.

(2) 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 shall consist of a review of their current medical history and medication use. However, patients with significant medical considerations (ASA III, IV) require review of their current medical history and medication use, as well as documented verbal or written consultation with the patients' primary care physician or consulting medical specialist.

(3) 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 rules 108.7 and 108.8.

(4) 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.

(5) 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.

(6) 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.

(E) The dentist's record of the patient's treatment shall include all records created by or for the sedation provider.

(7) 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 operator chair as needed.

(B) Patients who have unusual reactions to nitrous oxide/oxygen inhalation sedation should be assisted and monitored either in an operator 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.

(8) 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.

{(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 pro-

visions in subsequent sections address dentists and are not intended to address the scope of practice of persons licensed by any other agency.]

[(e) 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 operator chair as needed.]

[(B) Patients who have unusual reactions to nitrous oxide/oxygen inhalation sedation should be assisted and monitored either in an operator 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:]

[(f) [(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.

§110.4. Minimal Sedation - Level 1.

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

(1) current certification in Basic Life Support (BLS) for Healthcare Providers; and

(2) satisfactory completion of one of the following education programs:

(A) an advanced education program accredited by the American Dental Association (ADA) Commission on Dental Accreditation (CODA) that affords comprehensive training in administering and managing minimal sedation, commensurate with the ADA's Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students; or

(B) a board-approved education program of at least sixteen (16) hours of didactic training and instruction in which competency in enteral and/or combined inhalation-enteral minimal sedation technique is demonstrated. A board-approved education program shall include, at a minimum, the following components: training in phar-

macology; pre-procedure evaluation, patient selection, anatomy, and ASA classification; anesthesia technique and monitoring, equipment, and emergency preparedness, including running scenarios and management of complications; and managing special needs patients.

{(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) Maintenance of Permit. A dentist must comply with the requirements of rule 110.9 to qualify for annual renewal of a Level 1 permit.

(c) Administration of Level 1 Sedation/Anesthesia to Pediatric Patients. A dentist shall comply with all requirements regarding the treatment of pediatric patients, including those described in rule 110.11. Additionally, 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) Delegation and Supervision Requirements. A dentist must maintain the minimum standard of care, including, but not limited to the requirements outlined in (e) below, and in addition, shall:

(1) 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;

(2) 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

(3) not supervise a Certified Registered Nurse Anesthetist (CRNA) performing any level of sedation unless the dentist holds a permit issued by the board for the level of sedation to be administered during the dental procedure being performed.

(e) Standard of Care and Clinical Requirements. A dentist must maintain the minimum standard of care in the administration of sedation/anesthesia in accordance with rule 108.7, including, but not limited to the following requirements:

(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 patients (ASA I, II), this shall consist of a review of the patients' current medical history and medication use. Patients with significant medical considerations (ASA III, IV) require review of the patients' current medical history and medication use, as well as documented verbal or written consultation with the patients' 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 rules 108.7 and 108.8.

(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 operator 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 rules 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.

(D) The dentist's record of the patient's treatment shall include all records created by or for the sedation provider.

(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.

[(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.]

[(e) 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.}

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

§110.5. *Moderate Sedation - Levels 2 and 3.*

(a) Initial Application Requirements for Level 2 Moderate Sedation (enteral). A dentist applying for a Level 2 Moderate Sedation Permit shall demonstrate the following: [Education and Professional Requirements.}

(1) current certification in Basic Life Support (BLS) for Healthcare Providers;

(2) current certification in Advanced Cardiac Life Support (ACLS); and

(3) satisfactory completion of one of the following education programs:

(A) an advanced education program accredited by the American Dental Association (ADA) Commission on Dental Accreditation (CODA) that affords comprehensive and appropriate training in administering and managing enteral moderate sedation, commensurate with the ADA's Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students; or

(B) completion of a board-approved education program that includes a minimum of sixty (60) hours of didactic training and instruction, and satisfactory management of at least twenty (20) case experiences in moderate sedation. These twenty (20) case experiences must include at least ten 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. A board-approved education program shall include, at a minimum, the following components:

(i) Eight hours pharmacology;

(ii) 12 hours pre-procedure evaluation, patient selection, anatomy, and ASA classification;

(iii) Four hours anesthesia technique, monitoring, and equipment;

(iv) 12 hours inter-operative management and recognition of emergencies and complications;

(v) Six hours emergency preparedness, including running scenarios and management of complications; and

(vi) Four hours management of geriatric patients.

{(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 neces-

sary 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) Initial Application Requirements for Level 3 Moderate Sedation (parenteral). A dentist applying for a Level 3 Moderate Sedation permit shall demonstrate the following:

(1) current certification in Basic Life Support (BLS) for Healthcare Providers;

(2) current certification in Advanced Cardiac Life Support (ACLS); and

(3) satisfactory completion of one of the following education programs:

(A) an advanced education program accredited by the ADA CODA that affords comprehensive and appropriate training in administering and managing parenteral moderate sedation, commensurate with the ADA's Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students; or

(B) an internship or residency that included intravenous moderate sedation training equivalent to that defined in this subsection; or

(C) a board-approved education program that 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. A board-approved education program shall include, at a minimum, the following components:

(i) Eight hours pharmacology;

(ii) 12 hours pre-procedure evaluation, patient selection, anatomy, and ASA classification;

(iii) Four hours anesthesia technique, monitoring, and equipment;

(iv) 12 hours inter-operative management and recognition of emergencies and complications;

(v) Six hours emergency preparedness, including running scenarios and management of complications; and

(vi) Four hours management of geriatric patients.

(c) Maintenance of Permit. A dentist must comply with the requirements of rule 110.9 to qualify for annual renewal of a Level 2 or Level 3 sedation/anesthesia permit.

(d) Administration of Level 2 or Level 3 Sedation/Anesthesia to Pediatric Patients. A dentist shall comply with all requirements regarding the treatment of pediatric patients, including those described in rule 110.11. Additionally 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.

(e) Delegation and Supervision Requirements. A dentist must maintain the minimum standard of care, including, but not limited to the requirements outlined in (f) below, and in addition shall:

(1) 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;

(2) 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

(3) not supervise a Certified Registered Nurse Anesthetist (CRNA) performing any level of sedation unless the dentist holds a

permit issued by the board for the level of sedation to be administered during the dental procedure being performed.

(f) Standard of Care and Clinical Requirements. A dentist must maintain the minimum standard of care in the administration of sedation/anesthesia in accordance with rule 108.7, including but not limited to the following 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 shall consist of at least a review of the patient's current medical history and medication use. Patients with significant medical considerations (ASA III, IV) require review of their current medical history and medication use, as well as documented verbal or written consultation with the patients' 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 rules 108.7 and 108.8 of this title.

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

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

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

(3) Personnel and Equipment Requirements.

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

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

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

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

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

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

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

(4) Monitoring. The dentist administering moderate sedation must remain in the operator 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 dis-

charged 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.

(D) The dentist's record of the patient's treatment shall include all records created by or for the sedation provider.

(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 must be available when 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.

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

[(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.]

[(e) Clinical Requirements.]

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

[(2) Pre-Procedure Preparation and Informed Consent.]

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

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

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

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

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

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

[(3) Personnel and Equipment Requirements.]

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

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

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

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

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

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

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

[(4) Monitoring. The dentist administering moderate sedation must remain in the operator 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.}

§110.6. Deep Sedation or General Anesthesia - Level 4.

(a) Initial Application Requirements for Level 4 Deep Sedation or General Anesthesia Permit. A Dentist applying for a Level 4

Deep Sedation or General Anesthesia permit shall demonstrate the following: [Education and Professional Requirements.]

(1) current certification in Basic Life Support (BLS) for Healthcare Providers;

(2) current certification in Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS) course; and

(3) 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 in administering and managing deep sedation or general anesthesia.

{(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) Maintenance of Permit. A dentist must comply with the requirements of rule 110.9 to qualify for annual renewal of a Level 4 sedation/general anesthesia permit.

(c) Administration of Level 4 Sedation/anesthesia to Pediatric Patients. A dentist shall comply with all requirements regarding the treatment of pediatric patients, including those described in rule 110.11. Additionally 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) Delegation and Supervision Requirements. A dentist must maintain the minimum standard of care, including, but not limited to the requirements outlined in (e) below, and in addition shall:

(1) 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;

(2) 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

(3) not supervise a Certified Registered Nurse Anesthetist (CRNA) performing any level of sedation unless the dentist holds a permit issued by the board for the level of sedation to be administered during the dental procedure being performed.

(e) Standard of Care and Clinical Requirements. A dentist must maintain the minimum standard of care in the administration of sedation/anesthesia in accordance with rule 108.7, including but not limited to the following 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. Patients with significant medical considerations (ASA III, IV) require review of their current medical history, medication use, and NPO status, as well as documented verbal or written consultation with the patients' 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 Special Situations 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

(ii) two additional individuals who hold current certification 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 operator 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 continually 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.

(D) The dentist's record of the patient's treatment shall include all records created by or for the sedation provider.

(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 and 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.

(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.

[(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.]

[(e) 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 operator 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.]

§110.9. Sedation/General Anesthesia Permit Renewal.

(a) The Board shall renew a sedation/general anesthesia [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 consider disciplinary history in Texas and in other jurisdictions in its review of a sedation/general anesthesia permit renewal application. The Board shall not renew a sedation/general anesthesia [an anesthesia/sedation] permit if, after notice and opportunity for hearing, the Board finds the permit holder has provided, or is likely to provide, sedation/general anesthesia [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) Emergency Management Training. To renew a sedation/general anesthesia permit, a dentist shall demonstrate maintenance of competency in emergency management. Specifically, a dentist must provide proof of the emergency management certification required of the dentist's highest sedation/general anesthesia permit level, as follows:

(1) Nitrous Oxide/Oxygen Inhalation Sedation and Level 1 Minimal Sedation - current certification in Basic Life Support (BLS).

(2) Levels 2 and 3: Moderate Sedation - current certification in BLS and current certification in Advanced Cardiac Life Support (ACLS). A dentist who obtained pediatric privileges by meeting the requirements of rule 110.11(b)(1), may meet this requirement by maintaining current certification in BLS and current certification in Pediatric Advanced Life Support (PALS).

(3) Level 4: Deep Sedation/General Anesthesia - current certification in BLS and current certification in ACLS. A dentist who obtained pediatric privileges by meeting the requirements of rule 110.11(b)(1), may meet this requirement by maintaining current certification in BLS and current certification in Pediatric Advanced Life Support (PALS).

(d) Continuing Education. In addition to the continuing education required for renewal of dental licensure, a dentist seeking to renew a minimal sedation, moderate sedation, or deep sedation/general anesthesia permit must submit proof of completion of additional continuing education to maintain a sedation/anesthesia permit. A dentist shall, at a minimum, complete the following hours of continuing education every two years on the administration of or medical emergencies associated with the permitted level of sedation:

(1) Level 1: Minimal Sedation - twelve (12) hours, including eight hours of sedation/general anesthesia emergency preparedness training

(2) Levels 2 and 3: Moderate Sedation - twelve (12) hours, including eight hours of sedation/general anesthesia emergency preparedness training

(3) Level 4: Deep Sedation/General Anesthesia - sixteen (16) hours, including eight hours of sedation/general anesthesia emergency preparedness training.

(e) The emergency management training and continuing education requirements required by this rule shall be in addition to any additional continuing education required to maintain dental licensure. ACLS, BLS, and Pediatric Advanced Life Support (PALS) courses may not be used to fulfill continuing education required for renewal of dental licensure or renewal of a sedation/anesthesia permit under this section.

(f) A licensee's emergency management and continuing education is subject to audit in Board investigation and as described in rule 104.5.

(g) Continuing education courses must meet the provider endorsement requirements of rule 104.2.

~~[(e) Continuing Education.]~~

~~[(1) In conjunction with the annual renewal of a dental license, a dentist seeking to renew a minimal sedation, moderate seda-~~

~~tion, 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.]~~

§110.11. Sedation/General Anesthesia of Pediatric Patients.

(a) Pediatric patients include all patients under the age of thirteen (13) at the time of a dental treatment or procedure.

(b) Initial Requirement for Pediatric Sedation/General Anesthesia Privileges. A dentist may obtain pediatric privileges on a Level 1, Level 2, Level 3, or Level 4 sedation/general anesthesia permit by demonstrating compliance with one of the following requirements at the time the dentist renews or seeks a sedation/general anesthesia permit:

(1) completion of an advanced education program accredited by the Commission on Dental Accreditation that provided didactic and clinical education in pediatric sedation/general anesthesia;

(2) successful administration of sedation/general anesthesia to at least 20 (twenty) pediatric patients, in the six months preceding the date of initial application for a sedation/general anesthesia permit with pediatric privileges or the date of renewal application for a sedation/general anesthesia permit with initial application for pediatric privileges; or

(3) completion of an in-person board-approved education program of at least 24 (twenty-four) hours of training in pediatric sedation/general anesthesia. The board-approved education program shall include, at a minimum, the following 21 (twenty-one) hours of training:

(A) A minimum of three hours of training in pharmacology;

(B) A minimum of three hours of training in pre-procedure evaluation, patient selection, anatomy, and ASA classification;

(C) A minimum of six hours of training in sedation/general anesthesia technique, monitoring, and equipment;

(D) A minimum of six hours of training in emergency preparedness, including running scenarios and management of complications; and

(E) A minimum of three hours of training in treating special needs pediatric patients.

(c) For the time period from September 1, 2017, through a dentist's next sedation/general anesthesia permit renewal occurring prior to September 1, 2018, a dentist may sedate pediatric patients pursuant to the dentist's underlying sedation/general anesthesia permit without demonstrating to the agency compliance with (b) above.

(d) If a dentist does not demonstrate compliance with (b) above at the time of the sedation/general anesthesia permit renewal occurring between September 1, 2017, and August 31, 2018, the dentist does not hold pediatric sedation privileges and may no longer sedate pediatric patients, as of the date of the dentist's sedation/general anesthesia permit renewal.

(e) A dentist may seek pediatric sedation privileges at any time by completing an application and demonstrating compliance with (b) above and any other requirements.

(f) Continuing Education Requirements for Pediatric Sedation/General Anesthesia Privileges. In addition to continuing education required by other rules, a dentist who administers Level 1, 2, 3, or 4 sedation/general anesthesia to a pediatric patient must complete a minimum of eight hours of continuing education in pediatric sedation/general anesthesia every two years. This continuing education is in addition to continuing education required for license renewal, renewal of sedation/anesthesia permits, or any other continuing education requirement. BLS, ACLS, or PALS do not satisfy the continuing education requirement for renewal of sedation/general anesthesia permits under this section. A dentist must submit proof of compliance at the time of permit renewal.

(g) The initial training requirements in subsection (b) and the continuing education requirements in subsection (f) are subject to audit by the agency.

(h) Emergency Preparedness. In addition to the requirements of emergency preparedness in other sections of these rules, a dentist administering sedation/general anesthesia to a pediatric patient must be prepared to rescue a child from a deeper level of sedation than intended, and comply with the following requirements:

(1) A dentist administering sedation to a pediatric patient must maintain current certification in Pediatric Advanced Life Support (PALS). A dentist delegating the administration of sedation to a pediatric patient must maintain current certification in PALS or Advanced Cardiac Life Support (ACLS). A dentist must submit proof of compliance at the time of permit renewal.

(2) A dentist administering sedation to a pediatric patient or delegating the administration of sedation to a pediatric patient must maintain a protocol for immediate access to back-up emergency services, including, for nonhospital facilities a protocol for the immediate activation of the EMS system for life-threatening complications. The practitioners must be prepared to provide initial rescue for life-threatening complications.

(3) A dentist administering sedation to a pediatric patient or delegating the administration of sedation to a pediatric patient must ensure that an emergency cart or kit is immediately accessible and contains the necessary age- and size-appropriate equipment and emergency drugs to resuscitate a non-breathing and unconscious child. The contents of the kit must allow for the provision of continuous life support while the pediatric patient is being transported to a medical/dental facility or to another area within the facility. All equipment and drugs must be checked and maintained on a scheduled basis.

(A) An emergency cart or kit accompanying a pediatric sedation at Level 1 or 2 must include, at a minimum, the following components: oral and nasal airways, bag-valve-mask device, laryngeal mask airways or other supraglottic devices, face masks, blood pressure cuffs; and

(B) An emergency cart or kit accompanying a pediatric sedation at Level 3 or 4 must include, at a minimum, the following components: oral and nasal airways, bag-valve-mask device, laryngeal mask airways or other supraglottic devices, laryngoscope blades,

tracheal tubes, face masks, blood pressure cuffs, and intravenous catheters.

(i) Pediatric Standard of Care and Monitoring.

(1) Nitrous oxide shall not be administered to a pediatric patient at a concentration of greater than 50% unless the person administering the nitrous oxide holds a Level 2 or higher sedation/general anesthesia permit and meets all other requirements of this rule.

(2) Monitoring of a pediatric patient undergoing minimal sedation must include the use of pulse oximetry and precordial stethoscope.

(3) Monitoring of a pediatric patient undergoing moderate sedation must include the use of pulse oximetry, electrocardiography, and either capnography or a precordial/pretracheal stethoscope.

(4) Monitoring of a pediatric patient undergoing deep sedation/general anesthesia must include the use of pulse oximetry, electrocardiography, capnography and a precordial/pretracheal stethoscope.

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

Filed with the Office of the Secretary of State on December 5, 2016.

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Kelly Parker

Executive Director

State Board of Dental Examiners

Earliest possible date of adoption: January 15, 2017

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



PART 21. TEXAS STATE BOARD OF EXAMINERS OF PSYCHOLOGISTS

CHAPTER 469. COMPLAINTS AND ENFORCEMENT

22 TAC §469.13

The Texas State Board of Examiners of Psychologists proposed a repeal to §469.13, Non-Compliance with Professional Development Requirements. The proposed repeal reflects a shift in policy away from treating the failure to report compliance with the Board's professional development requirements as a rule violation that should result in discipline. The Board's intent behind this proposed change, together with the proposed change to Board rule 471.1, is to treat compliance with the professional development requirements as a prerequisite for renewing a license. This proposed change is also intended to ease the burden on enforcement staff by eliminating the need to open a CE complaint every time a licensee fails to indicate compliance with Board rule 461.11 when renewing his or her license.

Darrel D. Spinks, Executive Director, has determined that for the first five-year period the proposed repeal will be in effect, there will be no fiscal implications for state or local governments as a result of enforcing or administering the rule.

Mr. Spinks has also determined that for each year of the first five years the rule is in effect, the public benefit anticipated as a result of enforcing the rule will be to help the Board protect the