The American Society of Dentist Anesthesiologists, American Association of Oral & Maxillofacial Surgeons, & American Academy of Periodontology Model State Sedation/General Anesthesia Rules

This document is a regulatory and rules template to be used as a framework for legislators and regulatory agencies to develop fair and safe laws to provide oversight to sedation and general anesthesia being provided in the dental anesthesia facility.

This document represents a collaboration amongst multiple organizations with different and sometimes conflicting guidelines and/or parameters of care. While portions of this legislative template may differ from an individual organization's guidelines and/or parameters of care, it is intended to improve the margin of safety for sedation and general anesthesia in the dental anesthesia facility. Support of this document by an individual professional organization should not be interpreted as endorsement of those points which conflict with that organization's own guidelines and/or parameters of care.

SECTION 1. Definitions

- (A) "ACLS" means an Advanced Cardiac Life Support course approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.
- (B) "Analgesia" means the diminution or elimination of pain.
- (C) "Auxiliary Staff" means unlicensed staff who are not state certified/licensed to independently evaluate patient physical status and cannot legally provide emergency duties beyond Basic Life Support for Healthcare Providers. Auxiliary staff includes: dental assistants, registered/certified dental assistants, dental anesthesia/sedation assistants, medical assistants and other non-Independently Licensed Providers.
- (D) "BLS" means a Basic Life Support course approved by the American Heart Association (AHA) or an identical course that conforms to the current AHA Guidelines.
- (E) "Board" means the [INSERT STATE] Board of Dentistry.
- (F) "CMS" means The Center for Medicare and Medicaid Services.
- (G) "Continual" means repeated regularly and frequently in a steady succession.
- (H) "Continuous" means prolonged without any interruption at any time.
- (I) "CRNA" means a certified registered nurse anesthetist with a valid, unencumbered nursing license who has completed an accredited nurse anesthesia program as provided in [INSERT APPROPRIATE NURSING PRACTICE ACT CITATION].
- (J) "Deep sedation" means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.
- (K) "Dental Anesthesia Facility" means either a dental office/clinic or any ambulatory surgical facility affiliated with a dental practice where moderate sedation, deep sedation or general anesthesia may be provided.
- (L) "Direct Supervision" means that level of supervision where the dentist directs an auxiliary or independently licensed provider to perform a procedure while the dentist must be physically present in the dental facility and immediately available if needed.
- (M) "General Anesthesia" means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or druginduced depression of neuromuscular function. Cardiovascular function may be impaired.
- (N) "Hospital Facility" means an accredited hospital or accredited ambulatory surgical facility not affiliated with a dental practice.
- (O) "Immediately Available" means on-site in the dental anesthesia facility and available for immediate use.

- (P) "Independently Licensed Provider" means a licensed/certified dental or medical professional who may independently evaluate patient physical status and provide emergency care beyond Basic Life Support for Health Care Providers in accordance with state law (e.g., dentist, physician, resident dentist or physician on clinical rotation, registered nurse, advanced practice nurse, paramedic or emergency medical technician).
- (Q) "Local Anesthesia" means the elimination of sensations, especially pain, in one part of the body by the regional application or injection of a drug.
- (R) "May" or "Should" indicates freedom or liberty to follow a reasonable alternative.
- (S) "Minimal Sedation" means a drug-induced state during which patients respond normally to tactile simulation and verbal commands. Although cognitive function and physical coordination may be mildly impaired, airway reflexes and ventilatory and cardiovascular functions are unaffected.
- (T) "Moderate Sedation" (previously Conscious Sedation) means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway (e.g., head tilt and/or jaw thrust), and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.
- (U) "MRD" or "Maximum Recommended Dose" means the highest amount of drug, approved for the age of the patient to be sedated, as stipulated by the manufacturer that can be given safely for home, unmonitored use and utilized in accordance with the drug manufacturer's guidelines as set forth in US Food and Drug Administration (FDA) approved labeling.
- (V) "Must" or "Shall" indicates an imperative need or duty or both; an essential or indispensable item; mandatory.
- (W) "Nitrous Oxide-Oxygen Inhalation Sedation" means the inhalational use of dental nasal hood nitrous oxide with oxygen for minimal sedation and/or analgesia without other sedatives or analgesics administered, other than local anesthetics.
- (X) "PALS" means a Pediatric Advanced Life Support course approved by the American Heart Association (AHA) or an identical content course that conforms to the current AHA Guidelines.
- (Y) "Parenteral Sedation" means the intravenous, intramuscular, intranasal, subcutaneous, sublingual, submucosal, transdermal or rectal administration of pharmacological agents with the intent to obtain a depressed level of consciousness.
- (Z) "Pediatric Endorsement" means an added qualification to either a Moderate Sedation or Deep Sedation/General Anesthesia Permit allowing the permit holder to utilize sedation or general anesthesia, as applicable, for patients eight (8) years of age or under. Additional documentation of appropriate training and/or competency is required.
- (AA) "Time-oriented anesthesia record" means documentation, at appropriate time intervals, of all drugs, doses and monitored physiologic data obtained during sedation or general anesthesia.

SECTION 2. General Guidelines for Use of Sedation and General Anesthesia in a Dental Anesthesia Facility

- (A) When sedation or general anesthesia is administered in a dental anesthesia facility, the following guidelines apply:
 - 1. For any procedure that will utilize moderate sedation or deep sedation/general anesthesia for patients of any age, a licensed dentist acting as the sedation/general anesthesia provider must hold the appropriate Moderate Sedation or Deep Sedation/General Anesthesia Permit, and when treating patients eight (8) years and under, a Pediatric Endorsement.
 - When a dentist is only providing the dental, oral or maxillofacial surgery procedure, such
 dentist does not require an additional permit to work in conjunction with a licensed dentist who
 holds a Deep Sedation/General Anesthesia Permit, and Pediatric Endorsement as applicable,
 issued by the Board.
 - 3. A licensed dentist must hold a current Permit to Utilize a Non-Dentist Anesthesia Provider issued by the Dental Board in order to work in conjunction with a physician with an unencumbered [NAME OF STATE] license who has successfully completed an accredited medical anesthesiology residency program, to administer any route of moderate sedation, deep sedation or general anesthesia in a dental anesthesia facility.

This does not apply to a dentist holding a Deep Sedation/General Anesthesia Permit for any level of sedation or general anesthesia while following all rules in Section 4 or a dentist holding a Moderate Sedation Permit for moderate sedation while following all rules in Section 3. The physician anesthesiologist must provide the dentist with verification of having treated fifty (50) patients age eight (8) years of age or under with deep sedation/general anesthesia in the last two (2) years, if patients age eight (8) years of age or under are to be treated.

NOTE TO DRAFTER: In a state which requires a delegating order and/or clinical supervision of a CRNA by a dentist, the following Subparagraph 4. should be used:

4. A licensed dentist who does not possess a Deep Sedation/General Anesthesia Permit or a Moderate Sedation Permit may not work in conjunction with a CRNA in a dental anesthesia facility. A CRNA with documentation of at least two (2) years of full-time anesthesia practice or four thousand (4,000) post-graduate clinical hours of general anesthesia provision, may administer sedation or general anesthesia for a dentist holding a Deep Sedation/General Anesthesia Permit while following all rules in Section 4, or for a dentist holding a Moderate Sedation Permit only while following all rules in Section 3, in a dental anesthesia facility. The CRNA must provide the dentist with verification of having treated fifty (50) patients age eight (8) years of age or under with deep sedation/general anesthesia in the last two (2) years, if patients age eight (8) years of age or under are to be treated.

NOTE TO DRAFTER: In a state which does not require a delegating order and/or clinical supervision of a CRNA by a dentist, the following Subparagraph 4. should be used:

4. A licensed dentist must hold a current Permit to Utilize a Non-Dentist Anesthesia Provider issued by the Dental Board in order to work in conjunction with a CRNA, with documentation of at least two (2) years of full-time anesthesia practice or four thousand (4,000) post-graduate clinical hours of general anesthesia provision, to administer any route of moderate sedation, deep sedation or general anesthesia in a dental anesthesia facility.

This permit requirement does not apply to a dentist holding a Deep Sedation/General Anesthesia Permit for any level of sedation or general anesthesia while following all rules in

Section 4 or to a dentist holding a Moderate Sedation Permit for moderate sedation while following all rules in Section 3. The CRNA must provide the dentist with verification of having treated fifty (50) patients age eight (8) years of age or under with deep sedation/general anesthesia in the last two (2) years, if patients age eight (8) years of age or under are to be treated.

- (B) Centers for Disease Control and Prevention (CDC) guidelines for use of parenteral agents and fluid infusion systems in a dental facility must be followed.
- (C) Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners trained in minimal, moderate and deep sedation should be able to diagnose and manage the physiological consequences for patients whose level of sedation becomes deeper than originally intended. The dentist must be skilled in the rescue of patients from at least one level of sedation deeper than that which was intended.
- (D) The permitted dentist must ensure that the dental anesthesia facility where sedation or general anesthesia is administered is adequate for all the procedures to be performed safely and that the size and layout provide for safe management of emergencies including evacuation of patients and staff, if needed.
- (E) All sedation/anesthesia equipment and vital signs equipment should be serviced at manufacturer recommended intervals.
- (F) If a patient is transferred to a separate recovery area following moderate sedation, deep sedation or general anesthesia, the recovery area must be equipped with appropriate monitoring equipment, suction appropriate for the hypopharynx and the ability to deliver positive pressure and supplemental oxygen.
- (G) The permitted dentist, or another qualified moderate sedation or deep sedation/general anesthesia provider as appropriate for the level of sedation/general anesthesia provided, must remain on the premises until adequate recovery is assured for any patient receiving moderate sedation or deep sedation/general anesthesia.
- (H) The permitted dentist must determine if a patient is an appropriate candidate for the intended level of sedation or general anesthesia in a dental anesthesia facility, and if the management of that patient is within their level of training and/or experience. Based on American Society of Anesthesiologists (ASA) Physical Status Classification, the following is appropriate:
 - 1. ASA Physical Status I and II Generally acceptable candidates for minimal sedation, moderate sedation, deep sedation, or general anesthesia.
 - 2. ASA Physical Status III and IV May be candidates for minimal or moderate sedation by experienced providers. Select patients can be candidates for deep sedation or general anesthesia. Comprehensive medical record review by the permitted dentist must be performed. Formal medical consultation with appropriate healthcare providers should be obtained as needed, unless a documented emergency condition exists.
- (I) All Moderate Sedation and Deep Sedation/General Anesthesia Permit holders must:
 - 1. Develop written emergency preparedness policies consisting of the responsibilities of all team members during management of emergencies and policies for patient transport in case of an emergency, which must be reviewed with applicable staff, including the operating dentist if

- he/she is not providing the sedation or general anesthesia, for the first time and at least annually thereafter.
- 2. Develop written guidelines outlining the management of common sedation and/or general anesthesia emergencies specific to the permit holder's equipment and drugs for responding to emergency situations which must be reviewed at least annually with dedicated anesthesia staff member(s) or all applicable staff, including the operating dentist if he/she is not providing the sedation or general anesthesia.
- 3. Common sedation and general anesthesia emergencies must include those associated with impaired ventilation/oxygenation including: upper airway obstruction, laryngospasm, bronchospasm, aspiration of gastric contents, foreign body obstruction (upper and lower airway) and excessive drug administration.
- 4. Emergency preparedness review sessions must be maintained in a log and be available to the Board upon request.
- (J) All Moderate Sedation and Deep Sedation/General Anesthesia Permit holders must maintain current completion of Basic Life Support at the Healthcare Provider Level.
- (K) A licensed dentist may utilize the following without a Moderate Sedation or Deep Sedation/General Anesthesia Permit:
 - 1. Local Anesthesia.
 - 2. Minimal Sedation, as defined below:
 - (a) Nitrous Oxide-Oxygen Inhalation Sedation administered by a nasal hood without other sedative agents for patients of any age. When a dental nitrous oxide-oxygen inhalation sedation unit is being used for any level of sedation or general anesthesia, there must be adequate scavenging, and flow safe and fail-safe devices must be functional, in lieu of an oxygen analyzer.
 - (b) Minimal Sedation for patients nine (9) years of age and older which is limited to the MRD of an oral sedative agent approved for the home, unmonitored setting, administered in a single dose or divided doses, during a single treatment day. Nitrous Oxide-Oxygen Inhalation Sedation may be co-administered as long as the dose used maintains a state of minimal sedation.
 - (c) Minimal Sedation, other than Nitrous Oxide-Oxygen Inhalation Sedation, for patients eight (8) years of age and younger which is limited to a single oral agent that is FDA approved for pediatric use (e.g., antihistamines) at no more than the maximum recommended single dose approved for the home, unmonitored setting administered in the immediate presence of the licensed dentist. Redosing during a single treatment day with further oral medication(s) is prohibited. No other sedatives may be coadministered.
 - (d) A minimum of two (2) people with current completion in BLS for the Healthcare Provider must be present during minimal sedation.

SECTION 3. Moderate Sedation

- (A) Educational requirements for moderate sedation:
 - 1. A dentist must meet the following conditions for obtaining a Moderate Sedation Permit for treating patients nine (9) years of age or older:
 - (a) Documentation of completion of either an accredited pre-doctoral program, accredited advanced dental education residency program or Board-approved non-accredited continuing education program provided that the program provides comprehensive training in administering and managing moderate sedation including, at a minimum:
 - (i) Sixty (60) hours of didactic, simulation and interactive instruction covering the following areas for adult, pediatric and medically compromised patients:
 - a. Review of human physiology, medical assessment and physical evaluation;
 - b. Behavior management as an alternative to pharmacologic sedation;
 - c. Pharmacology of sedative, opioid and adjunctive medications commonly used for moderate sedation;
 - d. Techniques for the safe administration of moderate sedation;
 - e. Monitoring and the use of monitoring equipment;
 - f. Management of sedation and medical emergencies;
 - Recognizing and rescuing patients from a deeper level of sedation than intended, including managing the airway, intravascular access (intravenous or intraosseous), and use of pharmacological reversal medications;
 - h. The importance of, and techniques for, maintaining proper documentation;
 - i. The abuse potential, occupational hazards and other untoward effects of the agents utilized to achieve moderate sedation; and
 - (ii) Hands-on supervised personal administration of moderate sedation for at least twenty (20) dental patients receiving moderate sedation; and
 - (iii) Clinical or simulation training in managing sedation emergencies, use of airway adjuncts and obtaining intravascular access (intravenous or intraosseous), if intravenous sedation is not the route of administration; and
 - (iv) Current completion of ACLS.
 - (b) For those dentists possessing a current Moderate Sedation Permit, such permit will remain active, within the limitations of that permit, until renewal of the permit in accord with the requirements outlined in Section 5(C).
 - 2. Pediatric Endorsement for moderate sedation of patients eight (8) years of age or younger.
 - (a) With the exception of minimal sedation that does not require a permit, a Pediatric Endorsement is required for moderate sedation of patients eight (8) years of age or younger.

- (b) In addition to the educational requirements listed in <u>Section 3(A)1</u>, the following additional requirements must be met for a Pediatric Endorsement:
 - (i) Clinical training including at least twenty (20) cases of moderate sedation for pediatric dental patients eight (8) years of age and younger, fifteen (15) of which must be under six (6) years of age, which must follow the rules set forth in <u>Section</u> 3(A)1 and may be included as part of the twenty (20) patients listed in <u>Section</u> 3(A)1(a)(ii); or
 - (ii) Documentation of personal administration of moderate sedation for dentistry for twenty (20) patients eight (8) years of age or younger during the last two (2) years of clinical practice for dentists who currently possess a [NAME OF STATE] Moderate Sedation Permit. Such documentation is required at permit renewal; and
 - (iii) Completion of PALS training.
- (c) Completion of an accredited US or Canadian pediatric dental residency program within the last two (2) years will qualify the dentist to obtain a Moderate Sedation Permit with Pediatric Endorsement. Current completion of PALS is required.
- 3. A licensed dentist who holds a Deep Sedation/General Anesthesia Permit, with or without Pediatric Endorsement, may administer moderate sedation for patients of any age without any additional permit. If treating patients eight (8) years or younger, current completion of PALS is required.
- (B) Guidelines for administration of moderate sedation.
 - 1. Before administering moderate sedation in a dental facility, a dentist must possess a Moderate Sedation Permit issued by the Board, with the following exceptions/restrictions:
 - (a) A licensed dentist who holds a Deep Sedation/General Anesthesia Permit, with or without Pediatric Endorsement, may administer moderate sedation to a patient of any age without possessing a Moderate Sedation Permit.
 - (b) A licensed dentist who holds a Moderate Sedation Permit may administer moderate sedation by any route to patients nine (9) years of age or older. A Pediatric Endorsement is required for moderate sedation of patients eight (8) years of age or younger.
 - 2. When using oral medications to provide moderate sedation for patients eight (8) years of age and under:
 - (a) Redosing during a single treatment day with further oral or non-intravenous parenteral medications is prohibited.
 - (b) All sedation medications must be administered in the immediate presence of the permit holder.
 - (c) For holders of a moderate sedation permit, the maximum dose of oral medication(s) used must follow the drug manufacturer's guidelines as set forth in FDA approved labeling, common hospital protocols or peer-reviewed scientific literature.
 - (d) Pharmacy compounded medications are not to be used for sedation.

- 3. A Moderate Sedation Permit holder must not administer or employ any techniques or agents designed or intended for general anesthesia, including but not limited to, the use of ultra-short acting barbiturates (e.g. methohexital), propofol, ketamine, etomidate, or halogenated inhalation agents (e.g., sevoflurane), or any combination thereof, that would likely render a patient deeply sedated, generally anesthetized or otherwise not meeting the conditions for moderate sedation.
- 4. A licensed dentist who holds a Moderate Sedation Permit must be capable of rescue from unintended deep sedation/general anesthesia regardless of the route of administration. The drugs and/or techniques used should 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. If the patient enters a state of deep sedation or general anesthesia, the dentist must the stop the procedure and/or use reversal agents until the patient recovers to a state of moderate sedation.
- 5. Recognized fasting guidelines for moderate sedation must be followed.
- 6. The Moderate Sedation Permit holder must utilize supplemental oxygen for patients receiving moderate sedation for the duration of the procedure. Oxygen administration may be modified when elevated risk of intraoperative fire is present. The Moderate Sedation Permit holder is responsible for ensuring adequate oxygen supply and backup in treatment and recovery areas.
- 7. Moderate sedation for cases anticipated to be longer than four (4) hours in an office setting should be evaluated on a case-by-case basis.
- 8. The Moderate Sedation Permit holder must continuously monitor the patient from the initiation of sedation until the patient is adequately recovered. The Moderate Sedation Permit holder must not commence with the administration of a subsequent sedation until he/she personally determines that the patient maintains wakefulness, is stable and will meet the criteria for discharge. Direct supervision is appropriate for recovery of awake patients by auxiliary staff following sedation/general anesthesia.

(C) Recordkeeping.

- 1. The Moderate Sedation Permit holder will have the patient, or in the case of a minor or adult not able to legally give consent, the parent or legally responsible adult/agency, undergo a separate process of consent for the sedation procedure and sign a consent form indicating understanding of the risks, benefits and alternatives, and acceptance of, the sedation procedure. This consent can be completed by properly executed witnessed verbal consent when the party able to give legal consent is unable to be physically present.
- 2. A Moderate Sedation Permit holder must complete, at a minimum, the following:
 - (a) A pre-sedation evaluation documenting, at a minimum, a comprehensive medical history review, review of previous medical consultations if indicated, laboratory studies and other testing (e.g., ECG, cardiac echocardiography) as indicated based on the patient's medical condition(s), requested medical consultations as indicated, and anesthetic risk assessment (e.g., ASA Physical Status).

- (b) Documentation on a time-oriented moderate sedation record, at a minimum, the following:
 - (i) A focused pre-sedation physical evaluation including, at a minimum, evaluation of current or recent respiratory disease, vitals signs, room air oxygen saturation, airway, current height and weight, calculation of BMI or BMI% for children where indicated, and appropriate interval fasting period (NPO status).
 - (ii) Intra-operative, and when appropriate, post-operative documentation of the continuous evaluation of cardiac rhythm by electrocardiography, if used, at least every fifteen (15) minutes.
 - (iii) Intra-operative documentation of the continuous evaluation of oxygen saturation, at least every fifteen (15) minutes.
 - (iv) Intra-operative documentation of the continuous evaluation of capnography, at least every fifteen (15) minutes. If capnography is precluded or invalidated by the nature of the patient, procedure, or equipment, a pre-tracheal/pre-cordial stethoscope must be used and respiratory rate documented.
 - (v) Intra-operative documentation of the continual evaluation of blood pressure and the continuous evaluation of heart and/or pulse rate, at least every ten (10) minutes.
 - (vi) Post-operatively, at a minimum, documentation of the continuous evaluation of oxygen saturation and pulse rate, at least every fifteen (15) minutes until discharge. For appropriate patients, blood pressure and electrocardiographic monitoring should also be performed and documented.
 - (vii) A list of all medications given, with dosage, time, and route of administration.
 - (viii) Size and site of intravenous catheter placed and type of intravenous maintenance fluids, when intravenous sedation is used.
 - (ix) Documentation that patients meet discharge criteria, time of discharge and name of escort.
 - (x) The names and credentials of all clinical staff involved in the sedation/general anesthesia procedure.
 - (xi) If patient cooperation does not allow for any of the above to be completed, documentation of the reason(s) must be noted.
- (D) Equipment and medication requirements for moderate sedation.
 - 1. At a minimum, the Moderate Sedation Permit holder will have the following properly operating equipment with back up devices and supplies, appropriate for the age and size of any patient treated, during the provision of moderate sedation:
 - (a) Oxygen in adequate supply and equipment to deliver oxygen with positive pressure ventilation (e.g., bag-valve mask device or other oxygen positive pressure ventilation device) in any location where a patient is treated or recovered.
 - (b) Respiratory Support Equipment:
 - (i) Oropharyngeal and nasopharyngeal airways;

- (ii) Full face mask(s); and
- (iii) Supraglottic airways (e.g., laryngeal mask and/or other airway rescue devices [e.g., King airway]).
- (c) Monitors/Devices (with backup battery source, where applicable):
 - (i) Blood pressure automatic monitoring device and backup blood pressure measuring device (may be manual);
 - (ii) Capnograph;
 - (iii) Defibrillator, manual or automated (AED), including pediatric pads if treating patients eight (8) years of age or younger;
 - (iv) Electrocardiograph, which should be used when treating patients with significant cardiovascular disease:
 - (v) Pretracheal stethoscope;
 - (vi) Pulse oximeter; and
 - (vii) Stethoscope.
- (d) Auxiliary powered lighting.
- (e) Equipment to establish intravascular access with appropriate connectors, tubing and fluids.
- (f) Suction equipment appropriate for the hypopharynx.
- 2. At a minimum, the Moderate Sedation Permit holder will have the following emergency drugs, with appropriate delivery devices, capable of managing sedation and medical emergencies and urgencies:
 - (a) Atropine;
 - (b) Albuterol;
 - (c) Anticonvulsant (e.g., benzodiazepine);
 - (d) Nitroglycerin, sublingual;
 - (e) Epinephrine, multiple;
 - (f) Antihistamine;
 - (g) Agent(s) to treat hypoglycemia;
 - (h) Aspirin, preferably chewable 325 mg;
 - (i) Flumazenil, when benzodiazepines are used; and
 - (j) Naloxone, when opioids are used.

- (E) Personnel requirements for moderate sedation.
 - 1. For patients nine (9) years of age and older during moderate sedation:
 - (a) A minimum of two (2) people must be present at all times during the sedation procedure. They will include the:
 - (i) Moderate Sedation Permit holder who must maintain current completion of ACLS; and
 - (ii) A second person who must maintain current completion in BLS at the Healthcare Provider level with sufficient didactic/clinical training to assist the permit holder in sedation monitoring and management of sedation emergencies.
 - 2. For patients eight (8) years of age and younger during moderate sedation:
 - (a) A minimum of two (2) people must be present during the sedation procedure. They will include:
 - (i) Moderate Sedation Permit holder with Pediatric Endorsement who must maintain current completion of PALS; and
 - (ii) A second person who must maintain current completion in BLS at the Healthcare Provider level and with sufficient didactic/clinical training to assist the permit holder in sedation monitoring and management of pediatric sedation emergencies.
- (F) Continuing education for moderate sedation.
 - 1. To maintain a Moderate Sedation Permit, a dentist must participate in:
 - (a) At least fourteen (14) hours of continuing education every two (2) years, not including BLS, ACLS and/or PALS training, in any of the following areas:
 - (i) Moderate sedation;
 - (ii) Physical evaluation and medicine;
 - (iii) Medical emergencies;
 - (iv) Sedation emergencies or urgencies:
 - (v) Monitoring and use of monitoring equipment;
 - (vi) Pharmacology of drugs used in sedation; or
 - (vii) Infection control related to sedation procedures.
 - (b) At least once every five (5) years, at least four (4) hours of a sedation emergency simulation course must be completed, which may be included in the fourteen (14) hours above: and
 - (c) Maintain current completion of ACLS when treating patients nine (9) years of age or older and/or maintain current completion of PALS when treating patients eight (8) years of age or younger.

- (G) Reports of adverse occurrences.
 - 1. If a death or an adverse sedation incident requiring hospital admission for more than twenty-four (24) hours occurs in a dental facility or accredited surgery center affiliated with a dental practice during the administration of, or recovery from, any level of sedation/general anesthesia, the permit holder and the treating dentist involved must notify the Board of the incident within three (3) business days and submit a complete report of the incident to the Board within thirty (30) days of the occurrence.

SECTION 4. Deep Sedation/General Anesthesia

- (A) Educational requirements for a Deep Sedation/General Anesthesia Permit and Pediatric Endorsement.
 - 1. The dentist must meet the following conditions for obtaining a Deep Sedation/General Anesthesia Permit valid for treating patients nine (9) years of age or older:
 - (a) Successful completion of an accredited US or Canadian residency in oral and maxillofacial surgery; or
 - (b) Successful completion of an accredited US or Canadian residency in dental anesthesiology. For graduates of a dental anesthesiology residency program prior to CODA or Canadian provincial accreditation, the program must have met the educational and duration requirements of the American Dental Association Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry at the Advanced Education Level (Part II), in effect at the time of residency completion; and
 - (c) Documentation of successful completion of ACLS.
 - 2. For a Pediatric Endorsement of a General Anesthesia Permit, the dentist must meet one of the following conditions for treating patients eight (8) years of age or younger:
 - (a) Completion of an accredited dental anesthesiology residency within the last two (2) years with documentation of supervised personal administration of deep sedation/general anesthesia for fifty (50) patients eight (8) years of age or younger during training; or
 - (b) Completion of an accredited oral and maxillofacial surgery residency within the last two (2) years with documentation of supervised personal administration of deep sedation/general anesthesia for fifty (50) patients eight (8) years of age or younger during training; or
 - (c) Documentation of personal administration of deep sedation/general anesthesia for dentistry for fifty (50) patients eight (8) years of age or younger during the last two (2) years of clinical practice for dentists who currently possess a Board-issued Deep Sedation/General Anesthesia Permit. Such documentation is required at the time of first renewal of the general anesthesia permit, or as prescribed by the Board. Prior to the first renewal of the non-provisional Deep Sedation/General Anesthesia Permit, the permit holder may administer deep sedation/general anesthesia to patients of any age.
 - (i) If the permittee lacks a sufficient number of pediatric cases for initial endorsement, the permittee may personally administer dental office-based deep sedation or general anesthesia while not involved in the conduct of the surgical procedure to children eight (8) years of age or younger under the direct supervision of a permit holder who meets the qualifications of Sections 4(A)2(a)-4(A)2(c), which will then be accepted as meeting the case requirement. If within one (1) years of residency completion, cases from residency may also be used to meet the case requirement; and
 - (d) Documentation of current completion of PALS.
- (B) Procedures for administration of deep sedation/general anesthesia.

- 1. Before administering deep sedation or general anesthesia by any means in a dental anesthesia facility, a dentist must possess a Deep Sedation/General Anesthesia Permit issued by the Board, with the following exceptions/restrictions:
 - (a) A Pediatric Endorsement is required for administering deep sedation/general anesthesia for children eight (8) years of age or younger.
 - (b) Recognized fasting guidelines for sedation/general anesthesia must be followed.
 - (c) The Deep Sedation/General Anesthesia Permit holder must utilize supplemental oxygen for patients receiving general anesthesia for the procedure, and if appropriate, in recovery. Oxygen administration may be modified when elevated risk of intraoperative fire is present. The Deep Sedation/General Anesthesia Permit holder is responsible for ensuring adequate oxygen supply and backup in treatment and recovery areas.
 - (d) The Deep Sedation/General Anesthesia Permit holder must position and protect the patient to help avoid injury to the patient, himself/herself, or others during the period of sedation/general anesthesia.
 - (i) Extremities should be secured and/or padded when indicated to avoid peripheral nerve injury.
 - (ii) Appropriate eye protection should be provided for the patient during times of potential vulnerability.
 - (e) During a deep sedation/general anesthesia procedure, the dentist administering sedation/general anesthesia must be physically present in the immediate treatment area during the entire procedure unless following rules governing administration of sedatives by licensed nurses consistent with nursing and Board laws/rules regarding sedation/general anesthesia. [Note to Drafter: Ensure state law allows for this provision prior to adoption.]
 - (f) The Deep Sedation/General Anesthesia Permit holder must continuously monitor the patient from the initiation of sedation/general anesthesia until the patient is able to maintain oxygen saturation of ≥ 95% on room air, or return to baseline oxygen saturation, can independently maintain their own airway (e.g., spontaneously ventilating in the head down/airway obstructed position) and is responsive to light tactile stimulation and/or verbal command. Further:
 - (i) Reflex withdrawal from repeated or painful stimulus is not considered adequate awakening for transfer of monitoring to recovery staff.
 - (ii) When the Deep Sedation/General Anesthesia Permit holder determines that the patient is awake and stable, auxiliary staff trained in recovery may monitor the patient.
 - (iii) When utilized, intravenous access will remain in place until the permit holder is assured that adequate recovery has taken place.
 - (g) Deep sedation or general anesthesia for cases anticipated to be longer than four (4) hours in an office setting should be evaluated on a case-by-case basis.

- (h) The Deep Sedation/General Anesthesia Permit holder must not commence with the administration of a subsequent anesthetic until he/she, or another qualified dental office general anesthesia provider in accordance with <u>Sections 4</u> and <u>6</u> of these rules, personally determines that the previous patient is awake and stable and will meet the criteria for discharge. Direct supervision is appropriate for recovery of awake patients by auxiliary staff following sedation/general anesthesia.
- (i) A licensed dentist who holds a Deep Sedation/General Anesthesia Permit, with or without Pediatric Endorsement, may administer moderate sedation to a patient of any age without possessing a Moderate Sedation Permit.
- (j) Registered nurses or other appropriately licensed staff, may administer intravenous agents, including sedatives such as benzodiazepines, under the direct supervision of the Deep Sedation/General Anesthesia permit holder. With the exception of CRNAs, drugs designed or intended for general anesthesia, including but not limited to, ultrashort acting barbiturates (e.g. methohexital), propofol, ketamine, etomidate, or halogenated inhalation anesthetic agents (e.g., sevoflurane) may only be administered in the immediate presence of the Deep Sedation/General Anesthesia Permit holder and under his/her direct visual supervision and control. [Note to Drafter: Ensure state law allows for this provision prior to adoption.]

(C) Recordkeeping.

- 1. A Deep Sedation/General Anesthesia Permit holder will have the patient or, in the case of a minor or adult deemed not able to provide consent, the parent or legally responsible adult/agency, undergo a separate process of consent for the sedation/general anesthesia procedure and sign a consent form indicating understanding of the risks, benefits and alternatives, and acceptance of, the sedation/general anesthesia procedure. This consent can be completed by a properly executed witnessed verbal consent when the party able to give legal consent is unable to be physically present.
- 2. A Deep Sedation/General Anesthesia Permit holder must complete, at a minimum, the following:
 - (a) A pre-anesthesia evaluation by the permitted dentist documenting, at a minimum, a medical history review, review of previous medical consultations if indicated, laboratory studies and other testing (e.g., ECG, cardiac echocardiography) as indicated based on the patient's medical condition(s), requested medical consultations as indicated, and anesthetic risk assessment (e.g., ASA Physical Status).
 - (b) Documentation on a time-oriented anesthesia record, at a minimum, the following:
 - A focused pre-anesthesia physical evaluation including evaluation of the heart, lungs and airway, vital signs, room air oxygen saturation, current height, weight, calculation of BMI or BMI% for children where indicated, and appropriate interval fasting period (NPO status);
 - (ii) Intraoperative, and when appropriate, post-operative documentation of the continuous evaluation of cardiac rhythm by electrocardiography, at least every fifteen (15) minutes;
 - (iii) Pre-sedation oxygen saturation; intra-operative documentation of the continuous evaluation of oxygen saturation, at least every fifteen (15) minutes;

- (iv) Intraoperative documentation of the continuous evaluation of capnography and respiratory rate, at least every fifteen (15) minutes. If capnography is precluded or invalidated by the nature of the patient, procedure, or equipment, a pretracheal/pre-cordial stethoscope must be used and respiratory rate documented;
- (v) Pre-sedation blood pressure and heart/pulse rate; Intra-operative documentation of the continual evaluation of blood pressure and the continuous evaluation of heart/pulse rate, at least every five (5) minutes;
- (vi) Post-operatively, at a minimum, documentation of the continuous evaluation of oxygen saturation and pulse rate, at least every fifteen (15) minutes until discharge. For appropriate patients, blood pressure and electrocardiographic monitoring should be performed and documented;
- (vii) A list of all medications given, with dosage, time, and route of administration;
- (viii) Size and site of intravenous catheter placed, and type and volume of intravenous maintenance fluids used:
- (ix) Documentation by the anesthesia provider that the patient meets discharge criteria, time of discharge and name of escort;
- (x) The names and credentials of all clinical staff involved in the sedation/general anesthesia procedure; and
- (xi) If patient cooperation does not allow for any of the above to be completed, documentation of the reason(s) must be noted.
- (D) Equipment and medication requirements.
 - At a minimum, the General Anesthesia Permit holder will have the following properly functioning monitors, equipment and supplies with back up devices and supplies, appropriate for the age and size of any patient treated, during the provision of sedation/general anesthesia:
 - (a) Oxygen in adequate supply and equipment to deliver oxygen by positive pressure ventilation (e.g., bag-valve mask device or other oxygen positive pressure ventilation device) in any location where a patient is treated or recovered.
 - (b) Respiratory Support Equipment:
 - (i) Oropharyngeal Airways/Nasopharyngeal Airways:
 - (ii) Endotracheal Tubes with stylettes;
 - (iii) Full Face Masks:
 - (iv) Laryngoscope with variety of blades and backup laryngoscope;
 - (v) Magill Forceps;
 - (vi) Supra-Glottic Airways, (e.g., laryngeal mask and/or other airway rescue devices [e.g., King airway]); and

- (vii) Equipment for performing needle or percutaneous cricothyroidotomy or tracheostomy for emergency oxygenation.
- (c) Monitoring Equipment (with backup battery source, where applicable):
 - (i) Stethoscope;
 - (ii) Defibrillator, Manual or Automated External Defibrillator (AED), including pediatric pads if treating patients eight (8) years of age or younger;
 - (iii) Blood Pressure automatic measuring device and backup blood pressure measuring device (may be manual);
 - (iv) Pretracheal stethoscope;
 - (v) Pulse Oximeter;
 - (vi) Capnograph;
 - (vii) Electrocardiograph; and
 - (viii) Body Temperature Measuring Device, which must be used when triggering agents for malignant hyperthermia are administered.
- (d) Oxygen analyzer with low oxygen concentration alarm when an anesthesia machine is being used, unless it is only capable of delivering oxygen.
- (e) Equipment and supplies to establish a continuous intravenous infusion.
- (f) Suction equipment appropriate for the hypopharynx and/or endotracheal tubes and an effective emergency backup suction device.
- (g) Auxiliary powered lighting.
- 2. Emergency drugs with appropriate delivery devices:
 - (a) Albuterol;
 - (b) Antiarrhythmics, consistent with ACLS/PALS protocols (e.g., amiodarone, adenosine, intravenous lidocaine, magnesium sulfate):
 - (c) Anticonvulsant (e.g., benzodiazepine);
 - (d) Antihistamine;
 - (e) Anti-hypoglycemic (e.g., IV dextrose solution);
 - (f) Antiemetic;
 - (g) Aspirin, preferably chewable 325 mg;
 - (h) Atropine;
 - (i) Beta-adrenergic blocker(s);

- (j) Glucocorticosteroid;
- (k) Dantrolene and sterile water for injection, whenever triggering agents for malignant hyperthermia may be used;
- (I) Ephedrine;
- (m) Epinephrine (multiple);
- (n) Intravenous fluids;
- (o) Neuromuscular blocker appropriate for laryngospasm;
- (p) Nitroglycerin;
- (q) Phenylephrine;
- (r) Pharmacological reversal agents for benzodiazepines and opioids; and
- (s) Vasodilator, intravenous (e.g., hydralazine).
- (E) Personnel requirements.
 - 1. A minimum of three (3) persons must be present at all times during the deep sedation/general anesthesia procedure, including:
 - (a) A Deep Sedation/General Anesthesia Permit holder who must maintain current completion in ACLS, or its equivalent when treating patients nine (9) years of age and older; or
 - (b) A Deep Sedation/General Anesthesia Permit holder with Pediatric Endorsement who must maintain current completion in PALS when treating patients eight (8) years of age and younger; and
 - (c) A second person who can assist the anesthesia provider, if needed, during anesthetic induction, maintenance and emergence/initial recovery following the procedure, and during emergencies. This second person must be one of the following:
 - (i) An operating dentist holding a Deep Sedation/General Anesthesia Permit or a Moderate Sedation Permit; or
 - (ii) An Independently Licensed Provider, whether the operating dentist or another provider, meeting the following requirements:
 - a. Current completion of BLS at the Healthcare Provider level;
 - b. Current completion of ACLS and/or PALS;
 - c. Completion of a minimum of two (2) hours of clinical training every two years in assisting an anesthesia provider in the management of dental office deep sedation/general anesthesia emergencies, including the use of bag-valve-mask ventilation with and without airway adjuncts and assisting in advanced airway management, taught by either a qualified dental office deep sedation/general anesthesia provider, in accordance with <u>Sections 4</u> and <u>6</u> of these rules, or in an anesthesia emergency simulation course;

- d. Completion of four (4) hours of instruction every two (2) years in any area related to sedation/general anesthesia, pre-anesthetic assessment, medicine, pharmacology or medical emergencies via continuing education course(s) approved by the Board in addition to ACLS, PALS and BLS recertification hours, as appropriate. This CE requirement may be applied to the total CE requirement required for dental licensure renewal; and,
- e. Maintenance by the Independently Licensed Provider of a log of each activity identified in Section 4(E)1(c)(ii)c signed by the anesthesia provider who provides that training, on a Board-approved form; or
- (iii) A trained auxiliary dedicated to assisting with sedation/general anesthesia, meeting, at a minimum, the following requirements:
 - a. Thirty-six (36) hours of didactic instruction in the underlying physiology and interpretation of monitoring used for patients under deep sedation/general anesthesia and principles of office-based anesthesia and anesthesia equipment taught by either a qualified dental office deep sedation/general anesthesia provider, in accordance with <u>Sections 4</u> and <u>6</u> of these rules, or in a continuing education course approved by the Board; and
 - b. A minimum of four (4) hours of clinical training in assisting an anesthesia provider in the management of dental office deep sedation/general anesthesia emergencies, including the use of bag-valve-mask ventilation with and without airway adjuncts and assisting in advanced airway management, taught by either a qualified dental office deep sedation/general anesthesia provider, in accordance with Sections 4 and General Anesthesia emergency simulation course;
 - i) The Trained Auxiliary shall maintain a log of didactic and clinical training activities identified in <u>Sections 4(E)1(c)(iii)a</u> and <u>4(E)1(c)(iii)b</u> signed by the anesthesia provider who provides that training, on a Board-approved form; and
 - c. Maintain current completion in BLS at the Healthcare Provider level whenever assisting in sedation or general anesthesia;
 - d. Every two (2) years, the trained auxiliary must also complete a minimum of twelve (12) hours of instruction in dental office-based deep sedation/general anesthesia monitoring, techniques and/or emergency management in a continuing education course approved by the Board. ACLS and PALS recertification hours may be credited towards this requirement; and
 - e. At least two (2) hours of clinical training every two years as required in Section4(E)1(c)(iii)d in assisting an anesthesia provider in the management of dental office deep sedation/general anesthesia emergencies, including the use of bagvalve-mask ventilation with and without airway adjuncts and assisting in advanced airway management, taught by either a qualified dental office deep sedation/general anesthesia provider, in accordance with Sections 4 and 6 of these rules, or in an anesthesia emergency simulation course.
- (d) A third person, who may assist with the surgical procedure, must maintain current completion in BLS at the Healthcare Provider level.

- (e) When the deep sedation/general anesthesia provider is also the operating dentist, the second person defined above must be designated for monitoring the patient during the anesthetic procedure. The monitored vital signs will be relayed to the permit holder every five (5) minutes and whenever alterations in vital signs indicate potential concern for patient safety, following written protocols developed by the Deep Sedation/General Anesthesia Permit holder.
- (f) The Deep Sedation/General Anesthesia Permit holder working in conjunction with an Independently Licensed Provider or trained auxiliary is responsible for documenting and ensuring compliance with these personnel requirements.
- (F) Continuing Education.
 - 1. To maintain a Deep Sedation/General Anesthesia Permit, a dentist must participate in at least fourteen (14) hours of continuing education every two (2) years, in addition to BLS, ACLS and/or PALS training, in any of the following areas:
 - (a) Deep sedation and general anesthesia provision;
 - (b) Physical evaluation and medicine;
 - (c) Medical and sedation/general anesthesia emergencies or urgencies;
 - (d) Monitoring and use of monitoring equipment;
 - (e) Pharmacology of drugs used in general anesthesia or sedation; or
 - (f) Other areas directly related to general anesthesia practice; and
 - 2. At least four (4) hours of the above must include management of deep sedation/general anesthesia emergencies, preferably with high-fidelity simulation. At least once every five (5) years, at least four (4) hours of an anesthesia emergency simulation course must be completed, which may be included in the fourteen (14) hours above.
- (G) Reports of adverse occurrences.
 - 1. If a death or an adverse sedation/general anesthesia incident requiring hospital admission of more than twenty-four (24) hours occurs in a dental facility or accredited surgery center affiliated with a dental practice during the administration of, or recovery from, any level of sedation/general anesthesia, the permit holder and the treating dentist involved must submit to the Board an initial report of the incident within three (3) working days and a complete report of the incident to the Board within thirty (30) days after the occurrence.

SECTION 5. Obtaining Permits, Inspections & Renewals

- (A) Obtaining a permit.
 - 1. Initial applicants for a Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit must:
 - (a) Submit a completed Application for a Moderate Sedation or Deep Sedation/General Anesthesia Permit, as applicable, and if requested, a Pediatric Endorsement, provided by the Board and submit the fee set forth by the Board; and
 - (b) On a form provided by the Board, provide a dated and signed affidavit attesting that any facility where the dentist will administer moderate sedation or deep sedation/general anesthesia contains at the time of administration, at a minimum, the monitors, equipment and medications listed in <u>Sections 3(D)</u> or <u>4(D)</u>, as applicable, and comply with the personnel requirements and other requirements outlined in <u>Sections 3(E)</u> or <u>4(E)</u>, as applicable, or as set forth by the Board; and
 - (c) Document a current permit to prescribe and administer controlled substances in this state issued by the United States Drug Enforcement Administration and any applicable state permit when utilizing controlled substance.
 - (d) Provide documentation of past or ongoing adverse event records, disciplinary reviews or Board actions related to sedation/general anesthesia or substance use disorder in this or any jurisdiction where sedation or general anesthesia was provided.
 - 2. Following receipt of a completed initial application for a Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit, the Board will render a decision on the application within six (6) weeks as to whether all educational and other requirements have been met. Following approval by the Board of the initial application for a Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit, with or without Pediatric Endorsement, a provisional permit may be issued for up to twelve (12) months.
 - 3. The applicant must then successfully complete a Board-approved evaluation within twelve (12) months prior to issuance of a full active Moderate Sedation or Deep Sedation/General Anesthesia Permit.
 - 4. After twelve (12) months with a provisional permit, the licensed dentist cannot administer any level of sedation or general anesthesia, other than minimal sedation that does not require a special permit, until successful issuance of the applicable full, active permit, unless otherwise notified by the Dental Board.
- (B) Initial provider evaluations.
 - 1. The Board must schedule an evaluation within twelve (12) months following issuance of the provisional Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit at a mutually agreed upon time and place between the provisional permit holder and the Board, unless notified by the Board that an extension is needed.
 - 2. After the applicant successfully completes the initial provider evaluation, the Board must issue a full active Moderate Sedation or Deep Sedation/General Anesthesia Permit, as applicable, to the applicant.
 - 3. The initial provider evaluation must include the following:

- (a) Review of the dental anesthesia facility for equipment, staffing, records, and emergency medications, specifically associated with the administration of moderate sedation or deep sedation/general anesthesia, as applicable, and for medical emergencies.
- (b) Review of ten (10) previous moderate sedation or deep sedation/general anesthesia records, as applicable, redacted of personal identifying information, representing a variety of patients (e.g., age, ASA Physical Status, etc.) and procedures during the provisional permit period to ensure adequate moderate sedation or deep sedation/general anesthesia provision and documentation, as applicable. If a Pediatric Endorsement is sought, an additional three (3) records must be presented for patients aged eight (8) years of age or younger.
- (c) Review of emergency preparedness policies and demonstration of the ability to adequately manage deep sedation/general anesthesia emergencies and urgencies and medical emergencies using scripted scenarios prepared by consultants approved by the Board. Documentation of review of emergency preparedness policies, guidelines and logs of practice sessions for managing emergencies, as delineated in Section 2(I), must be made available for review.
- (d) Review of documentation of the use of controlled substances, including an inventory log that complies with state and federal requirements indicating the receipt, administration, storage, dispensing, and destruction of controlled substances.
- 4. The evaluation team selected by the Board will recommend one of the following:
 - (a) Pass: Successful completion of the onsite evaluation.
 - (b) Conditional Approval: For failing to have appropriate drugs or equipment, proper documentation of controlled substances, or proper recordkeeping. The applicant must submit proof of correcting the deficiencies before a full permit is issued and may provide only minimal sedation that does not require a special permit until a full, active permit has been issued.
 - (c) Not Pass: This category is reserved for deficiencies in anesthetic technique based on sedation/general anesthesia records review and/or in knowledge related to the administration of sedation/general anesthesia, management of sedation or general anesthetic emergencies or urgencies and medical emergencies. The applicant must complete Board approved remedial continuing education in the subject matter identified by the evaluators and re-apply for a full evaluation, consistent with an initial evaluation. Until successful completion of the re-evaluation, the applicant must not provide any form of sedation or general anesthesia, except for minimal sedation that does require a special permit until a full, active permit has been issued.
- 5. Following successful completion of initial provider evaluation, the Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit Holder will submit an affidavit attesting that the equipment, drugs and supplies and personnel for the provision of moderate sedation or deep sedation/general anesthesia, as applicable, and as required for initial application, will be present in any dental anesthesia facility at the time of sedation/general anesthesia administration by the permit holder.
- Only one provider evaluation at only one location is required to receive a Moderate Sedation
 or Deep Sedation/General Anesthesia Permit. This permit may then be used in any location
 where the permit holder provides moderate sedation or deep sedation/general anesthesia, as

- applicable. The onsite evaluation of any additional facility at which the permit holder provides moderate sedation or deep sedation/general anesthesia is not required.
- 7. All evaluators must complete Board-approved calibration education prior to any evaluation. Periodic calibration education will be at the Board's discretion. The Board must ensure that there are adequate evaluators to ensure prompt evaluations.
- 8. The evaluators for an initial evaluation of a Moderate Sedation Permit must consist of two (2) dentists, at least one (1) of which must be permitted to provide deep sedation/general anesthesia. The second evaluator must possess a Moderate Sedation Permit, unless this requirement is waived by the applicant. The evaluators for a Deep Sedation/General Anesthesia Permit must consist of two (2) dentists permitted to provide general anesthesia. At least one (1) evaluator must be of the same specialty as the applicant, unless this requirement is waived by the applicant. The dentist to be evaluated may request a different evaluator(s) if he/she perceives a conflict of interest.
- 9. The Board also will have the discretion to inspect any dental anesthesia facility at any time for good cause. Any permitted dentist with missing or malfunctioning drugs or equipment must cease administering sedation/general anesthesia until his/her dental anesthesia facility has been properly equipped with the required equipment or until such malfunctioning equipment has been satisfactorily repaired and until such time as the Board is in receipt of proof that the equipment has been repaired to the Board's satisfaction.
- (C) Permit renewal for moderate sedation and deep sedation/general anesthesia.
 - 1. Any dentist holding a Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit issued by the Board will be subject to review and renewal at the Board's discretion.
 - 2. The Board must, in accordance with its state's laws, rules, and regulations, together with the appropriate and required information and renewal fee, renew the Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit, unless the holder is informed in writing that a reevaluation of moderate sedation provision and/or facilities is to be required. In determining whether such re-evaluation is necessary, the Board must consider such factors as it deems pertinent, including, but not limited to, results of the onsite re-evaluation, review of deep sedation/general anesthesia clinical records, review of emergency preparedness guidelines, patient complaints and reports of adverse occurrences.
 - 3. At the time the dentist renews his/her dental license, he/she must submit:
 - (a) Attestation of current completion of ACLS if utilizing moderate sedation or deep sedation/general anesthesia for patients nine (9) years of age and older; and
 - (b) If renewing a Pediatric Endorsement:
 - (i) Attestation of current completion of PALS if treating patients eight (8) years of age or younger; and
 - (ii) For Moderate Sedation Permit holders, attestation of having provided moderate sedation for at least twenty (20) children eight (8) years of age or younger in the previous two (2) years; or
 - (iii) For Deep Sedation/General Anesthesia Permit holders, attestation of having provided deep sedation or general anesthesia for at least fifty (50) children eight (8) years of age or younger in the previous two (2) years;

- a. If the permittee lacks a sufficient number of deep sedation/general anesthesia pediatric cases for endorsement renewal, the permittee may personally administer dental office-based deep sedation or general anesthesia while not involved in the conduct of the surgical procedure to children eight (8) years of age or younger under the direct supervision of a permit holder who meets the qualifications of Section 4(A)2 which will then be accepted in the meeting the case requirement; and
- (c) Attestation of compliance with the continuing education requirements set forth in Sections 3(F) or 4(F), as applicable;
- (d) If a practice interruption (e.g., illness, pregnancy, family leave of absence due to birth or immediate family member illness, natural disaster, etc.) occurs that renders compliance with this Section impossible, unsafe, or commercially impracticable, documentation from the most recent period in practice may be used at the discretion of the Board; and
- (e) The Board may, at its discretion, request documentation of any of the above requirements. Inability to produce documentation may result in loss of the dentist's Moderate Sedation Permit, Deep Sedation/General Anesthesia Permit and/or Pediatric Endorsement and other disciplinary action.

(D) Onsite Re-evaluations.

- 1. Every five (5) years, or as designated by the Board, the permitted dentist must be provided with adequate advanced notice by the Board that he/she must undergo a dental anesthesia facility inspection and audit of any records related to sedation/general anesthesia in only one location where that provider will administer sedation or general anesthesia for the Moderate Sedation Permit, or the Deep Sedation/General Anesthesia Permit as applicable, to be renewed. If a legitimate practice interruption (e.g., illness, pregnancy, family leave of absence due to birth or immediate family member illness, natural disaster, etc.) occurs, or if the Board is unable to complete this re-evaluation within the five (5) year period, the Board has discretion in scheduling the inspection/audit.
- 2. The onsite re-evaluation for a Moderate Sedation Permit or Deep Sedation/General Anesthesia Permit need only be performed in only one location where that permit holder provides moderate sedation or deep sedation/general anesthesia, as applicable. The onsite re-evaluation of any additional facility at which the permit holder provides moderate sedation or deep sedation/general anesthesia is not required.
- 3. The dental anesthesia facility onsite re-evaluation will include a dental facility inspection and audit of sedation records consisting of the following:
 - (a) Inspection of the dental anesthesia facility for equipment, supplies and medications required for moderate sedation or deep sedation/general anesthesia, as applicable, and management of emergencies, as noted in Sections 2(J), 3(D), 4(D), as well as controlled substance records as noted in Section 5(B)3(d), which may be completed by a trained Board staff member or trained dentist consultant. This requirement is waived for permit holders who document exclusive practice in a dental anesthesia facility(s) with current accreditation from an accrediting authority recognized by CMS;
 - (b) Audit of ten (10) copies of previous moderate sedation or deep sedation/general anesthesia records, as applicable, redacted of personal identification, representing a variety of patients (e.g., age, ASA physical status, etc.) and procedures from within the last two (2) years of practice to ensure adequate moderate sedation or deep

sedation/general anesthesia provision, as applicable, with appropriate personnel and documentation; and

- (c) If a Pediatric Endorsement renewal is requested:
 - (i) For a Moderate Sedation Permit, documentation of the administration of twenty (20) cases of moderate sedation for patients eight (8) years of age or younger in the previous two (2) years, and an audit of ten (10) redacted copies of these moderate sedation records, which may be included in the ten (10) cases above. This review must be completed by a dentist consultant who has completed Boardapproved calibration training and possesses a Deep Sedation/General Anesthesia Permit; or
 - (ii) For a Deep Sedation/General Anesthesia Permit, documentation of the administration of fifty (50) cases of deep sedation/general anesthesia for patients eight (8) years of age or younger in the previous two (2) years, and an audit of ten (10) redacted copies of these cases previous sedation/general anesthesia records, which may be included in the ten (10) cases above. This review must be completed by a dentist consultant who has completed Board-approved calibration training and possesses a Deep Sedation/General Anesthesia Permit.
- (d) Audit of emergency preparedness policies, guidelines for management of emergencies and documentation of staff review as noted in <u>Section 2(I)</u>, submitted to the Board. This review must be completed by a Board appointed consultant who has completed Board-approved calibration training and possesses a Deep Sedation/General Anesthesia Permit.
- (e) The result of such re-evaluation must follow the provisions set forth in <u>Section 5(B)</u>.

SECTION 6. Non-Dentist Anesthesia Provider in a Dental Facility

NOTE TO DRAFTER: In states that require a delegating order and/or clinical supervision of CRNAs, the following paragraph A should be used.

- (A) A dentist who does not qualify for a Deep Sedation/General Anesthesia Permit or a Moderate Sedation Permit must possess a Permit to Utilize a Non-dentist Anesthesia Provider issued by the Board in order to provide dental treatment while deep sedation/general anesthesia or moderate sedation, as appropriate to the level of permit, is administered by:
 - 1. A physician holding an unencumbered [NAME OF STATE] medical license who has successfully completed an accredited anesthesiology residency program.
 - 2. The physician anesthesiologist must provide the dentist with verification of having treated fifty (50) patients eight (8) years of age or under with deep sedation/general anesthesia in the last two (2) years, if patients eight (8) years of age or under are to be treated with deep sedation/general anesthesia, unless that dentist holds a Deep Sedation/General Anesthesia Permit with Pediatric Endorsement.

NOTE TO DRAFTER: In states that do not require a delegating order and/or clinical supervision of CRNAs, the following Paragraph A should be used.

- (A) A dentist who does not qualify for a Deep Sedation/General Anesthesia Permit or a Moderate Sedation Permit must possess a Permit to Utilize a Non-dentist Anesthesia Provider issued by the Board in order to provide dental treatment while deep sedation/general anesthesia or moderate sedation, as appropriate to the level of permit, is administered by either:
 - 1. A physician holding an unencumbered [NAME OF STATE] medical license who has successfully completed an accredited anesthesiology residency program; or
 - 2. A CRNA holding an unencumbered [NAME OF STATE] license who does not require a delegating order or clinical supervision for the administration of sedation or general anesthesia by the dentist. The CRNA must document of at least two (2) years of post-graduate full-time anesthesia practice or four thousand (4,000) post-graduate clinical hours of general anesthesia provision; and
 - 3. The physician anesthesiologist or CRNA must provide the dentist with verification of having treated fifty (50) patients eight (8) years of age or under with deep sedation/general anesthesia in the last two (2) years, if patients eight (8) years of age or under are to be treated with deep sedation/general anesthesia, unless that dentist holds a Deep Sedation/General Anesthesia Permit with Pediatric Endorsement.
- (B) Obtaining a permit.
 - 1. To obtain a Permit to Utilize a Non-dentist Anesthesia Provider, a licensed dentist must:
 - (a) Submit a completed Application for Permit to Utilize a Non-dentist Anesthesia Provider provided by the Board and submit the fee set forth by the Board.
 - (b) Submit with the application and a signed contract with each non-dentist anesthesia provider that includes the following requirements:
 - (i) That all dental anesthesia facility requirements as outlined in <u>Section 2</u> of these rules have been met and approved by the anesthesia provider.

- (ii) That all monitors, emergency drugs and equipment outlined in <u>Section 4(D)</u> of these rules must be present, and monitors utilized, whenever sedation or general anesthesia is administered. The dentist and the anesthesia provider must agree upon and arrange for the provision of such monitors, emergency drugs and equipment, to be met by either party.
- (iii) That the anesthesia provider is responsible for the consent for sedation/general anesthesia and the pre-, intra-, and postoperative anesthetic management of the patient.
- (iv) That the procedures for administration of sedation or general anesthesia follow the clinical requirements for a general anesthesia permitted dentist outlined in Section 4(B) of these rules.
- (v) That the personnel requirements outlined in <u>Section 4(E)</u> are followed whenever sedation or general anesthesia is administered.
- (vi) That the anesthesia provider is responsible for determining fitness for discharge and must remain on the premises until this is assured.
- (vii) That the anesthesia provider provide the dentist with verification of treating fifty (50) patients eight (8) years of age or under for deep sedation/general anesthesia in the last two (2) years if patients eight (8) years of age or under will be managed with sedation/general anesthesia in the dentist's facility.
- (viii) That the anesthesia provider must maintain current completion in ACLS when treating patients nine (9) years and older; and PALS completion when treating patients eight (8) years of age and younger.
- (ix) That written emergency preparedness policies must be developed with the nondentist anesthesia provider consisting of the responsibilities of all team members during management of emergencies and policies for patient transport in case of an emergency, which must be reviewed with applicable staff, including the operating dentist, at least semi-annually. In offices where moderate sedation and/or deep sedation/general anesthesia is performed less frequently than quarterly, or for the first time, review of emergency preparedness policies must be performed, at a minimum, immediately preceding the administration of moderate sedation or deep sedation/general anesthesia for an actual patient. Additionally, common sedation and/or general anesthesia emergencies specific to the drugs and equipment referenced in Section 4(D) for responding to emergency situations should be addressed but must include emergencies associated with impaired ventilation/oxygenation including: upper airway obstruction, laryngospasm, bronchospasm, aspiration of gastric contents, foreign body obstruction (upper and lower airway) and excessive drug administration. These emergency preparedness review sessions must be maintained in a log and be available to the Board upon request.
- (x) That all rules regarding the use of controlled substances, including an inventory log that complies with state and federal requirements indicating the receipt, administration, storage, dispensing, and destruction of controlled substances are followed. The dentist and the anesthesia provider must agree upon and arrange for the provision of controlled substances and their documentation, to be met by either party.

- (xi) That the anesthesia provider must leave a copy of all pre-op, intra op and post op sedation/anesthesia records with the dentist for possible review by the dental Board.
- (c) Documentation from the anesthesia provider of any past or ongoing adverse event records, professional liability actions, disciplinary reviews or Board actions related to sedation/general anesthesia or substance use disorder in this or any other jurisdiction where sedation or general anesthesia was provided.
- (d) Following receipt of a completed initial application for a Permit To Utilize a Non-dentist Anesthesia Provider from the applicant dentist, the Board will render a decision on the application within six (6) weeks. Following approval by the Board of the initial application for a Permit to Utilize a Non-dentist Anesthesia Provider, a provisional permit may be issued for up to twelve (12) months.
- (e) The applicant must then successfully complete an onsite evaluation within twelve (12) months prior to issuance of a full, active Permit to Utilize a Non-dentist Anesthesia Provider as prescribed by the Board.
- (f) After twelve (12) months with a provisional permit, the licensed dentist cannot utilize a non-dentist anesthesia provider until successful issuance of the applicable full active permit, unless notified otherwise by the Dental Board.

(C) Onsite evaluations.

- 1. The Board must schedule an onsite evaluation with the presence of the non-dentist anesthesia provider within twelve (12) months following issuance of the provisional Permit To Utilize a Non-dentist Anesthesia Provider.
- 2. The initial onsite evaluation must include the following:
 - (a) Review of the dental anesthesia facility for equipment, records, and emergency medications, specifically associated with the administration of deep sedation/general anesthesia, as applicable, and for medical emergencies.
 - (b) Review of ten (10) previous dental office-based deep sedation/general anesthesia records, redacted of personal identifying information, representing a variety of patients (e.g., age, ASA Physical Status, etc.) and procedures during the provisional permit period to ensure adequate moderate sedation or deep sedation/general anesthesia provision and documentation, as applicable. If a Pediatric Endorsement is sought, an additional three (3) records must be presented for patients eight (8) years of age or younger.
 - (c) Review of emergency preparedness policies and demonstration of the ability to adequately manage deep sedation/general anesthesia emergencies and urgencies and medical emergencies using scripted scenarios prepared by consultants approved by the Board. Documentation of review of emergency preparedness policies, guidelines and logs of practice sessions for managing emergencies, as delineated in Section 2(I), must be made available for review.
 - (d) Review of documentation of the use of controlled substances, including an inventory log that complies with state and federal requirements indicating the receipt, administration, storage, dispensing, and destruction of controlled substances.

- 3. The evaluation team selected by the Board will recommend one of the following:
 - (a) Pass: Successful completion of the onsite evaluation.
 - (b) Conditional Approval: For failing to have appropriate drugs or equipment, proper documentation of controlled substances, or proper recordkeeping. The applicant must submit proof of correcting the deficiencies before a full permit is issued. Until that time, the applicant must not allow the provision of any form of sedation or general anesthesia by a non-dentist anesthesia provider in their dental facility.
 - (c) Not Pass: This category is reserved for deficiencies that are judged to potentially be a patient safety concern. The applicant will be notified by the Board of corrective action. Until that corrective action, the applicant must not allow the provision of any form of sedation or general anesthesia by a non-dentist anesthesia provider in their dental facility.
- 4. After the applicant successfully completes the onsite evaluation, the Board must issue a full, active Permit to Utilize a Non-dentist Anesthesia Provider to the applicant dentist.
- 5. The onsite evaluation of any additional dental anesthesia facility in which the permit holder will utilize a non-dentist anesthesia provider that was involved in a dentist's successful onsite evaluation is not required.
- 6. A dentist holding a Permit to Utilize a Non-dentist Anesthesia Provider who wishes to utilize a different non-dentist anesthesia provider in their dental facility must undergo a separate onsite evaluation to ensure compliance with the agreed upon contract, the cost of such evaluation borne by the applicant dentist.
 - (a) Exception: If a dentist holding a full, active Permit to Utilize a Non-dentist Anesthesia Provider utilizes a non-dentist anesthesia provider who has been involved in a successful evaluation with another dentist holding a Permit To Utilize a Non-dentist Anesthesia Provider, such anesthesia provider may provide anesthesia in the dental facility of any dentist holding a Permit to Utilize a Non-dentist Anesthesia Provider, provided the operating dentist has submitted a properly executed contract with that anesthesia provider which has been approved by the Board. The Board may, at its discretion, schedule an onsite evaluation with the dentist who utilizes a different non-dentist anesthesia provider other than that provider involved in the initial permit evaluation.
- 7. The Board will maintain a list of all physician anesthesiologists/CRNAs who have completed a successful onsite evaluation and collaborated with a dentist holding a Permit to Utilize a Non-dentist Anesthesia Provider which shall be made available at the request of any dentist.
- 8. All onsite evaluators must complete Board-approved calibration education prior to any evaluation. Periodic calibration education will be at the Board's discretion.
- (D) Permit renewal.
 - 1. At the time the dentist renews his/her dental license, he/she must submit:
 - (a) Completion of four (4) hours of instruction every two (2) years in any area related to sedation/general anesthesia, pre-anesthetic assessment, medicine, pharmacology or medical emergencies via continuing education course(s) approved by the Board in addition to ACLS, PALS and BLS recertification hours, as appropriate. This CE

requirement may be applied to the total CE requirement required for dental licensure renewal; and,

(b) Either:

- (i) Attestation of current completion of either ACLS and/or PALS; and
- (ii) Attestation of completion of a minimum of two (2) hours of simulation or clinical training in the previous two years in assisting the anesthesia provider in the management of deep sedation/general anesthesia emergencies, including the use of bag-valve-mask ventilation with and without airway adjuncts and assisting in advanced airway management, taught by either a qualified dental office deep sedation/general anesthesia provider, in accordance with Section 4 of these rules or in an emergency simulation course; or
- (iii) Attestation that the non-dentist anesthesia provider utilizes a separate Independently Licensed Provider, meeting the requirements in <u>Section 4(E)(1)c(ii)</u>, whenever any level of sedation or general anesthesia is administered.
- (c) The Board may, at its discretion, request documentation of any of the above requirements.

(E) Onsite Re-evaluations.

- 1. A dentist must undergo an onsite re-evaluation, consistent with the initial evaluation of the Permit to Utilize a Non-dentist Anesthesia Provider as noted in <u>Section 6(C)</u> at least once every five (5) years beginning from the date of issuance of the initial, full active Permit to Utilize a Non-dentist Anesthesia Provider. If the Board is unable to complete this re-evaluation within the five (5) year period, the Board has discretion in scheduling of this re-evaluation.
- 2. The onsite re-evaluation for a dentist to renew a Permit to Utilize a Non-dentist Anesthesia Provider must include:
 - (a) Submission of a completed renewal application on a form provided by the Board and submit the fee set forth by the Board.
 - (b) Inspection of the dental anesthesia facility, sedation and emergency equipment, and emergency medications, as noted in <u>Section 5(B)</u>, as well as controlled substance records as noted in <u>Section 5(B)3(d)</u>, which may be completed by a trained Board staff member or trained consultant. If needed, the physician anesthesiologist/CRNA should be present for this inspection.
 - (i) If a non-dentist anesthesia provider has passed this inspection within the last five (5) years with this dentist or another dentist holding a Permit to Utilize a Nondentist Anesthesia Provider, this requirement is waived for that anesthesia provider.
 - (c) Audit of contract(s) with each non-dentist anesthesia provider that includes the requirements outlined in <u>Section 6(B)1(b)</u>.
 - (d) Audit of ten (10) redacted copies of previous deep sedation/general anesthesia records, submitted to the Board, with personal identifying information redacted, representing a variety of patients (e.g., age, ASA physical status, etc.) and procedures from within the last year of practice to ensure adequate deep sedation/general anesthesia provision,

appropriate personnel and documentation of deep sedation/general anesthesia for each non-dentist anesthesia provider from each anesthesia provider utilized. If multiple anesthesia providers are utilized, a minimum of three (3) redacted records from each anesthesia provider is required. This review must be completed by a dentist consultant who has completed Board-approved calibration training and possesses a Deep Sedation/General Anesthesia Permit.

- (e) If a Pediatric Endorsement is sought, documentation of fifty (50) cases of deep sedation/general anesthesia for patients eight (8) years of age or younger by each non-dentist anesthesia provider in the last two (2) years and an audit of an additional ten (10) redacted copies of these sedation/general anesthesia records, which may be used for the ten (10) cases above. If multiple anesthesia providers are utilized, a minimum of three (3) redacted records from each non-dentist anesthesia provider is required. This review must be completed by a dentist consultant who has completed Board-approved calibration training and possesses a Deep Sedation/General Anesthesia Permit.
- (f) Audit of emergency preparedness policies, guidelines for management of emergencies and documentation of staff review as noted in <u>Section 2(I)</u>, submitted to the Board for each non-dentist anesthesia provider. This review must be completed by a Board appointed consultant who has completed Board-approved calibration training and possesses a General Anesthesia Permit.
- 3. The result of such re-evaluation must follow the provisions set forth in Section 5(B).
- (F) Reports of adverse occurrences.
 - 1. If a death or an adverse sedation/general anesthesia incident requiring admission to a hospital for greater than 24 hours occurs in a dental anesthesia facility during the administration of or recovery from any level of sedation or general anesthesia, the dentist holding a Permit To Utilize a Non-dentist Anesthesia Provider involved must submit to the Board an initial report of the incident within three (3) working days followed by a complete report of the incident to the Board within thirty (30) days after the occurrence.
 - The Dental Board must submit a report to the Medical Board, as appropriate, outlining the adverse sedation/general anesthesia incident for review, and if needed, investigation by the Medical or Nursing Board.