

**BOARD OF DENTISTRY
ANESTHESIA COMMITTEE AGENDA
November 17, 2016
Marriott Miami Airport
1201 NW LeJune Road, Building A
Miami, Florida 33126
1:30 P.M.**

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

- I. CALL TO ORDER/ROLL CALL**
- II. REVIEW OF CHAPTER 64B5-14, F.A.C.**
- III. DISCUSSION**
 - A. Correspondence from the Florida Society of Oral and Maxillofacial Surgeons**
 - B. ADA Resolution 37**
- IV. OLD BUSINESS**
- V. NEW BUSINESS**
- VI. ADJOURNMENT**

CHAPTER 64B5-14 ANESTHESIA

64B5-14.001	Definitions
64B5-14.002	Prohibitions
64B5-14.003	Training, Education, Certification, and Requirements for Issuance of Permits
64B5-14.0032	Itinerate/Mobile Anesthesia – Physician Anesthesiologist
64B5-14.0034	Itinerate/Mobile Anesthesia – General Anesthesia Permit Holders
64B5-14.0036	Treatment of Sedated Patients by Dentists Without an Anesthesia Permit
64B5-14.0038	Use of a Qualified Anesthetist
64B5-14.004	Additional Requirements
64B5-14.005	Application for Permit
64B5-14.006	Reporting Adverse Occurrences
64B5-14.007	Inspection of Facilities and Demonstration of Sedation Technique
64B5-14.008	Requirements for General Anesthesia or Deep Sedation: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring
64B5-14.009	Conscious Sedation Requirements: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring
64B5-14.010	Pediatric Conscious Sedation Requirements: Operatory; Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring

64B5-14.001 Definitions.

- (1) Anesthesia – The loss of feeling or sensation, especially loss of the sensation of pain.
- (2) General anesthesia – A controlled state of unconsciousness, produced by a pharmacologic agent, accompanied by a partial or complete loss of protective reflexes, including inability to independently maintain an airway and respond purposefully to physical stimulation or verbal command. This modality includes administration of medications via parenteral routes; that is: intravenous, intramuscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal.
- (3) Deep Sedation – A controlled state of depressed consciousness accompanied by partial loss of protective reflexes, including either or both the inability to continually maintain an airway independently or to respond appropriately to physical stimulation or verbal command, produced by pharmacologic or non-pharmacologic method or combination thereof. Deep sedation includes administration of medications via parenteral routes; that is intravenous, intra muscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal.
- (4) Conscious sedation – A depressed level of consciousness produced by the administration of pharmacologic substances, that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation and verbal command. This modality includes administration of medications via all parenteral routes, that is, intravenous, intramuscular, subcutaneous, submucosal, or inhalation, as well as enteral routes, that is oral, rectal, or transmucosal. The drugs, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely.
- (5) Pediatric Conscious Sedation – A depressed level of consciousness produced by the administration of pharmacologic substances, that retains a child patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command. This modality includes administration of medication via all parenteral routes; that is intravenous, intramuscular, subcutaneous, submucosal, or inhalation, and all enteral routes; that is oral, rectal, or transmucosal. The drugs, doses, and techniques used should carry a margin of safety wide enough to render unintended loss of consciousness unlikely. For the purposes of this chapter, a child is defined as an individual under 18 years of age, or any person who has special needs, which means having a physical or mental impairment that substantially limits one or more major life activities.
- (6) Nitrous-oxide inhalation analgesia – The administration by inhalation of a combination of nitrous-oxide and oxygen producing an altered level of consciousness that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.
- (7) Local anesthesia – The loss of sensation of pain in a specific area of the body, generally produced by a topically applied agent or injected agent without causing the loss of consciousness.
- (8) Analgesia – Absence of sensibility of pain, designating particularly the relief of pain without loss of consciousness.

(9) Office team approach – A methodology employed by a dentist in the administration of general anesthesia, deep sedation, conscious sedation, and pediatric sedation whereby the dentist uses one or more qualified assistants/dental hygienists who, working under the direct supervision of the dentist, assist the dentist, and assist in emergency care of the patient.

(10) Minimal Sedation (anxiolysis) – The perioperative use of medication to relieve anxiety before or during a dental procedure which does not produce a depressed level of consciousness and maintains the patient’s ability to maintain an airway independently and to respond appropriately to physical and verbal stimulation. This minimal sedation shall include the administration of a single enteral sedative or a single narcotic analgesic medication administered in doses appropriate for the unsupervised treatment of anxiety and pain. If clinically indicated, an opioid analgesic may also be administered during or following a procedure if needed for the treatment of pain. Except in extremely unusual circumstances, the cumulative dose shall not exceed the maximum recommended dose (as per the manufacturers recommendation). It is understood that even at appropriate doses a patient may occasionally drift into a state that is deeper than minimal sedation. As long as the intent was minimal sedation and all of the above guidelines were observed, this shall not automatically constitute a violation. A permit shall not be required for the perioperative use of medication for the purpose of providing anxiolysis.

(11) Titration of Oral Medication – The administration of small incremental doses of an orally administered medication until an intended level of conscious sedation is observed.

(12) Physician anesthesiologist – Any physician licensed pursuant to Chapter 458 or 459, F.S., who is currently board certified or board eligible by the American Board of Anesthesiology or the American Osteopathic Board of Anesthesiology, or is credentialed to administer anesthesia in a hospital or ambulatory surgical facility licensed by the Department of Health.

(13) Qualified Anesthetist: means an Advanced Registered Nurse Practitioner who is licensed in this state to practice professional nursing and who is certified in the advanced or specialized nursing practice as a certified registered nurse anesthetist pursuant to Chapter 464, Part I, F.S.

(14) Certified Registered Dental Hygienist: means any Florida licensed dental hygienist who is certified by the Board and has received a certificate from the Department of Health that allows the administration of local anesthesia while the CRDH is appropriately supervised by a Florida licensed dentist.

Rulemaking Authority 466.004(4), 466.017(3), 466.17(6) FS. Law Implemented 466.002(3), 466.017(3), 466.017(5) FS. History–New 1-31-80, Amended 4-7-86, Formerly 21G-14.01, Amended 12-31-86, 6-1-87, 9-1-87, 2-1-93, Formerly 21G-14.001, Amended 12-20-93, Formerly 61F5-14.001, Amended 8-8-96, Formerly 59Q-14.001, Amended 3-9-03, 11-4-03, 7-3-06, 6-11-07, 8-5-12.

64B5-14.002 Prohibitions.

(1) General anesthesia or deep sedation. No dentists licensed in this State shall administer general anesthesia or deep sedation in the practice of dentistry until they have obtained a permit as required by the provisions of this rule chapter.

(2) Conscious sedation. No dentists licensed in this State shall administer conscious sedation in the practice of dentistry until they have obtained a permit as required by the provisions of this rule chapter.

(3) Pediatric Conscious Sedation: No dentist licensed in this State shall administer Pediatric Conscious Sedation in the practice of dentistry until such dentist has obtained a permit as required by the provisions of this rule chapter.

(4) Nitrous-oxide inhalation analgesia. No dentists licensed in this State shall administer nitrous-oxide inhalation analgesia in the practice of dentistry until they have complied with the provisions of this rule chapter.

(5) Local anesthesia. Dentists licensed in this State may use local anesthetics to produce local anesthesia in the course of their practice of dentistry. Certified Registered Dental Hygienists are the only hygienists allowed to administer local anesthesia.

(6) The only agents that can be used for inhalation analgesia pursuant to Rule 64B5-14.003, F.A.C., below are nitrous-oxide and oxygen.

(7) Titration of Oral Medication. The Board of Dentistry has determined that the perioperative titration of oral medication(s) with the intent to achieve a level of conscious sedation poses a potential overdosing threat due to the unpredictability of enteral absorption and may result in an alteration of the state of consciousness of a patient beyond the intent of the practitioner. Such potentially adverse consequences may require immediate intervention and appropriate training and equipment. Beginning with the effective date of this rule, no dentist licensed in this state shall use any oral medication(s) to induce conscious sedation until such dentist has obtained a permit as required by the provisions of this rule chapter. The use of enteral sedatives or narcotic analgesic medications for the purpose of providing minimal sedation (anxiolysis) as defined by and in accordance with subsection 64B5-14.001(10), F.A.C., shall not be deemed titration of oral medication and shall not be prohibited by this rule.

(8) The following general anesthetic drugs shall not be employed on or administered to a patient by a dentist unless the dentist possesses a valid general anesthesia permit issued by the Board pursuant to the requirements of this chapter: propofol, methohexital, thiopental, etomidate, ketamine, or volatile gases (i.e., sevoflurane, isoflurane).

(9) A hygienist certified by the board to administer local anesthesia shall not administer local anesthesia to a patient sedated by general anesthesia, deep sedation, conscious sedation, or pediatric conscious sedation. If a dentist has administered nitrous-oxide to the patient, the certified dental hygienist may administer local anesthesia under the direct supervision of the supervising dentist. A patient who has been prescribed a medical drug by their licensed health care provider for the purposes of life functions may be administered local anesthesia by the certified dental hygienist under the direct supervision of the supervising dentist. If, however, the medical drug is prescribed or administered for the purposes of a dental procedure which is intended to induce minimal sedation (anxiolysis), the hygienist may not administer local anesthesia to the patient.

Rulemaking Authority 466.004(4), 466.017(3), 466.017(6) FS. Law Implemented 466.017(3), 466.017(5) FS. History—New 1-31-80, Amended 4-20-81, 2-13-86, Formerly 21G-14.02, 21G-14.002, Amended 12-20-93, Formerly 61F5-14.002, Amended 8-8-96, Formerly 59Q-14.002, Amended 3-9-03, 11-4-03, 6-15-06, 12-25-06, 12-11-11, 8-5-12, 12-15-14, 7-14-16.

64B5-14.003 Training, Education, Certification, and Requirements for Issuance of Permits.

(1) General Anesthesia Permit.

(a) A permit shall be issued to an actively licensed dentist authorizing the use of general anesthesia or deep sedation at a specified practice location or locations on an outpatient basis for dental patients provided the dentist:

1. Has completed a minimum of a two year residency program accredited by the Commission on Dental Accreditation in dental anesthesiology or has completed an oral and maxillofacial surgical residency program accredited by the Commission on Dental Accreditation beyond the undergraduate dental school level; or

2. Is a diplomate of the American Board of Oral and Maxillofacial Surgery; or

3. Is eligible for examination by the American Board of Oral and Maxillofacial Surgery; or

4. Is a member of the American Association of Oral and Maxillofacial Surgeons.

(b) A dentist employing or using general anesthesia or deep sedation shall maintain a properly equipped facility for the administration of general anesthesia, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems and emergencies incident thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of general anesthesia or deep sedation requires at least three individuals, each appropriately trained: the operating dentist, a person responsible for monitoring the patient, and a person to assist the operating dentist.

(c) A dentist employing or using general anesthesia or deep sedation and all assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one person CPR, two person CPR, infant resuscitation and obstructed airway, with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing general anesthesia or deep sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).

(d) A dentist permitted to administer general anesthesia or deep sedation under this rule may administer conscious sedation and nitrous-oxide inhalation conscious sedation.

(e) A dentist employing or using deep sedation shall maintain an active and current permit to perform general anesthesia.

(2) Conscious Sedation Permit.

(a) A permit shall be issued to a dentist authorizing the use of conscious sedation at a specified practice location or locations on an outpatient basis for dental patients provided such dentist:

1. Has received formal training in the use of conscious sedation; and

2. Is certified by the institution where the training was received to be competent in the administration of conscious sedation; and

3. Is competent to handle all emergencies relating to conscious sedation.

(b) Such certification shall specify the type, the number of hours, the number of patients treated and the length of training. The minimum number of didactic hours shall be sixty, which must include four (4) hours of airway management. Airway management

must include emergency airway management protocols. Clinical training shall include personal administration for at least twenty patients including supervised training, clinical experience and demonstrated competence in airway management of the compromised airway. The program must certify that a total of three (3) hours of clinical training was dedicated to hands-on simulated competence in airway management of the compromised airway.

(c) Personal Administration of Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from pre-anesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergence, recovery, and approval for discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of conscious sedation.

(d) This formal training program shall be offered through an accredited dental school or program; or through an accredited, teaching hospital.

(e) A dentist utilizing conscious sedation shall maintain a properly equipped facility for the administration of conscious sedation, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems, and emergencies incident thereto. The facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of conscious sedation requires at least two individuals: a dentist, and an auxiliary trained in basic cardiac life support. It shall be incumbent upon the operating dentist to insure that the patient is appropriately monitored.

(f) A dentist utilizing conscious sedation and his assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one person CPR, two person CPR, infant resuscitation, and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support) or ATLS (Advanced Trauma Life Support).

(g) Dentists permitted to administer conscious sedation may administer nitrous-oxide inhalation conscious sedation.

(h) Dentists permitted to administer conscious sedation may administer pediatric conscious sedation in compliance with Rule 64B5-14.010, F.A.C.

(3) Pediatric Conscious Sedation Permit.

(a) A permit shall be issued to a dentist authorizing the use of pediatric conscious sedation at a specified practice location or locations on an outpatient basis for dental patients provided such dentist:

1. Has received formal training in the use of pediatric conscious sedation. This formal training program shall be offered through an accredited dental school or program; or through an accredited teaching program; and,

2. Is certified by the institution where the training was received to be competent in the administration of pediatric conscious sedation. This certification shall specify the type, the number of hours, the number of patients treated and the length of training. The minimum number of didactic hours shall be sixty, which must include four (4) hours of airway management. Clinical training shall include personal administration for at least twenty patients including supervised training, management of sedation, clinical experience and demonstrated competence in airway management of the compromised airway. The program must certify that three (3) hours of clinical training was dedicated to hands-on simulated competence in airway management of the compromised airway; and

3. Personal Administration of Pediatric Conscious Sedation: The board shall award credit towards the required 20 dental patients, if and only if, the applicant is responsible for and remains with the patient from pre-anesthetic evaluation through discharge. The evaluation and responsibilities include the following: pre-anesthetic evaluation, induction, maintenance, emergency, recovery, and approval for discharge. The board will not award credit for dental anesthetic procedures performed that are greater than or less than the administration of pediatric conscious sedation; or

4. The applicant demonstrates that the applicant graduated, within 24 months prior to application for the permit, from an accredited post-doctoral pediatric residency. The pediatric residency anesthesia requirements must meet the minimum number of sedation cases as required in subsection (2).

5. Is competent to handle all emergencies relating to pediatric conscious sedation. A dentist utilizing pediatric conscious sedation shall maintain a properly equipped facility for the administration of pediatric conscious sedation, staffed with supervised assistant/dental hygienist personnel, capable of reasonably handling procedures, problems, and emergencies incidental thereto. The

facility must have the equipment capability of delivering positive pressure oxygen ventilation. Administration of pediatric conscious sedation requires at least two individuals: a dentist, and an auxiliary trained in basic cardiac life support. It shall be incumbent upon the operating dentist to insure that the patient is appropriately monitored.

(b) A dentist utilizing pediatric conscious sedation and his assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one person CPR, two person CPR, infant resuscitation, and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing pediatric conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), PALS (Pediatric Advanced Life Support), or a course providing similar instruction which has been approved by the Board. An entity seeking approval of such a course shall appear before the Board and demonstrate that the content of such course and the hours of instruction are substantially equivalent to those in an ACLS or PALS course.

(c) Dentists permitted to administer pediatric conscious sedation may administer nitrous-oxide inhalation conscious sedation.

(d) Dentists permitted to administer conscious sedation may administer pediatric conscious sedation.

(4) Nitrous-Oxide Inhalation Analgesia.

(a) A dentist may employ or use nitrous-oxide inhalation analgesia on an outpatient basis for dental patients provided such dentist:

1. Has completed no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; or
2. Has training equivalent to that described above while a student in an accredited school of dentistry; and
3. Has adequate equipment with fail-safe features and a 25% minimum oxygen flow.

(b) A dentist utilizing nitrous-oxide inhalation analgesia and such dentist's assistant/dental hygienist personnel shall be certified in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to include one man CPR, two man CPR, infant resuscitation and obstructed airway with a periodic update not to exceed two years. Starting with the licensure biennium commencing on March of 2000, a dentist and all assistant/dental hygienist personnel shall also be trained in the use of either an Automated External Defibrillator or a defibrillator and electrocardiograph as part of their cardiopulmonary resuscitation course at the basic life support level. In addition to CPR certification, a dentist utilizing pediatric conscious sedation must be currently trained in ACLS (Advanced Cardiac Life Support), ATLS (Advanced Trauma Life Support), or PALS (Pediatric Advanced Life Support).

(c) A dentist who regularly and routinely utilized nitrous-oxide inhalation analgesia on an outpatient basis in a competent and efficient manner for the three-year period preceding January 1, 1986, but has not had the benefit of formal training outlined in subparagraphs 1. and 2. of paragraph (4)(a) above, may continue such use provided the dentist fulfills the provisions set forth in paragraph 3. of paragraph (4)(a) and the provisions of paragraph (b) above.

(d) Nitrous oxide may be used in combination with a single dose enteral sedative or a single dose narcotic analgesic to achieve a minimally depressed level of consciousness so long as the manufacturer's maximum recommended dosage of the enteral agent is not exceeded. Nitrous oxide may not be used in combination with more than one (1) enteral agent, or by dosing a single enteral agent in excess of the manufacturer's maximum recommended dosage unless the administering dentist holds a conscious sedation permit issued in accordance with subsection 64B5-14.003(2), F.A.C., or a pediatric conscious sedation permit issued in accordance with Rule 64B5-14.010, F.A.C.

(5) Local Anesthesia Certificate or Permit: A permit or certificate to administer local anesthesia under the direct supervision of a Florida licensed dentist to non-sedated patients eighteen (18) years of age or older shall be issued by the Department of Health to a Florida licensed dental hygienist who has completed the appropriate didactic and clinical education and experience as required by Section 466.017(5), F.S., and who has been certified by the Board as having met all the requirements of Section 466.017, F.S.

(a) A registered dental hygienist who is seeking a permit or certificate for administering local anesthesia must apply to the department on form DH-MQA 1261 (May 2012), Application for Dental Hygiene Certification Administration of Local Anesthesia, herein incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-01469>, or available on the Florida Board of Dentistry website at <http://www.doh.state.fl.us/mqa/dentistry>.

(b) An applicant shall submit the following with the application:

1. A thirty-five dollar (\$35) non refundable certificate or permit fee;
2. A certified copy of the applicant's transcripts that reflect the required didactic and clinical education and experience;
3. A certified copy of the diploma or certificate issued by the applicant's institution, program, or school; and
4. Proof of acceptable certification in Cardiopulmonary Resuscitation for health professionals or Advanced Cardiac Life Support as defined in Section 466.017, F.S.

Rulemaking Authority 466.004(4), 466.017(3), (6) FS. Law Implemented 466.017(3), (4), (5), (6) FS. History—New 1-31-80, Amended 4-20-81, 2-13-86, Formerly 21G-14.03, Amended 12-31-86, 11-8-90, 2-1-93, Formerly 21G-14.003, Amended 12-20-93, Formerly 61F5-14.003, Amended 8-8-96, 10-1-96, Formerly 59Q-14.003, Amended 2-17-98, 12-20-98, 5-31-00, 6-7-01, 11-4-03, 6-23-04, 6-11-07, 2-8-12, 8-16-12 (1)(a)-(f), 8-16-12 (5), 8-19-13, 12-16-13, 3-9-14, 7-14-16.

64B5-14.0032 Itinerate/Mobile Anesthesia – Physician Anesthesiologist.

The provisions of this rule control the treatment of dental patients in an outpatient dental office setting where a physician anesthesiologist has performed the sedation services. This rule shall control notwithstanding any rule provision in this Chapter that prohibits such conduct. The level of sedation is not restricted to the level of the permit held by the treating dentist. The level of sedation may be any level necessary for the safe and effective treatment of the patient.

(1) General Anesthesia Permit Holders:

A dentist who holds a general anesthesia permit may treat their adult, pediatric, or special needs patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

(a) The physician anesthesiologist performs the administration of the anesthesia and the physician anesthesiologist is responsible for the anesthesia procedure;

(b) The dental treatment takes place in the general anesthesia permit holder's board-inspected and board-registered dental office.

(2) Pediatric Conscious Sedation Permit Holders:

A pediatric dentist, as recognized by the American Dental Association, who holds a pediatric conscious sedation permit may treat their pediatric or special needs dental patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

(a) The physician anesthesiologist performs the administration of the anesthesia, and the physician anesthesiologist is responsible for the anesthesia procedure;

(b) The treatment takes place in the permit holder's board-inspected and board-registered dental office;

(c) The dental office meets the supply, equipment, and facility requirements as mandated in Rule 64B5-14.008, F.A.C.;

(d) A board-approved inspector performs an inspection of the dental office and the inspector reports the office to be in full compliance with the minimum supply, equipment, and facility requirements.

A pediatric dentist who holds an active conscious sedation permit and not a pediatric conscious sedation permit shall meet the sedation permit requirement of this rule until the next biennial license renewal cycle that follows the effective date of this rule. At the next biennial license renewal cycle that follows the effective date of this rule, a pediatric dentist who hold a conscious sedation permit may transfer the permit to a pediatric conscious sedation permit without any additional cost besides the renewal fee.

(3) Conscious Sedation Permit Holders:

A dentist who holds a conscious sedation permit may treat their adult or adult special needs dental patients when a physician anesthesiologist performs the sedation services. The following conditions shall apply:

(a) The physician anesthesiologist performs the administration of the anesthesia, and the physician anesthesiologist is responsible for the anesthesia procedure;

(b) The treatment takes place in the permit holder's properly board-inspected and board-registered dental office;

(c) The dental office meets the supply, equipment, and facility requirements as mandated in Rule 64B5-14.008, F.A.C.;

(d) A board-approved inspector performs an inspection of the dental office and the inspector reports the office to be in full compliance with the minimum supply, equipment, and facility requirements.

(4) Non-Sedation Permit Holders:

All provisions of this Chapter relating to the administration of any type of anesthesia or sedation and treatment to sedated patients shall remain in full force and effect. Nothing in this section supersedes, alters, or creates a variance to any prohibitions and mandates applicable to non-sedation permit holding dentists.

(5) Staff or Assistants:

A dentist treating a patient pursuant to this rule must have at least three (3) properly credentialed individuals present as mandated in Rule 64B5-14.003, F.A.C. To fulfill the mandatory minimum required personnel requirements of Rule 64B5-14.003, F.A.C., a physician anesthesiologist assistant or a certified registered nurse anesthetist in addition to, or in lieu of a dental assistant or dental hygienist may be utilized. However, the dentist must have a dedicated member of the team to assist in the dental procedure or during dental emergencies.

(6) Equipment:

A dentist may comply with the electrocardiograph and end tidal carbon dioxide monitor equipment standards set by Rule 64B5-14.008, F.A.C., by utilizing mobile or non-fixed equipment if the dentist meets the following conditions:

(a) During the required board inspection, the equipment is available for inspection, or the dentist supplies an inspection of the equipment, which a licensed health care risk manager performed. A licensed health care risk manager inspection is valid for a period of twelve months; and

(b) The dentist shall make the inspected equipment available during all required inspections, if specifically requested within 48 hours in advance of the inspection, and the equipment must be immediately available for an adverse incident inspection.

(7) Records:

The treating dentist shall maintain a complete copy of the anesthesia records in the patient's dental chart. The dentist shall make certain that name and license numbers identify the treating dentist, the physician anesthesiologist, and all personnel utilized during the procedure.

Rulemaking Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History—New 8-20-12, Amended 11-19-12, 2-21-13, 12-16-13.

64B5-14.0034 Itinerate/Mobile Anesthesia – General Anesthesia Permit Holders.

The provisions of this rule control the treatment of dental patients in an outpatient dental office where a dentist with a general anesthesia permit performs the sedation services for a treating dentist. The treating dentist must possess a general anesthesia permit, conscious sedation permit, or pediatric conscious sedation permit. The level of anesthesia administered shall be to any level necessary to safely and effectively treat the dental patient. This rule shall control notwithstanding any rule provision in this Chapter that prohibits such conduct.

(1) General Anesthesia Permit Holder's Office:

A general anesthesia permit holder may perform sedation services for a dental patient of another general anesthesia permit holder or conscious or pediatric conscious sedation permit holder in his or her office or in another general anesthesia permit holder's office. In this setting, the following shall apply:

(a) The dental treatment may only be performed by a treating dentist who holds a valid anesthesia permit of any level;

(b) The treating dentist and the anesthesia provider are both responsible for the adverse incident reporting under Rule 64B5-14.006, F.A.C.

(2) Conscious and Pediatric Conscious Sedation Permit Holder's Office:

A general anesthesia permit holder may perform sedation services for a dental patient of another dentist who holds a conscious sedation permit or a pediatric conscious sedation permit at the office of the treating dentist. In this setting, the following shall apply:

(a) The dental treatment may only be performed by the conscious sedation or pediatric conscious sedation permit holder;

(b) The general anesthesia permit holder may perform general anesthesia services once an additional board-inspection establishes that the office complies with the facility, equipment and supply requirements of Rule 64B5-14.008, F.A.C.;

(c) The treating dentist and the anesthesia provider are both responsible for the adverse incident reporting requirements under Rule 64B5-14.006, F.A.C.

(3) Equipment:

When the general anesthesia permit holder performs the anesthesia services in a dental office of a conscious or pediatric conscious sedation permit holder's office, the electrocardiograph and end tidal carbon dioxide monitor equipment mandates may be met as follows:

(a) The general anesthesia permit holder provides the equipment which has already been inspected during the general anesthesia permit holder's required inspection;

(b) The equipment is available for inspection during the office's mandated inspection; and

(c) The equipment is immediately available for an adverse incident report inspection.

(4) Staff or Personnel:

An anesthesia provider and the treating dentist are both responsible for ensuring that a minimum number of three (3) personnel are present during the procedure. The personnel must meet the minimum credentialing requirements of Rule 64B5-14.003, F.A.C.

(5) Records: The treating dentist shall maintain a complete copy of the anesthesia records in the patient's dental chart. The dentist performing the anesthesia must maintain the original anesthesia records. The treating dentist must identify by name and license number all personnel utilized during the procedure.

Rulemaking Authority 466.004(4), 466.017 FS. Law Implemented 466.017 FS. History—New 3-14-13.

64B5-14.0036 Treatment of Sedated Patients by Dentists Without an Anesthesia Permit.

The provisions of this rule control the treatment of patients where an anesthesia permitted dentist sedates the dental patient in his or her board-inspected and board-registered dental office and a Florida licensed dentist without an anesthesia permit performs the dental treatment. This rule shall control notwithstanding any rule provision in this Chapter to the contrary, which prohibits such conduct.

(1) The permitted dentist shall perform the sedation in his or her out-patient dental office where the permitted dentist is registered to perform the anesthesia services;

(2) The permitted dentist shall remain with the patient from the onset of the performance of the anesthesia until discharge of the patient;

(3) The permitted dentist shall have no other patient induced with anesthesia or begin the performance of any other anesthesia services until the patient is discharged;

(4) The treating dentist shall have taken a minimum of four hours of continuing education in airway management prior to treating any sedated patient. Two hours must be in didactic training in providing dentistry on sedated patients with compromised airways and two hours must include hands-on training in airway management of sedated patients. After the initial airway management course, the treating dentist shall continue to repeat a minimum of four hours in airway management every four years from the date the course was last taken by the dentist. The continuing education courses taken may be credited toward the mandatory thirty hours of continuing education required for licensure renewal. The requirement that a dentist must first have taken an initial airway management course before treating a sedated patient shall not take effect until March 1, 2014.

Rulemaking Authority 466.004(4), 466.017 FS. Law Implemented 466.017 FS. History—New 3-14-13, Amended 8-19-13.

64B5-14.0038 Use of a Qualified Anesthetist.

In an outpatient dental office, and pursuant to Section 466.002(2), F.S., a dentist may supervise a qualified anesthetist who is administering anesthetic for a dental procedure on a patient of the supervising dentist. The type of supervision required is direct supervision as defined in Section 466.003(8), F.S. In an outpatient dental office, the supervising dentist must have a valid permit for administering sedation to the level of sedation that the qualified anesthetist will be administering to the dental patient during the dental procedure. The dentist must maintain all office equipment and medical supplies required by this chapter to the level of the sedation that the qualified anesthetist will administer to the dental patient.

Rulemaking Authority 466.004(4), 466.017 FS. Law Implemented 466.002(2), 466.017, 466.003(8) FS. History—New 11-11-13.

64B5-14.004 Additional Requirements.

(1) Office Team – A dentist licensed by the Board and practicing dentistry in Florida and who is permitted by these rules to induce and administer general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation or nitrous-oxide inhalation analgesia may employ the office team approach.

(2) Dental Assistants, Dental Hygienists – Dental assistants and dental hygienists may monitor nitrous-oxide inhalation analgesia under the direct supervision of a dentist who is permitted by rule to use general anesthesia, conscious sedation, pediatric conscious sedation, or nitrous-oxide inhalation analgesia, while rendering dental services allowed by Chapter 466, F.S., and under the following conditions:

(a) Satisfactory completion of no less than a two-day course of training as described in the American Dental Association's "Guidelines for Teaching and Comprehensive Control of Pain and Anxiety in Dentistry" or its equivalent; and

(b) Maintenance of competency in cardiopulmonary resuscitation evidenced by certification in an American Heart Association or American Red Cross or equivalent Agency sponsored cardiopulmonary resuscitation course at the basic life support level to

include one man CPR, two man CPR, infant resuscitation and obstructed airway, with a periodic update not to exceed two years.

(3) After the dentist has induced a patient and established the maintenance level, the assistant or hygienist may monitor the administration of the nitrous-oxide oxygen making only adjustments during this administration and turning it off at the completion of the dental procedure.

(4) Nothing in this rule shall be construed to allow a dentist or dental hygienist or assistant to administer to himself or to any person any drug or agent used for anesthesia, analgesia or sedation other than in the course of the practice of dentistry.

(5) A dentist utilizing conscious sedation in the dental office may induce only one patient at a time. A second patient shall not be induced until the first patient is awake, alert, conscious, spontaneously breathing, has stable vital signs, is ambulatory with assistance, is under the care of a responsible adult, and that portion of the procedure requiring the participation of the dentist is complete. In an office setting where two or more permit holders are present simultaneously, each may sedate one patient provided that the office has the necessary staff and equipment, as set forth in paragraph 64B5-14.003(2)(d), F.A.C., for each sedated patient.

(6) All dentists who hold an active sedation permit of any level must complete four (4) hours of continuing education in airway management and four (4) hours of continuing education in medical emergencies, every four (4) years from the last date the dentist took the continuing education course. The four (4) hours in airway management must include two hours didactic training in providing dentistry on sedated patients with compromised airways and two hours must include hands-on training in airway management of sedated patients. The continuing education must be taken through a board approved continuing education provider. The continuing education required by this subsection will take effect on March 1, 2014. The continuing education required by this subsection may be included in the thirty (30) hours required by Section 466.0135, F.S.

Rulemaking Authority 466.004(4), 466.017(3) FS. Law Implemented 466.017(3) FS. History—New 1-31-80, Amended 2-13-86, Formerly 21G-14.04, Amended 12-31-86, 12-28-92, Formerly 21G-14.004, Amended 12-20-93, Formerly 61F5-14.004, Amended 8-8-96, Formerly 59Q-14.004, Amended 11-4-03, 6-23-04, 5-24-05, 8-19-13.

64B5-14.005 Application for Permit.

(1) No dentist shall administer, supervise or permit another health care practitioner, as defined in Section 456.001, F.S., to perform the administration of general anesthesia, deep sedation, conscious sedation or pediatric conscious sedation in a dental office for dental patients, unless such dentist possesses a permit issued by the Board. A permit is required even when another health care practitioner, as defined in Section 456.001, F.S., administers general anesthesia, deep sedation, conscious sedation, or pediatric conscious sedation in a dental office for a dental patient. The dentist holding such a permit shall be subject to review and such permit must be renewed biennially. Each dentist in a practice who performs the administration of general anesthesia, deep sedation, conscious sedation or pediatric conscious sedation shall each possess an individual permit. Nothing in this paragraph shall be construed to prohibit administration of anesthetics as part of a program authorized by Rule 64B5-14.003, F.A.C., any other educational program authorized by Board rule, for training in the anesthetic being administered, or pursuant to a demonstration for inspectors pursuant to Rule 64B5-14.007, F.A.C.

(2) An applicant for any type of anesthesia permit must demonstrate both:

(a) Training in the particular type of anesthesia listed in Rule 64B5-14.003, F.A.C.; and

(b) Documentation of actual clinical administration of anesthetics to 20 dental or oral and maxillofacial patients within two (2) years prior to application of the particular type of anesthetics for the permit applied for.

(3) Prior to the issuance of such permit, an on-site inspection of the facility, equipment and personnel will be conducted pursuant to Rule 64B5-14.007, F.A.C., to determine if the requirements of this chapter have been met.

(4) An application for a general anesthesia permit must include the application fee specified in Rule 64B5-15.017, F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ general anesthesia or deep sedation.

(5) An application for a conscious sedation permit must include the application fee specified in Rule 64B5-15.017, F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ conscious sedation.

(6) An application for a pediatric conscious sedation permit must include the application fee specified in Rule 64B5-15.017,

F.A.C., which is non-refundable; the permit fee specified in Rule 64B5-15.018, F.A.C., which may be refunded if the application is denied without inspection of the applicant's facilities; evidence indicating compliance with all the provisions of this chapter; and identification of the location or locations at which the licensee desires to be authorized to use or employ pediatric conscious sedation.

(7) The Board shall renew the permit biennially upon application by the permit holder, proof of continuing education required by subsection 64B5-14.004(6), F.A.C., and payment of the renewal fee specified by Rule 64B5-15.019, F.A.C., unless the holder is informed in writing that a re-evaluation of his credentials and facility is to be required. In determining whether such re-evaluation is necessary, the Board shall consider such factors as it deems pertinent including, but not limited to, patient complaints, reports of adverse occurrences and the results of inspections conducted pursuant to Rule 64B5-14.007, F.A.C. Such re-evaluation shall be carried out in the manner described in subsection (2) set forth above. A renewal fee of \$25.00 must accompany the biennial application.

(8) The holder of any general anesthesia, conscious sedation, or pediatric conscious sedation permit is authorized to practice pursuant to such permit only at the location or locations previously reported to the Board office.

Rulemaking Authority 466.004, 466.017(3), 466.017(6) FS. Law Implemented 466.017, 466.017(5) FS. History—New 4-7-86, Amended 1-29-89, 11-16-89, 11-8-90, 4-24-91, Formerly 21G-14.005, Amended 12-20-93, Formerly 61F5-14.005, Amended 8-8-96, Formerly 59Q-14.005, Amended 12-12-00, 11-4-03, 6-23-04, 2-22-06, 6-28-07, 7-5-10, 8-5-12.

64B5-14.006 Reporting Adverse Occurrences.

(1) Definitions:

(a) *Adverse occurrence* – means any mortality that occurs during or as the result of a dental procedure, or an incident that results in the temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment of a dental patient that occurred during or as a direct result of the use of general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation, oral sedation, minimal sedation (anxiolysis), nitrous oxide, or local anesthesia.

(b) *Supervising Dentist* – means the dentist that was directly responsible for supervising the Certified Registered Dental Hygienist (CRDH) who is authorized by proper credentials to administer local anesthesia.

(2) Dentists: Any dentist practicing in the State of Florida must notify the Board in writing by registered mail within forty-eight hours (48 hrs.) of any mortality or other adverse occurrence that occurs in the dentist's outpatient facility. A complete written report shall be filed with the Board within thirty (30) days of the mortality or other adverse occurrence. The complete written report shall, at a minimum, include the following:

- (a) The name, address, and telephone number of the patient;
- (b) A detailed description of the dental procedure;
- (c) A detailed description of the preoperative physical condition of the patient;
- (d) A detailed list of the drugs administered and the dosage administered;
- (e) A detailed description of the techniques utilized in administering the drugs;
- (f) A detailed description of the adverse occurrence, to include 1) the onset and type of complications and the onset and type of symptoms experienced by the patient; 2) the onset and type of treatment rendered to the patient; and 3) the onset and type of response of the patient to the treatment rendered; and

(g) A list of all witnesses and their contact information to include their address.

(3) A failure by the dentist to timely and completely comply with all the reporting requirements mandated by this rule is a basis for disciplinary action by the Board, pursuant to Section 466.028(1), F.S.

(4) Certified Registered Dental Hygienists: Any CRDH administering local anesthesia must notify the Board, in writing by registered mail within forty-eight hours (48 hrs.) of any adverse occurrence that was related to or the result of the administration of local anesthesia. A complete written report shall be filed with the Board within thirty (30) days of the mortality or other adverse occurrence. The complete written report shall, at a minimum, include the following:

- (a) The name, address, and telephone number of the supervising dentist;
- (b) The name, address, and telephone number of the patient;
- (c) A detailed description of the dental procedure;
- (d) A detailed description of the preoperative physical condition of the patient;
- (e) A detailed list of the local anesthesia administered and the dosage of the local anesthesia administered;

- (f) A detailed description of the techniques utilized in administering the drugs;
 - (g) A detailed description of any other drugs the patient had taken or was administered;
 - (h) A detailed description of the adverse occurrence, to include 1) the onset and type of complications and the onset and type of symptoms experienced by the patient; 2) the onset and type of treatment rendered to the patient; and 3) the onset and type of response of the patient to the treatment rendered; and
 - (i) A list of all witnesses and their contact information to include their address.
- (5) A failure by the hygienist to timely and completely comply with all the reporting requirements mandated by this rule is a basis for disciplinary action by the Board pursuant to Section 466.028(1), F.S.

(6) Supervising Dentist:

If a Certified Registered Dental Hygienist is required to file a report under the provisions of this rule, the supervising dentist shall also file a contemporaneous report in accordance with subsection (2).

(7) The initial and complete reports required by this rule shall be mailed to: The Florida Board of Dentistry, 4052 Bald Cypress Way, Bin #C08, Tallahassee, Florida 32399-3258.

Rulemaking Authority 466.004(4), 466.017(3), (6) FS. Law Implemented 466.017(3), (5) FS. History—New 2-12-86, Amended 3-27-90, Formerly 21G-14.006, Amended 12-20-93, Formerly 61F5-14.006, Amended 8-8-96, Formerly 59Q-14.006, Amended 11-4-03, 12-25-06, 8-5-12.

64B5-14.007 Inspection of Facilities and Demonstration of Sedation Technique.

(1) The Chairman of the Board or the Board by majority vote shall appoint consultants who are Florida licensed dentists to inspect facilities where general anesthesia, deep sedation, conscious sedation, or pediatric conscious sedation is performed. Consultants shall receive instruction in inspection procedures from the Board prior to initiating an inspection.

(2) Prior to issuance of a general anesthesia permit, conscious sedation permit, or pediatric conscious sedation permit, the applicant must demonstrate that he or she has knowledge of the use of the required equipment and drugs as follows:

(a) Demonstration of General Anesthesia/Deep Sedation. A dental procedure utilizing general anesthesia/deep sedation must be observed and evaluated. Any general anesthesia/deep sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:

1. Airway obstruction;
2. Bronchospasm;
3. Aspiration of foreign object;
4. Angina pectoris;
5. Myocardial infarction;
6. Hypotension;
7. Hypertension;
8. Cardiac arrest;
9. Allergic reaction;
10. Convulsions;
11. Hypoglycemia;
12. Syncope; and
13. Respiratory depression.

(b) Demonstration of Conscious Sedation. A dental procedure utilizing conscious sedation must be observed and evaluated. Any conscious sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:

1. Airway obstruction;
2. Bronchospasm;
3. Aspiration of foreign object;
4. Angina pectoris;
5. Myocardial infarction;
6. Hypotension;

7. Hypertension;
8. Cardiac arrest;
9. Allergic reaction;
10. Convulsions;
11. Hypoglycemia;
12. Syncope; and
13. Respiratory depression.

(c) Demonstration of Pediatric Conscious Sedation. A dental procedure utilizing pediatric conscious sedation must be observed and evaluated. Any pediatric conscious sedation technique that is routinely employed may be demonstrated. The patient shall be monitored while sedated and during recovery. Furthermore, the dentist and his or her team must physically demonstrate by simulation an appropriate response to the following emergencies:

1. Airway obstruction;
2. Bronchospasm;
3. Aspiration of foreign object;
4. Angina pectoris;
5. Myocardial infarction;
6. Hypotension;
7. Hypertension;
8. Cardiac arrest;
9. Allergic reaction;
10. Convulsions;
11. Hypoglycemia;
12. Syncope; and
13. Respiratory depression.

(3) Any dentist who has applied for or received a general anesthesia permit, conscious sedation permit, or pediatric conscious sedation permit shall be subject to announced or unannounced on-site inspection and evaluation by an inspection consultant. This inspection and evaluation shall be required prior to issuance of an anesthesia permit. However, if the Department cannot complete the required inspection prior to licensure, such inspection shall be waived until such time that it can be completed following licensure.

(4) The inspection consultant shall determine compliance with the requirements of Rules 64B5-14.008, 64B5-14.009 and 64B5-14.010, F.A.C., as applicable, by assigning a grade of pass or fail.

(5) Any applicant who receives a failing grade as a result of the on-site inspection shall be denied a permit for general anesthesia and conscious sedation.

(6) Any permit holder who fails the inspection shall be so notified by the anesthesia inspection consultant and shall be given a written statement at the time of inspection which specifies the deficiencies which resulted in a failing grade. The inspection team shall give the permit holder 20 days from the date of inspection to correct any documented deficiencies. Upon notification by the permit holder to the inspection consultant that the deficiencies have been corrected, the inspector shall reinspect to insure that the deficiencies have been corrected. If the deficiencies have been corrected, a passing grade shall be assigned. No permit holder who has received a failing grade shall be permitted 20 days to correct deficiencies unless he voluntarily agrees in writing that no general anesthesia or deep sedation or conscious sedation will be performed until such deficiencies have been corrected and such corrections are verified by the anesthesia inspection consultant and a passing grade has been assigned.

(7) Upon a determination of the inspection consultant that a permit holder has received a failing grade and that the permit holder has not chosen to exercise his option by taking immediate remedial action and submitting to reinspection, or reinspection has established that remedial action has not been accomplished, the Inspection Consultant shall determine whether the deficiencies constitute an imminent danger to the public. Should an imminent danger exist, the consultant shall report his findings to the Executive Director of the Board. The Executive Director shall immediately request an emergency meeting of the Probable Cause Panel. The Probable Cause Panel shall determine whether an imminent danger exists and upon this determination of imminent danger request the Secretary of the Department to enter an emergency suspension of the anesthesia permit. If no imminent danger exists, the consultant shall report his findings to the Probable Cause Panel for further action against the permit holder. Nothing

herein is intended to affect the authority of the Secretary of the Department to exercise his emergency suspension authority independent of the Board or the Probable Cause Panel.

(8) When a patient death or other adverse occurrence as described in subsection 64B5-14.006(1), F.A.C., is reported to the Department pursuant to Rule 64B5-14.006, F.A.C., the initial report shall be faxed or otherwise telephonically transmitted to the Chairman of the Board's Probable Cause Panel or another designated member of the Probable Cause Panel to determine if an emergency suspension order is necessary. If so, the Department shall be requested to promptly conduct an investigation which shall include an inspection of the office involved in the patient death.

(a) If the results of the investigation substantiate the previous determination, an emergency suspension order shall be drafted and presented to the Secretary of the Department for consideration and execution. Thereafter, a conference call meeting of the Probable Cause Panel shall be held to determine the necessity of further administrative action.

(b) If the determination is made that an emergency does not exist, the office involved with the patient death shall be inspected as soon as practicable following receipt of the notice required by Rule 64B5-14.006, F.A.C. However, in the event that the office has previously been inspected with a passing result, upon review of the inspection results, the Chairman of the Probable Cause Panel or other designated member of the Probable Cause Panel shall determine whether or not a reinspection is necessary. The complete written report of the adverse occurrence as required in Rule 64B5-14.006, F.A.C., shall be provided to the Probable Cause Panel of the Board to determine if further action is appropriate.

(c) If a routine inspection reveals a failure to comply with Rule 64B5-14.006, F.A.C., the Inspection Consultant shall obtain the information which was required to be reported and shall determine whether the failure to report the death or incident reveals that an imminent danger to the public exists and report to the Executive Director or Probable Cause Panel as set forth in subsection 64B5-14.007(6), F.A.C.

(9) The holder of any general anesthesia, conscious sedation, or pediatric conscious sedation permit shall inform the Board office in writing of any change in authorized locations for the use of such permits prior to accomplishing such changes. Written notice shall be required prior to the addition of any location or the closure of any previously identified location.

(10) Failure to provide access to an inspection team on two successive occasions shall be grounds for the issuance of an emergency suspension of the licensee's permit pursuant to the provisions of Section 120.60(8), F.S.

Rulemaking Authority 466.017(3) FS. Law Implemented 120.60(8), 466.017(3) FS. History—New 10-24-88, Amended 3-27-90, 11-8-90, 4-24-91, 2-1-93, Formerly 21G-14.007, Amended 12-20-93, Formerly 61F5-14.007, Amended 8-8-96, Formerly 59Q-14.007, Amended 11-4-03, 6-11-07.

64B5-14.008 Requirements for General Anesthesia or Deep Sedation: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

General Anesthesia Permit applicants and permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

(1) Operatory: The operatory where anesthesia is to be administered must:

(a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;

(b) Be equipped with a chair or table adequate for emergency treatment, including a chair or cardiopulmonary resuscitation (CPR) board suitable for CPR;

(c) Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.

(2) Recovery Room: If a recovery room is present, it shall be equipped with suction and back up suction equipment, positive pressure oxygen and sufficient light to provide emergency treatment. The recovery room shall also be of adequate size and design to allow emergency access and management. The recovery room shall be situated to allow the patient to be observed by the dentist or an office team member at all times.

(3) Standard Equipment: The following equipment must be readily available to the operatory and recovery room and maintained in good working order:

(a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;

(b) Oral and nasal airways of various sizes;

(c) Blood pressure cuff and stethoscope;

- (d) Cardioscope – electrocardiograph (EKG) machine, pulse oximeter, and capnograph;
- (e) Precordial stethoscope;
- (f) Suction with backup suction, including suction catheters and tonsil suction;
- (g) Thermometer (Continuous temperature monitoring device, if volatile gases are used);
- (h) A backup lighting system; and
- (i) A scale to weigh patients.

(4) Emergency Equipment: The following emergency equipment must be present, readily available and maintained in good working order:

- (a) Appropriate I.V. set-up, including appropriate supplies and fluids;
- (b) Laryngoscope with spare batteries and spare bulbs;
- (c) McGill forceps, endotracheal tubes, and stylet;
- (d) Appropriate syringes;
- (e) Tourniquet and tape;
- (f) CPR board or chair suitable for CPR;
- (g) Defibrillator equipment appropriate for the patient population being treated;
- (h) Cricothyrotomy equipment; and
- (i) A Supraglottic Airway Device (SAD) or a Laryngeal Mask Airway (LMA).

(5) Medicinal Drugs: The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operatory and recovery room:

- (a) Epinephrine;
- (b) A narcotic (e.g., Naloxone) and benzodiazepine (e.g., Flumazenil) antagonist, if these agents are used;
- (c) An antihistamine (e.g., Diphenhydramine);
- (d) A corticosteroid (e.g., Dexamethasone);
- (e) Nitroglycerin;
- (f) A bronchodilator (e.g., Albuterol inhaler);
- (g) An antihypoglycemic agent (e.g., D50W IV solution);
- (h) Amiodarone;
- (i) A vasopressor (e.g., Ephedrine);
- (j) An anticonvulsant (e.g., Valium or Versed);
- (k) Antihypertensive (e.g., Labetalol);
- (l) Anticholinergic (e.g., atropine);
- (m) Antiemetic;
- (n) A muscle relaxant (e.g., Succinylcholine);
- (o) An appropriate antiarrhythmic medication (e.g., Lidocaine);
- (p) Adenosine; and
- (q) Dantrolene, if volatile gases are used.

(6) Emergency Protocols: The applicant or permit holder shall provide written emergency protocols, and shall provide training to familiarize office personnel in the treatment of the following clinical emergencies:

- (a) Laryngospasm;
- (b) Bronchospasm;
- (c) Emesis and aspiration;
- (d) Airway blockage by foreign body;
- (e) Angina pectoris;
- (f) Myocardial infarction;
- (g) Hypertension/Hypotension;
- (h) Hypertensive crisis;
- (i) Allergic and toxicity reactions;
- (j) Seizures;
- (k) Syncope;

- (l) Phlebitis;
- (m) Intra-arterial injection;
- (n) Hyperventilation/Hypoventilation;
- (o) Cardiac arrest; and
- (p) Cardiac arrhythmias.

The applicant or permit holder shall maintain for inspection a permanent record, which reflects the date, time, duration, and type of training provided to named personnel.

(7) Records: The following records are required when general anesthesia or deep sedation is administered:

- (a) The patient's current written medical history, including known allergies and previous surgery;
- (b) Physical examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);
- (c) Base line vital signs, including blood pressure, and pulse; and
- (d) An anesthesia record which shall include:
 1. Continuous monitoring of vital signs, which are taken and recorded at a minimum of every 5 minute intervals during the procedure;
 2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
 3. Duration of the procedure;
 4. Documentation of complications or morbidity (See Rule 64B5-14.006, F.A.C., for Adverse Incident Reporting Requirements);
 5. Status of patient upon discharge, and to whom the patient is discharged; and
 6. Names of participating personnel.

(8) Continuous Monitoring: The patient who is administered drug(s) for general anesthesia or deep sedation must be continuously monitored intra-operatively by electrocardiograph (EKG), pulse oximeter, and capnograph to provide heart rhythm and rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide). This equipment shall be used for each procedure.

Rulemaking Authority 466.004, 466.017 FS. Law Implemented 466.017 FS. History—New 10-24-88, Amended 11-16-89, Formerly 21G-14.008, Amended 12-20-93, Formerly 61F5-14.008, Amended 8-8-96, Formerly 59Q-14.008, Amended 5-31-00, 6-23-04, 9-14-05, 3-23-06, 10-24-11, 3-9-14.

64B5-14.009 Conscious Sedation Requirements: Operatory, Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

Conscious Sedation Permit applicants and permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

- (1) Operatory: The operatory where anesthesia is to be administered must:
 - (a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;
 - (b) Be equipped with a chair or table adequate for emergency treatment, including a chair or cardiopulmonary resuscitation (CPR) board suitable for CPR;
 - (c) Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.
- (2) Recovery Room: If a recovery room is present, it shall be equipped with suction and backup suction equipment, positive pressure oxygen and sufficient light to provide emergency treatment. The recovery room shall also be of adequate size and design to allow emergency access and management. The recovery room shall be situated to allow the patient to be observed by the dentist or an office team member at all times.
- (3) Standard Equipment: The following standard equipment must be readily available to the operatory and recovery room and must be maintained in good working order:
 - (a) A positive pressure oxygen delivery system and backup system, including full face mask for adults and for pediatric patients, if pediatric patients are treated;
 - (b) Oral and nasal airways of various sizes;
 - (c) Blood pressure cuff and stethoscope;

(d) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;

- (e) A Precordial stethoscope;
- (f) Capnograph;
- (g) Suction with backup suction, also including suction catheters and tonsil suction;
- (h) Thermometer;
- (i) A backup lighting system; and,
- (j) A scale to weigh patients.

(4) Emergency Equipment: The following emergency equipment must be present, readily available and must be maintained in good working order:

- (a) Appropriate I.V. set-up, including appropriate supplies and fluids;
- (b) Laryngoscope with spare batteries and spare bulbs;
- (c) McGill forceps, endotracheal tubes, and stylet;
- (d) Appropriate syringes;
- (e) Tourniquet and tape;
- (f) CPR board or chair suitable for CPR;
- (g) Defibrillator equipment appropriate for the patient population being treated;
- (h) Cricothyrotomy equipment; and,
- (i) A Supraglottic Airway Device (SAD) or a Laryngeal Mask Airway (LMA).

(5) Medicinal Drugs: The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operatory and recovery room:

- (a) Epinephrine;
- (b) A narcotic (e.g., Naloxone) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
- (c) An antihistamine (e.g., Diphenhydramine);
- (d) A corticosteroid (e.g., Dexamethasone);
- (e) Nitroglycerin;
- (f) A bronchodilator (e.g., Albuterol inhaler);
- (g) An antihypoglycemic agent (e.g., D50W IV solution);
- (h) Amiodarone;
- (i) A vasopressor (e.g., Ephedrine);
- (j) An anticonvulsant (e.g., Valium or Versed);
- (k) Antihypertensive (e.g., Labetalol);
- (l) Anticholinergic (e.g., atropine);
- (m) Antiemetic;
- (n) A muscle relaxant (e.g., Succinylcholine);
- (o) An appropriate antiarrhythmic medication (e.g., Lidocaine); and,
- (p) Adenosine.

(6) Emergency Protocols: The applicant or permit holder shall provide written emergency protocols, and shall provide training to familiarize office personnel in the treatment of the following clinical emergencies:

- (a) Laryngospasm;
- (b) Bronchospasm;
- (c) Emesis and aspiration;
- (d) Airway blockage by foreign body;
- (e) Angina pectoris;
- (f) Myocardial infarction;
- (g) Hypertension/Hypotension;
- (h) Hypertensive crisis;
- (i) Allergic and toxicity reactions;
- (j) Seizures;

- (k) Syncope;
- (l) Phlebitis;
- (m) Intra-arterial injection;
- (n) Hyperventilation/Hypoventilation;
- (o) Cardiac arrest; and
- (p) Cardiac arrhythmias.

The applicant or permit holder shall maintain for inspection a permanent record, which reflects the date, time, duration, and type of training provided to named personnel.

(7) Records: The following records are required when conscious sedation is administered:

- (a) The patient's current written medical history, including known allergies and previous surgery;
- (b) Physical examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);
- (c) Base line vital signs, including blood pressure, and pulse; and,
- (d) A sedation or anesthesia record which shall include:
 1. Continuous monitoring of vital signs, which are taken and recorded at a minimum of every 5 minute intervals during the procedure;
 2. Drugs administered during the procedure, including route of administration, dosage, time and sequence of administration;
 3. Duration of the procedure;
 4. Documentation of complications or morbidity (See Rule 64B5-14.006, F.A.C., for Adverse Incident Reporting requirements);
 5. Status of patient upon discharge, and to whom the patient is discharged; and
 6. Names of participating personnel.

(8) Continuous Monitoring: The patient who is administered a drug(s) for conscious sedation must be continuously monitored intraoperatively by pulse oximetry, and capnograph to provide pulse rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide). A precordial/pretracheal stethoscope must be available to assist in the monitoring of the heart rate and ventilations.

Rulemaking Authority 466.004, 466.017 FS. Law Implemented 466.017 FS. History—New 10-24-88, Amended 11-16-89, 4-24-91, Formerly 21G-14.009, 61F5-14.009, Amended 8-8-96, 10-1-96, Formerly 59Q-14.009, Amended 8-2-00, 11-4-03, 6-23-04, 3-23-06, 10-26-11, 3-9-14, 4-17-16.

64B5-14.010 Pediatric Conscious Sedation Requirements: Operatory; Recovery Room, Equipment, Medicinal Drugs, Emergency Protocols, Records, and Continuous Monitoring.

Pediatric Conscious Sedation Permit applicants and permit holders shall comply with the following requirements at each location where anesthesia procedures are performed. The requirements shall be met and equipment permanently maintained and available at each location.

(1) Operatory: The operatory where the sedated child patient is to be treated must:

- (a) Be of adequate size and design to permit physical access of emergency equipment and personnel and to permit effective emergency management;
- (b) Be equipped with a chair or table adequate for emergency treatment, including a cardiopulmonary resuscitation (CPR) board of chair suitable for CPR;
- (c) Be equipped with suction and backup suction equipment, also including suction catheters and tonsil suction.

(2) Recovery Room: If a recovery room is present, it shall be equipped with suction and backup suction equipment, positive pressure oxygen and sufficient light to provide emergency treatment. The recovery room shall also be of adequate size and design to allow emergency access and management. The recovery room shall be situated so that the patient can be observed by the dentist or an office team member at all times.

(3) Standard Equipment: The following equipment must be readily available to the operatory and recovery room and maintained in good working order:

- (a) A positive pressure oxygen delivery system and backup system, including full face mask for pediatric patients;
- (b) Oral and Nasal Airways of appropriate size for the pediatric patient;
- (c) Blood pressure cuff and stethoscope or automated unit;
- (d) A pulse oximeter which provides continuous monitoring of pulse and rate of oxygen saturation of the blood shall be used during each procedure;

- (e) A Precordial stethoscope;
- (f) Capnograph;
- (g) Suction with backup suction, also including suction catheters and tonsil suction;
- (h) Thermometer;
- (i) A backup lighting system; and,
- (j) A scale for weighing pediatric patients.

(4) Emergency Equipment: The following emergency equipment must be present, readily available and maintained in good working order:

- (a) Appropriate I.V. set-up, including appropriate supplies and fluids;
- (b) Laryngoscope with spare batteries and spare bulbs;
- (c) McGill forceps, endotracheal tubes, and stylet;
- (d) Suction with backup suction, also including suction catheters and tonsil suction;
- (e) Appropriate syringes;
- (f) Tourniquet and tape;
- (g) CPR board or chair suitable for CPR;
- (h) Defibrillator equipment appropriate for the patient population being treated; and,
- (i) Cricothyrotomy equipment.
- (j) A Supraglottic Airway Device (SAD) or a Laryngeal Mask Airway (LMA).

(5) Medicinal Drugs: The following drugs or type of drugs with a current shelf life must be maintained and easily accessible from the operatory and recovery room:

- (a) Epinephrine;
- (b) A narcotic (e.g., Naloxone) and benzodiazepine (e.g., Flumazenil) antagonists, if these agents are used;
- (c) An antihistamine (e.g., Diphenhydramine HCl);
- (d) A corticosteroid (e.g., Dexamethasone);
- (e) Nitroglycerin;
- (f) A bronchodilator (e.g., Albuterol inhaler);
- (g) An antihypoglycemic agent (e.g., D50W IV solution);
- (h) Amiodarone;
- (i) A vasopressor (e.g., Ephedrine);
- (j) An anticonvulsant (e.g., Valium or Versed);
- (k) Antihypertensive (e.g., Labetalol);
- (l) Anticholinergic (e.g., atropine);
- (m) Antimetic;
- (n) A muscle relaxant (e.g., Succinylcholine);
- (o) An appropriate antiarrhythmic medication (e.g., Lidcaine); and
- (p) Adenosine.

(6) Emergency Protocols: The applicant or permit holder shall provide written emergency protocols, and shall provide training to familiarize office personnel in the treatment of the following clinical emergencies:

- (a) Laryngospasm;
- (b) Bronchospasm;
- (c) Emesis and aspiration;
- (d) Airway blockage by foreign body;
- (e) Angina pectoris;
- (f) Myocardial infarction;
- (g) Hypertension/Hypotension;
- (h) Hypertensive crisis;
- (i) Allergic and toxicity reactions;
- (j) Seizures;
- (k) Syncope;

- (l) Phlebitis;
- (m) Intra-arterial injection;
- (n) Hyperventilation/Hypoventilation;
- (o) Cardiac arrest; and
- (p) Cardiac arrhythmias.

The applicant or permit holder shall maintain for inspection a permanent record, which reflects the date, time, duration, and type of training provided to named personnel.

(7) Records: The following records are required when pediatric conscious sedation is administered:

(a) The patient's current written medical history, including known allergies, history of previous surgery and anesthesia, and the patient's age, weight, and calculation of maximum allowable local anesthesia;

(b) Physical examination including airway evaluation and risk assessment (e.g., Mallampati Classification, Body Mass Index, and ASA Classification);

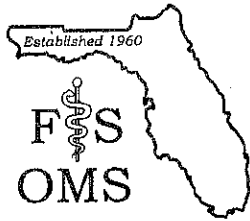
(c) Base line vital signs, including pulse, percent hemoglobin oxygen saturation, and when possible, blood pressure; and,

(d) An anesthesia or sedation record which shall include:

1. Periodic vital signs recorded a minimum of every 5 minute intervals during the procedure;
2. Drugs, including local anesthetics, administered during the procedure, including route of administration, dosage, time and sequence of administration;
3. Duration of the procedure;
4. Documentation of complications or morbidity (See Rule 64B5-14.0006, F.A.C., for Adverse Incident Reporting Requirements);
5. Status of patient upon discharge, and to whom the patient is discharged; and,
6. Names of participating personnel.

(8) Continuous Monitoring: The patient who is administered a drug(s) for conscious sedation must be continuously monitored intra-operatively by pulse oximetry and capnograph to provide pulse rate, oxygen saturation of the blood, and ventilations (end-tidal carbon dioxide).

Rulemaking Authority 466.004, 466.017 FS. Law Implemented 466.017 FS. History—New 8-8-96, Formerly 59Q-14.010, Amended 8-2-00, 5-20-01, 3-23-06, 10-26-11, 3-9-14, 4-17-16.



Florida Society of Oral and Maxillofacial Surgeons

July 25, 2016

Dr. T. J. Tejera, Chairman
Anesthesia Committee
Department of Health
Board of Dentistry
4052 Bald Cypress Way Bin C-08
Tallahassee, FL 32399-3258

Dear Dr. Tejera:

In response to recent media coverage of recent tragic deaths of patients under sedation in dental and OMS offices in California, Texas, and now in Florida, which attracted much media and legislative attention, FSOMS formed a task force to respond to the issue, and pro-actively present to the Board of Dentistry suggestions for improving the safety of sedation in dental offices in Florida.

The ADA is coincidentally soliciting comments to a planned revision and improvement of the ADA Guidelines on education, training, and administration of sedation in dental offices. However, Florida has always been at the forefront of education, office inspection, continuing education, equipment, and facilities requirements, and we do not feel bound by the ADA's suggested guidelines, which are at best minimum standards of practice. Rather we seek to promote "*best practices*" for dental office sedation and anesthesia in Florida.

1. Currently, there are CRNAs providing sedation and general anesthesia in dental offices that have no sedation permit or only a limited moderate sedation permit. This does not follow the "anesthesia team" model that we espouse, as the dentists are not trained to assist in the sedation and not capable of assisting the CRNA in the event of an emergency. Currently, CRNAs can only provide conscious sedation in the office of a dentist whose permit is limited to conscious sedation. This means no use of propofol or other anesthetic drugs with a narrow margin of safety as described in the dental practice act. CRNAs can provide deep sedation and general anesthesia in the office of a dentist with a general anesthesia permit. The Board of Dentistry should send a friendly letter and/or attend a Board of Nursing and Board of Medicine meeting to ask for their assistance in informing their members of the Board of Dentistry rules.
2. Currently there is a problem with CRNAs going into dental offices and not advising the dentist of the need for an office inspection, and of the need for the dentist to have a sedation permit. Although CRNAs cannot be legally supervised or regulated by the Board of Dentistry, CRNAs should be required to register with the Florida Board of Dentistry to administer sedation and anesthesia in a dental office, so that the medical and nurse providers can be made aware of the Board of Dentistry rules regarding administration of sedation in dental offices, and the

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- Board is aware of those offices using CRNA services. This is currently a requirement in many of other states.
3. Currently, the Board requires a four hour, hands-on course in airway management every other biennium to maintain a sedation or general anesthesia permit. This should be strengthened to require a five hour hands-on, "high-fidelity" simulation course in emergency management for both moderate sedation and general anesthesia providers and their anesthesia team, with SimMan (or other simulation) technology (such as now provided by the AAOMS, the ADA, the ADSA, or FDSA), consisting of one hour didactic training, and 4 hours hands-on simulation training/practice. This course should be required for both the issuance of the initial permit and every other biennium for permit renewal. The initial permit should be issued contingent on completing the emergency simulation training within six months of obtaining the permit, if it has not been accomplished during a formal residency prior to the permit application.
 4. Require that all dental or surgical assistants assisting during the administration of sedation or general anesthesia be certified in anesthesia assisting by the Dental Anesthesia Assistant National Certification Examination. RNs or EMTs used as dental or surgical assistants are exempt by the nature of their prior training. This requirement must be for all sedation & anesthesia providers, whether dentists, CRNAs, or MDs.
 5. Currently office inspectors are merely given a check-off list with no training or guidance on how to conduct the site visit, and as a result office inspectors vary widely in how they conduct the site visits. All too often the inspectors are not familiar with the state anesthesia rules and regulations themselves, and give incorrect information. They should be knowledgeable about the rules, and be able to educate the offices on these rules during the inspection.
 - a. The Board of Dentistry should conduct formal training for office anesthesia inspectors, and develop written guidelines and rules for both the initial and the recurring office anesthesia permit site inspections beyond the current simple check-off list.
 - b. The guidelines should describe the parameters of the inspection in detail, and office inspectors must be trained in how to conduct an office inspection.
 - c. The dentist and office being evaluated must be given parameters for dental patient and case selection, and guidelines for demonstrating his anesthesia technique. For example, guidelines for the depth of sedation to be demonstrated, the type of dental procedure to include, how many cases to demonstrate.
 - d. Specific guidelines should be developed on how to conduct the anesthesia emergency simulation portion of the site visit.
 - e. Guidelines must be given on how to grade an office, how to give probation, how to fail an office, and how to request an emergency office suspension if they find a dangerous situation.
 - f. The 4/5 year office re-inspection must include observation of at least one live patient sedation administration, to the level of the permit applied for.
 6. Moderate sedation providers are not allowed to provide itinerant sedation services, and this existing rule needs to be reinforced, strengthened, and enforced.
 7. All offices in which sedation or general anesthesia is administered must be individually inspected, and each dentist's facility, permit, equipment, supplies, and team evaluated. The mobile CRNA can certify that the anesthesia monitors

that they use, once inspected in one office, is inspected yearly and is the same monitor used in every office they attend.

Thank you for your consideration, and best regards,

Sincerely,

A handwritten signature in black ink that reads "Carlos Coro DDS". The signature is written in a cursive, slightly slanted style.

Carlos Coro, DDS
President

ADA American Dental Association®

Guidelines for the Use of Sedation and General Anesthesia by Dentists

Adopted by the ADA House of Delegates, October 2016

I. Introduction

The administration of local anesthesia, sedation and general anesthesia is an integral part of dental practice. The American Dental Association is committed to the safe and effective use of these modalities by appropriately educated and trained dentists. The purpose of these guidelines is to assist dentists in the delivery of safe and effective sedation and anesthesia.

Dentists must comply with their state laws, rules and/or regulations when providing sedation and anesthesia and will only be subject to Section III. Educational Requirements as required by those state laws, rules and/or regulations.

Level of sedation is entirely independent of the route of administration. Moderate and deep sedation or general anesthesia may be achieved via any route of administration and thus an appropriately consistent level of training must be established.

For children, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

II. Definitions

Methods of Anxiety and Pain Control

minimal sedation (previously known as anxiolysis) - a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient's ability to independently and continuously maintain an airway and respond *normally* to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.¹

Patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.

The following definitions apply to administration of minimal sedation:

maximum recommended dose (MRD) - maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.

dosing for minimal sedation via the enteral route – minimal sedation may be achieved by the administration of a drug, either singly or in divided doses, by the enteral route to achieve the desired clinical effect, not to exceed the maximum recommended dose (MRD).

The administration of enteral drugs exceeding the maximum recommended dose during a single appointment is considered to be moderate sedation and the moderate sedation guidelines apply.

Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.

If more than one enteral drug is administered to achieve the desired sedation effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. The use of the MRD to guide dosing for minimal sedation is intended to create this margin of safety.

moderate sedation - a drug-induced depression of consciousness during which patients respond *purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.¹

Note: In accord with this particular definition, 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. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The following definition applies to the administration of moderate or greater sedation:

titration - administration of incremental doses of an intravenous or inhalation drug until a desired effect is reached. Knowledge of each drug's time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.

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.¹

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.

Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.¹

For all levels of sedation, the qualified dentist must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

Routes of Administration

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

parenteral - a technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), intraosseous (IO)].

transdermal - a technique of administration in which the drug is administered by patch or iontophoresis through skin.

transmucosal - a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

inhalation - a technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

Terms

analgesia – the diminution or elimination of pain.

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

Note: Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthetics in themselves may result in central nervous system depression, especially in combination with sedative agents.

qualified dentist - a dentist providing sedation and anesthesia in compliance with their state rules and/or regulations.

operating dentist – dentist with primary responsibility for providing operative dental care while a qualified dentist or independently practicing qualified anesthesia healthcare provider administers minimal, moderate or deep sedation or general anesthesia.

competency – displaying special skill or knowledge derived from training and experience.

must/shall - indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

should - indicates the recommended manner to obtain the standard; highly desirable.

may - indicates freedom or liberty to follow a reasonable alternative.

continual - repeated regularly and frequently in a steady succession.

continuous - prolonged without any interruption at any time.

time-oriented anesthesia record - documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

immediately available – on site in the facility and available for immediate use.

American Society of Anesthesiologists (ASA) Patient Physical Status Classification²

Classification	Definition	Examples, including but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, *ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or *ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	

*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

American Society of Anesthesiologists Fasting Guidelines³

Ingested Material	Minimum Fasting Period
Clear liquids	2 hours
Breast milk	4 hours
Infant formula	6 hours
Nonhuman milk	6 hours
Light meal	6 hours
Fatty meal	8 hours

III. Educational Requirements

A. Minimal Sedation

1. To administer minimal sedation the dentist must demonstrate competency by having successfully completed:
 - a. training in minimal sedation consistent with that prescribed in the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*,

or

- b. comprehensive training in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced,

or

- c. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage minimal sedation commensurate with these guidelines;

and

- d. a current certification in Basic Life Support for Healthcare Providers.

- 2. Administration of minimal sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

B. Moderate Sedation

- 1. To administer moderate sedation, the dentist must demonstrate competency by having successfully completed:

- a. a comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced,

or

- b. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines;

and

- c. 1) A current certification in Basic Life Support for Healthcare Providers and
2) Either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.

- 2. Administration of moderate sedation by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support for Healthcare Providers.

C. Deep Sedation or General Anesthesia

- 1. To administer deep sedation or general anesthesia, the dentist must demonstrate competency by having completed:

- a. An advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with Part IV.C of these guidelines;

and

- b. 1) A current certification in Basic Life Support for Healthcare Providers and
2) either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same re-certification cycle that is required for ACLS.
2. Administration of deep sedation or general anesthesia by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support (BLS) Course for the Healthcare Provider.

IV. Clinical Guidelines

A. Minimal sedation

1. Patient History and 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 should consist of a review of their current medical history and medication use. In addition, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-Operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- An appropriate focused physical evaluation should be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, and respiration rate must be obtained unless invalidated by the nature of the patient, procedure or equipment. Body temperature should be measured when clinically indicated.
- Preoperative dietary restrictions must be considered based on the sedative technique prescribed.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.

3. Personnel and Equipment Requirements

Personnel:

- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers' recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.

4. Monitoring and Documentation

Monitoring: A dentist, or at the dentist's direction, an appropriately trained individual, must remain in the operatory during active dental treatment to monitor the patient continuously until the patient meets the criteria for discharge to the recovery area. The appropriately trained individual must be familiar with monitoring techniques and equipment. Monitoring must include:

Consciousness:

- Level of sedation (e.g., responsiveness to verbal commands) must be continually assessed.

Oxygenation:

- Oxygen saturation by pulse oximetry may be clinically useful and should be considered.

Ventilation:

- The dentist and/or appropriately trained individual must observe chest excursions.
- The dentist and/or appropriately trained individual must verify respirations.

Circulation:

- Blood pressure and heart rate should be evaluated pre-operatively, post-operatively and intraoperatively as necessary (unless the patient is unable to tolerate such monitoring).

Documentation: An appropriate sedative record must be maintained, including the names of all drugs administered, time administered and route of administration, including local anesthetics, dosages, and monitored physiological parameters.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must monitor the patient during recovery until the patient is ready for discharge by the dentist.
- The qualified dentist must determine and document that level of consciousness, oxygenation, ventilation and circulation are satisfactory prior to discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.

6. Emergency Management

- 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 is returned to the intended level of sedation.
- The qualified 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.

B. Moderate Sedation

1. Patient History and Evaluation

Patients considered for moderate sedation must undergo an evaluation prior to the administration of any sedative. This should consist of at least a review at an appropriate time of their medical history and

medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI)⁴ should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative agents and informed consent for the proposed sedation must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- An appropriate focused physical evaluation must be performed.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless precluded by the nature of the patient, procedure or equipment. Body temperature should be measured when clinically indicated.
- Pre-operative verbal or written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.

3. Personnel and Equipment Requirements

Personnel:

- At least one additional person trained in Basic Life Support for Healthcare Providers must be present in addition to the dentist.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers' recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration of sedation must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.
- The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available.
- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravascular or intraosseous access should be available until the patient meets discharge criteria.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are 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:

Consciousness:

- Level of sedation (e.g., responsiveness to verbal command) must be continually assessed.

Oxygenation:

- Oxygen saturation must be evaluated by pulse oximetry continuously.

Ventilation:

- The dentist must observe chest excursions continually.
- The dentist must monitor ventilation and/or breathing by monitoring end-tidal CO₂ unless precluded or invalidated by the nature of the patient, procedure or equipment. In addition, ventilation should be monitored by continual observation of qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.

Circulation:

- The dentist must continually evaluate blood pressure and heart rate unless invalidated by the nature of the patient, procedure or equipment and this is noted in the time-oriented anesthesia record.
- Continuous ECG monitoring of patients with significant cardiovascular disease should be considered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics, dosages and monitored physiological parameters.
- Pulse oximetry, heart rate, respiratory rate, blood pressure and level of consciousness must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The qualified dentist or appropriately trained clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The qualified dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.
- If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

6. Emergency Management

- 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 is returned to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.

C. Deep Sedation or General Anesthesia

1. Patient History and Evaluation

Patients considered for deep sedation or general anesthesia must undergo an evaluation prior to the administration of any sedative. This must consist of at least a review of their medical history and medication use and NPO (nothing by mouth) status. In addition, patients with significant medical considerations (e.g., ASA III, IV) should also require consultation with their primary care physician or consulting medical specialist. Assessment of Body Mass Index (BMI)⁴ should be considered part of a pre-procedural workup. Patients with elevated BMI may be at increased risk for airway associated morbidity, particularly if in association with other factors such as obstructive sleep apnea.

2. Pre-operative Evaluation and Preparation

- The patient, parent, legal guardian or care giver must be advised regarding the procedure associated with the delivery of any sedative or anesthetic agents and informed consent for the proposed sedation/anesthesia must be obtained.
- Determination of adequate oxygen supply and equipment necessary to deliver oxygen under positive pressure must be completed.
- A focused physical evaluation must be performed as deemed appropriate.
- Baseline vital signs including body weight, height, blood pressure, pulse rate, respiration rate, and blood oxygen saturation by pulse oximetry must be obtained unless invalidated by the patient, procedure or equipment. In addition, body temperature should be measured when clinically appropriate.
- Pre-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver, including pre-operative fasting instructions based on the ASA Summary of Fasting and Pharmacologic Recommendations.
- An intravenous line, which is secured throughout the procedure, must be established except as provided in part IV. C.6. Special Needs Patients.

3. Personnel and Equipment Requirements

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

- A dentist qualified in accordance with part III. C. of these Guidelines to administer the deep sedation or general anesthesia.
- Two additional individuals who have current certification of successfully completing a Basic Life Support (BLS) Course for the Healthcare Provider.
- When the same individual administering the deep sedation or general anesthesia is performing the dental procedure, one of the additional appropriately trained team members must be designated for patient monitoring.

Equipment:

- A positive-pressure oxygen delivery system suitable for the patient being treated must be immediately available.
- Documentation of compliance with manufacturers' recommended maintenance of monitors, anesthesia delivery systems, and other anesthesia-related equipment should be maintained. A pre-procedural check of equipment for each administration must be performed.
- When inhalation equipment is used, it must have a fail-safe system that is appropriately checked and calibrated. The equipment must also have either (1) a functioning device that prohibits the delivery of less than 30% oxygen or (2) an appropriately calibrated and functioning in-line oxygen analyzer with audible alarm.

- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravenous access must be available.
- Equipment and drugs necessary to provide advanced airway management, and advanced cardiac life support must be immediately available.
- The equipment necessary for monitoring end-tidal CO₂ and auscultation of breath sounds must be immediately available.
- Resuscitation medications and an appropriate defibrillator must be immediately available.

4. Monitoring and Documentation

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

Oxygenation:

- Oxygenation saturation must be evaluated continuously by pulse oximetry.

Ventilation:

- Intubated patient: End-tidal CO₂ must be continuously monitored and evaluated.
- Non-intubated patient: End-tidal CO₂ must be continually monitored and evaluated unless precluded or invalidated by the nature of the patient, procedure, or equipment. In addition, ventilation should be monitored and evaluated by continual observation of qualitative signs, including auscultation of breath sounds with a precordial or pretracheal stethoscope.
- Respiration rate must be continually monitored and evaluated.

Circulation:

- The dentist must continuously evaluate heart rate and rhythm via ECG throughout the procedure, as well as pulse rate via pulse oximetry.
- The dentist must continually evaluate blood pressure.

Temperature:

- A device capable of measuring body temperature must be readily available during the administration of deep sedation or general anesthesia.
- The equipment to continuously monitor body temperature should be available and must be performed whenever triggering agents associated with malignant hyperthermia are administered.

Documentation:

- Appropriate time-oriented anesthetic record must be maintained, including the names of all drugs, dosages and their administration times, including local anesthetics and monitored physiological parameters.
- Pulse oximetry and end-tidal CO₂ measurements (if taken), heart rate, respiratory rate and blood pressure must be recorded continually.

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The dentist or clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.

- Post-operative verbal and written instructions must be given to the patient, and parent, escort, guardian or care giver.

6. 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 should document the reasons preventing the recommended preoperative management.

In selected circumstances, deep sedation or general anesthesia may be utilized without establishing an indwelling intravenous line. These selected circumstances may include very brief procedures or periods of time, which, for example, may occur in some patients; or the establishment of intravenous access after deep sedation or general anesthesia has been induced because of poor patient cooperation.

7. Emergency Management

The qualified dentist is responsible for sedative/anesthetic management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of deep sedation or general anesthesia and providing the equipment, drugs and protocols for patient rescue.

1 Excerpted from Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, 2014, of the American Society of Anesthesiologists (ASA)

2 ASA Physical Status Classification System is reprinted with permission of the American Society of Anesthesiologists, Updated by ASA House of Delegates, October 15, 2014.

3 American Society of Anesthesiologists: Practice Guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. Anesthesiology 114:495. 2011. Reprinted with permission.

4 Standardized BMI category definitions can be obtained from the Centers for Disease Control and Prevention or the American Society of Anesthesiologists.

ADA American Dental Association®

Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students

Adopted by the ADA House of Delegates, October 2016

I. Introduction

The administration of local anesthesia, sedation and general anesthesia is an integral part of the practice of dentistry. The American Dental Association is committed to the safe and effective use of these modalities by appropriately educated and trained dentists.

Anxiety and pain control can be defined as the application of various physical, chemical and psychological modalities to the prevention and treatment of preoperative, operative and postoperative patient anxiety and pain to allow dental treatment to occur in a safe and effective manner. It involves all disciplines of dentistry and, as such, is one of the most important aspects of dental education. The intent of these *Guidelines* is to provide direction for the teaching of pain control and sedation to dentists and can be applied at all levels of dental education from predoctoral through continuing education. They are designed to teach initial competency in pain control and minimal and moderate sedation techniques.

These *Guidelines* recognize that many dentists have acquired a high degree of competency in the use of anxiety and pain control techniques through a combination of instruction and experience. It is assumed that this has enabled these teachers and practitioners to meet the educational criteria described in this document.

It is not the intent of the *Guidelines* to fit every program into the same rigid educational mold. This is neither possible nor desirable. There must always be room for innovation and improvement. They do, however, provide a reasonable measure of program acceptability, applicable to all institutions and agencies engaged in predoctoral and continuing education.

The curriculum in anxiety and pain control is a continuum of educational experiences that will extend over several years of the predoctoral program. It should provide the dental student with the knowledge and skills necessary to provide minimal sedation to alleviate anxiety and control pain without inducing detrimental physiological or psychological side effects. Dental schools whose goal is to have predoctoral students achieve competency in techniques such as local anesthesia and nitrous oxide inhalation and minimal sedation must meet all of the goals, prerequisites, didactic content, clinical experiences, faculty and facilities, as described in these *Guidelines*.

Techniques for the control of anxiety and pain in dentistry should include both psychological and pharmacological modalities. Psychological strategies should include simple relaxation techniques for the anxious patient and more comprehensive behavioral techniques to control pain. Pharmacological strategies should include not only local anesthetics but also sedatives, analgesics and other useful agents. Dentists should learn indications and techniques for administering these drugs enterally, parenterally and by inhalation as supplements to local anesthesia.

The predoctoral curriculum should provide instruction, exposure and/or experience in anxiety and pain control, including minimal and moderate sedation. The predoctoral program must also provide the knowledge and skill to enable students to recognize and manage any emergencies that might arise as a consequence of treatment. Predoctoral dental students must complete a course in Basic Life Support for the Healthcare Provider. Though Basic Life Support courses are available online, any course taken online should be followed up with a hands-on component and be approved by the American Heart Association or the American Red Cross.

Local anesthesia is the foundation of pain control in dentistry. Although the use of local anesthetics in dentistry has a long record of safety, dentists must be aware of the maximum safe dosage limit for each patient, since large doses of local anesthetics may increase the level of central nervous system depression with sedation. The use of minimal and moderate sedation requires an understanding of local anesthesia and the physiologic and pharmacologic implications of the local anesthetic agents when combined with the sedative agents.

Level of sedation is entirely independent of the route of administration. Moderate and deep sedation or general anesthesia may be achieved via any route of administration and thus an appropriately consistent level of training must be established.

For children, the American Dental Association supports the use of the American Academy of Pediatrics/American Academy of Pediatric Dentistry Guidelines for Monitoring and Management of Pediatric Patients During and After Sedation for Diagnostic and Therapeutic Procedures.

The knowledge, skill and clinical experience required for the safe administration of deep sedation and/or general anesthesia are beyond the scope of predoctoral and continuing education programs. Advanced education programs that teach deep sedation and/or general anesthesia to competency have specific teaching requirements described in the Commission on Dental Accreditation requirements for those advanced programs and represent the educational and clinical requirements for teaching deep sedation and/or general anesthesia in dentistry.

The objective of educating dentists to utilize pain control, sedation and general anesthesia is to enhance their ability to provide oral health care. The American Dental Association urges dentists to participate regularly in continuing education update courses in these modalities in order to remain current.

All areas in which local anesthesia and sedation are being used must be properly equipped with suction, physiologic monitoring equipment, a positive pressure oxygen delivery system suitable for the patient being treated and emergency drugs. Protocols for the management of emergencies must be developed and training programs held at frequent intervals.

II. Definitions

Methods of Anxiety and Pain Control

minimal sedation (previously known as anxiolysis) - a minimally depressed level of consciousness, produced by a pharmacological method, that retains the patient's ability to independently and continuously maintain an airway and respond *normally* to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.¹

Patients whose only response is reflex withdrawal from repeated painful stimuli would not be considered to be in a state of minimal sedation.

The following definitions apply to administration of minimal sedation:

maximum recommended dose (MRD) - maximum FDA-recommended dose of a drug, as printed in FDA-approved labeling for unmonitored home use.

dosing for minimal sedation via the enteral route - minimal sedation may be achieved by the administration of a drug, either singly or in divided doses, by the enteral route to achieve the desired clinical effect, not to exceed the maximum recommended dose (MRD).

The administration of enteral drugs exceeding the maximum recommended dose during a single appointment is considered to be moderate sedation and the moderate sedation guidelines apply.

Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.

If more than one enteral drug is administered to achieve the desired sedation effect, with or without the concomitant use of nitrous oxide, the guidelines for moderate sedation must apply.

Note: In accord with this particular definition, the drug(s) and/or techniques used should carry a margin of safety wide enough never to render unintended loss of consciousness. The use of the MRD to guide dosing for minimal sedation is intended to create this margin of safety.

moderate sedation - a drug-induced depression of consciousness during which patients respond *purposefully* to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.¹

Note: In accord with this particular definition, 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. Further, a patient whose only response is reflex withdrawal from a painful stimulus is not considered to be in a state of moderate sedation.

The following definition applies to administration of moderate and deeper levels of sedation:

titration - administration of incremental doses of an intravenous or inhalation drug until a desired effect is reached. Knowledge of each drug's time of onset, peak response and duration of action is essential to avoid over sedation. Although the concept of titration of a drug to effect is critical for patient safety, when the intent is moderate sedation one must know whether the previous dose has taken full effect before administering an additional drug increment.

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.¹

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.¹

Because sedation and general anesthesia are a continuum, it is not always possible to predict how an individual patient will respond. Hence, practitioners intending to produce a given level of sedation should be able to diagnose and manage the physiologic consequences (rescue) for patients whose level of sedation becomes deeper than initially intended.¹

For all levels of sedation, the qualified dentist must have the training, skills, drugs and equipment to identify and manage such an occurrence until either assistance arrives (emergency medical service) or the patient returns to the intended level of sedation without airway or cardiovascular complications.

Routes of Administration

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

parenteral - a technique of administration in which the drug bypasses the gastrointestinal (GI) tract [i.e., intramuscular (IM), intravenous (IV), intranasal (IN), submucosal (SM), subcutaneous (SC), intraosseous (IO)].

transdermal - a technique of administration in which the drug is administered by patch or iontophoresis through skin.

transmucosal - a technique of administration in which the drug is administered across mucosa such as intranasal, sublingual, or rectal.

inhalation - a technique of administration in which a gaseous or volatile agent is introduced into the lungs and whose primary effect is due to absorption through the gas/blood interface.

Terms

analgesia - the diminution or elimination of pain.

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

Note: Although the use of local anesthetics is the foundation of pain control in dentistry and has a long record of safety, dentists must always be aware of the maximum, safe dosage limits for each patient. Large doses of local anesthetics in themselves may result in central nervous system depression especially in combination with sedative agents.

qualified dentist - a dentist providing sedation and anesthesia in compliance with their state rules and/or regulations.

must/shall - indicates an imperative need and/or duty; an essential or indispensable item; mandatory.

should - indicates the recommended manner to obtain the standard; highly desirable.

may - indicates freedom or liberty to follow a reasonable alternative.

continual - repeated regularly and frequently in a steady succession.

continuous - prolonged without any interruption at any time.

time-oriented anesthesia record - documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

immediately available - on site in the facility and available for immediate use.

Levels of Knowledge

familiarity - a simplified knowledge for the purpose of orientation and recognition of general principles.

in-depth - a thorough knowledge of concepts and theories for the purpose of critical analysis and the synthesis of more complete understanding (highest level of knowledge).

Levels of Skill

exposed - the level of skill attained by observation of or participation in a particular activity.

competent - displaying special skill or knowledge derived from training and experience.

American Society of Anesthesiologists (ASA) Patient Physical Status Classification²

Classification	Definition	Examples, including but not limited to:
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Examples include (but not limited to): current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Examples include (but not limited to): poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, *ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (>3 months) of MI, CVA, TIA, or CAD/stents.
ASA IV	A patient with severe systemic disease that is a constant threat to life	Examples include (but not limited to): recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or *ESRD not undergoing regularly scheduled dialysis
ASA V	A moribund patient who is not expected to survive without the operation	Examples include (but not limited to): ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	
*The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)		

American Society of Anesthesiologists' Fasting Guidelines³

Ingested Material	Minimum Fasting Period
Clear liquids	2 hours
Breast milk	4 hours
Infant formula	6 hours
Nonhuman milk	6 hours
Light meal	6 hours
Fatty meal	8 hours

Education Courses

Education may be offered at different levels (competency, update, survey courses and advanced education programs). A description of these different levels follows:

1. Competency Courses are designed to meet the needs of dentists who wish to become competent in the safe and effective administration of local anesthesia, minimal and moderate sedation. They consist of lectures, demonstrations and sufficient clinical participation to assure the faculty that the dentist understands the procedures taught and can

safely and effectively apply them so that mastery of the subject is achieved. Faculty must assess and document the dentist's competency upon successful completion of such training. To maintain competency, periodic update courses must be completed.

2. Update Courses are designed for persons with previous training. They are intended to provide a review of the subject and an introduction to recent advances in the field. They should be designed didactically and clinically to meet the specific needs of the participants. Participants must have completed previous competency training (equivalent, at a minimum, to the competency course described in this document) and have current experience to be eligible for enrollment in an update course.

3. Survey Courses are designed to provide general information about subjects related to pain control and sedation. Such courses should be didactic and not clinical in nature, since they are not intended to develop clinical competency.

4. Advanced Education Courses are a component of an advanced dental education program, accredited by the Commission on Dental Accreditation in accord with the *Accreditation Standards* for advanced dental education programs. These courses are designed to prepare the graduate dentist or postdoctoral student in the most comprehensive manner to be competent in the safe and effective administration of minimal, moderate and deep sedation and general anesthesia.

III. Teaching Pain Control

These *Guidelines* present a basic overview of the recommendations for teaching pain control.

A. General Objectives: Upon completion of a predoctoral curriculum in pain control the dentist must:

1. have an in-depth knowledge of those aspects of anatomy, physiology, pharmacology and psychology involved in the use of various anxiety and pain control methods;
2. be competent in evaluating the psychological and physical status of the patient, as well as the magnitude of the operative procedure, in order to select the proper regimen;
3. be competent in monitoring vital functions;
4. be competent in prevention, recognition and management of related complications;
5. have in-depth knowledge of the appropriateness of and the indications for medical consultation or referral;
6. be competent in the maintenance of proper records with accurate chart entries recording medical history, physical examination, vital signs, drugs administered and patient response.

B. Pain Control Curriculum Content:

1. Philosophy of anxiety and pain control and patient management, including the nature and purpose of pain
2. Review of physiologic and psychologic aspects of anxiety and pain
3. Review of airway anatomy and physiology
4. Physiologic monitoring
 - a. Observation
 - (1) Central nervous system
 - (2) Respiratory system

- a. Oxygenation
 - b. Ventilation
 - (3) Cardiovascular system
- b. Monitoring equipment
- 5. Pharmacologic aspects of anxiety and pain control
 - a. Routes of drug administration
 - b. Sedatives and anxiolytics
 - c. Local anesthetics
 - d. Analgesics and antagonists
 - e. Adverse side effects
 - f. Drug interactions
 - g. Drug abuse
- 6. Control of preoperative and operative anxiety and pain
 - a. Patient evaluation
 - (1) Psychological status
 - (2) ASA physical status
 - (3) Type and extent of operative procedure
 - b. Nonpharmacologic methods
 - (1) Psychological and behavioral methods
 - (a) Anxiety management
 - (b) Relaxation techniques
 - (c) Systematic desensitization
 - (2) Interpersonal strategies of patient management
 - (3) Hypnosis
 - (4) Electronic dental anesthesia
 - (5) Acupuncture/Acupressure
 - (6) Other
- c. Local anesthesia
 - (1) Review of related anatomy, and physiology
 - (2) Pharmacology
 - (i) Dosing
 - (ii) Toxicity
 - (iii) Selection of agents
 - (3) Techniques of administration
 - (i) Topical
 - (ii) Infiltration (supraperiosteal)
 - (iii) Nerve block – maxilla-to include:
 - (aa) Posterior superior alveolar
 - (bb) Infraorbital
 - (cc) Nasopalatine
 - (dd) Greater palatine
 - (ee) Maxillary (2nd division)
 - (ff) Other blocks
 - (iv) Nerve block – mandible-to include:
 - (aa) Inferior alveolar-lingual
 - (bb) Mental-incisive
 - (cc) Buccal
 - (dd) Gow-Gates
 - (ee) Closed mouth
 - (v) Alternative injections-to include:

- (aa) Periodontal ligament
- (bb) Intraosseous
- d. Prevention, recognition and management of complications and emergencies

C. Sequence of Pain Control Didactic and Clinical Instruction: Beyond the basic didactic instruction in local anesthesia, additional time should be provided for demonstrations and clinical practice of the injection techniques. The teaching of other methods of anxiety and pain control, such as the use of analgesics and enteral, inhalation and parenteral sedation, should be coordinated with a course in pharmacology. By this time the student also will have developed a better understanding of patient evaluation and the problems related to prior patient care. As part of this instruction, the student should be taught the techniques of venipuncture and physiologic monitoring. Time should be included for demonstration of minimal and moderate sedation techniques.

Following didactic instruction in minimal and moderate sedation, the student must receive sufficient clinical experience to demonstrate competency in those techniques in which the student is to be certified. It is understood that not all institutions may be able to provide instruction to the level of clinical competence in pharmacologic sedation modalities to all students. The amount of clinical experience required to achieve competency will vary according to student ability, teaching methods and the anxiety and pain control modality taught.

Clinical experience in minimal and moderate sedation techniques should be related to various disciplines of dentistry and not solely limited to surgical cases. Typically, such experience will be provided in managing healthy adult patients.

Throughout both didactic and clinical instruction in anxiety and pain control, psychological management of the patient should also be stressed. Instruction should emphasize that the need for sedative techniques is directly related to the patient's level of anxiety, cooperation, medical condition and the planned procedures.

D. Faculty: Instruction must be provided by qualified faculty for whom anxiety and pain control are areas of major proficiency, interest and concern.

E. Facilities: Competency courses must be presented where adequate facilities are available for proper patient care, including drugs and equipment for the management of emergencies.

IV. Teaching Administration of Minimal Sedation

The faculty responsible for curriculum in minimal sedation techniques must be familiar with the ADA Policy Statement: *Guidelines for the Use of Sedation and General Anesthesia by Dentists*, and the Commission on Dental Accreditation's *Accreditation Standards* for dental education programs.

These *Guidelines* present a basic overview of the recommendations for teaching minimal sedation. These include courses in nitrous oxide/oxygen sedation, enteral sedation, and combined inhalation/enteral techniques.

General Objectives: Upon completion of a competency course in minimal sedation, the dentist must be able to:

1. Describe the adult anatomy and physiology of the respiratory, cardiovascular and central nervous systems, as they relate to the above techniques.
2. Describe the pharmacological effects of drugs.
3. Describe the methods of obtaining a medical history and conduct an appropriate physical examination.
4. Apply these methods clinically in order to obtain an accurate evaluation.
5. Use this information clinically for ASA classification risk assessment and pre-procedure fasting instructions.
6. Choose the most appropriate technique for the individual patient.

7. Use appropriate physiologic monitoring equipment.
8. Describe the physiologic responses that are consistent with minimal sedation.
9. Understand the sedation/general anesthesia continuum.
10. Demonstrate the ability to diagnose and treat emergencies related to the next deeper level of anesthesia than intended.

Inhalation Sedation (Nitrous Oxide/Oxygen)

A. Inhalation Sedation Course Objectives: Upon completion of a competency course in inhalation sedation techniques, the dentist must be able to:

1. Describe the basic components of inhalation sedation equipment.
2. Discuss the function of each of these components.
3. List and discuss the advantages and disadvantages of inhalation sedation.
4. List and discuss the indications and contraindications of inhalation sedation.
5. List the complications associated with inhalation sedation.
6. Discuss the prevention, recognition and management of these complications.
7. Administer inhalation sedation to patients in a clinical setting in a safe and effective manner.
8. Discuss the abuse potential, occupational hazards and other untoward effects of inhalation agents.

B. Inhalation Sedation Course Content:

1. Historical, philosophical and psychological aspects of anxiety and pain control.
2. Patient evaluation and selection through review of medical history taking, physical diagnosis and psychological considerations.
3. Definitions and descriptions of physiological and psychological aspects of anxiety and pain.
4. Description of the stages of drug-induced central nervous system depression through all levels of consciousness and unconsciousness, with special emphasis on the distinction between the conscious and the unconscious state.
5. Review of adult respiratory and circulatory physiology and related anatomy.
6. Pharmacology of agents used in inhalation sedation, including drug interactions and incompatibilities.
7. Indications and contraindications for use of inhalation sedation.
8. Review of dental procedures possible under inhalation sedation.
9. Patient monitoring using observation and monitoring equipment (i.e., pulse oximetry), with particular attention to vital signs and reflexes related to pharmacology of nitrous oxide.
10. Importance of maintaining proper records with accurate chart entries recording medical history, physical examination, vital signs, drugs and doses administered and patient response.

11. Prevention, recognition and management of complications and life-threatening situations.
12. Administration of local anesthesia in conjunction with inhalation sedation techniques.
13. Description, maintenance and use of inhalation sedation equipment.
14. Introduction to potential health hazards of trace anesthetics and proposed techniques for limiting occupational exposure.
15. Discussion of abuse potential.

C. Inhalation Sedation Course Duration: While length of a course is only one of the many factors to be considered in determining the quality of an educational program, the course should be a minimum of *14 hours* plus management of clinical dental cases, during which clinical competency in inhalation sedation technique is achieved. The inhalation sedation course most often is completed as a part of the predoctoral dental education program. However, the course may be completed in a postdoctoral continuing education competency course.

D. Participant Evaluation and Documentation of Inhalation Sedation Instruction: Competency courses in inhalation sedation techniques must afford participants with sufficient clinical experience to enable them to achieve competency. This experience must be provided under the supervision of qualified faculty and must be evaluated. The course director must certify the competency of participants upon satisfactory completion of training. Records of the didactic instruction and clinical experience, including the number of patients treated by each participant must be maintained and available.

E. Faculty: The course should be directed by a dentist or physician qualified by experience and training. This individual should possess an active permit or license to administer moderate sedation in at least one state, have had at least three years of experience, including the individual's formal postdoctoral training in anxiety and pain control. In addition, the participation of highly qualified individuals in related fields, such as anesthesiologists, pharmacologists, internists, and cardiologists and psychologists, should be encouraged.

A participant-faculty ratio of not more than ten-to-one when inhalation sedation is being used allows for adequate supervision during the clinical phase of instruction; a one-to-one ratio is recommended during the early state of participation.

The faculty should provide a mechanism whereby the participant can evaluate the performance of those individuals who present the course material.

F. Facilities: Competency courses must be presented where adequate facilities are available for proper patient care, including drugs and equipment for the management of emergencies.

Enteral and/or Combination Inhalation-Enteral Minimal Sedation

A. Enteral and/or Combination Inhalation-Enteral Minimal Sedation Course Objectives: Upon completion of a competency course in enteral and/or combination inhalation-enteral minimal sedation techniques, the dentist must be able to:

1. Describe the basic components of inhalation sedation equipment.
2. Discuss the function of each of these components.
3. List and discuss the advantages and disadvantages of enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation).

4. List and discuss the indications and contraindications for the use of enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation).
5. List the complications associated with enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation).
6. Discuss the prevention, recognition and management of these complications.
7. Administer enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation) to patients in a clinical setting in a safe and effective manner.
8. Discuss the abuse potential, occupational hazards and other effects of enteral and inhalation agents.
9. Discuss the pharmacology of the enteral and inhalation drugs selected for administration.
10. Discuss the precautions, contraindications and adverse reactions associated with the enteral and inhalation drugs selected.
11. Describe a protocol for management of emergencies in the dental office and list and discuss the emergency drugs and equipment required for management of life-threatening situations.
12. Demonstrate the ability to manage life-threatening emergency situations, including current certification in Basic Life Support for Healthcare Providers.
13. Discuss the pharmacological effects of combined drug therapy, their implications and their management. Nitrous oxide/oxygen when used in combination with sedative agent(s) may produce minimal, moderate, deep sedation or general anesthesia.

B. Enteral and/or Combination Inhalation-Enteral Minimal Sedation Course Content:

1. Historical, philosophical and psychological aspects of anxiety and pain control.
2. Patient evaluation and selection through review of medical history taking, physical diagnosis and psychological profiling.
3. Definitions and descriptions of physiological and psychological aspects of anxiety and pain.
4. Description of the stages of drug-induced central nervous system depression through all levels of consciousness and unconsciousness, with special emphasis on the distinction between the conscious and the unconscious state.
5. Review of adult respiratory and circulatory physiology and related anatomy.
6. Pharmacology of agents used in enteral and/or combination inhalation-enteral minimal sedation, including drug interactions and incompatibilities.
7. Indications and contraindications for use of enteral and/or combination inhalation-enteral minimal sedation (combined minimal sedation).
8. Review of dental procedures possible under enteral and/or combination inhalation-enteral minimal sedation).
9. Patient monitoring using observation, monitoring equipment, with particular attention to vital signs and reflexes related to consciousness.

10. Maintaining proper records with accurate chart entries recording medical history, physical examination, informed consent, time-oriented anesthesia record, including the names of all drugs administered including local anesthetics, doses, and monitored physiological parameters.
11. Prevention, recognition and management of complications and life-threatening situations.
12. Administration of local anesthesia in conjunction with enteral and/or combination inhalation-enteral minimal sedation techniques.
13. Description, maintenance and use of inhalation sedation equipment.
14. Introduction to potential health hazards of trace anesthetics and proposed techniques for limiting occupational exposure.
15. Discussion of abuse potential.

C. Enteral and/or Combination Inhalation-Enteral Minimal Sedation Course Duration: Participants must be able to document current certification in Basic Life Support for Healthcare Providers and have completed a nitrous oxide competency course to be eligible for enrollment in this course. While length of a course is only one of the many factors to be considered in determining the quality of an educational program, the course should include a minimum of *16 hours*, plus clinically-oriented experiences during which competency in enteral and/or combined inhalation-enteral minimal sedation techniques is demonstrated. Clinically-oriented experiences may include group observations on patients undergoing enteral and/or combination inhalation-enteral minimal sedation. Clinical experience in managing a compromised airway is critical to the prevention of life-threatening emergencies. The faculty should schedule participants to return for additional clinical experience if competency has not been achieved in the time allotted. The educational course may be completed in a predoctoral dental education curriculum or a postdoctoral continuing education competency course.

D. Participant Evaluation and Documentation of Instruction: Competency courses in combination inhalation-enteral minimal sedation techniques must afford participants with sufficient clinical understanding to enable them to achieve competency. The course director must certify the competency of participants upon satisfactory completion of the course. Records of the course instruction must be maintained and available.

E. Faculty: The course should be directed by a dentist or physician qualified by experience and training. This individual should possess a current permit or license to administer moderate sedation in at least one state, have had at least three years of experience, including the individual's formal postdoctoral training in anxiety and pain control. Dental faculty with broad clinical experience in the particular aspect of the subject under consideration should participate. In addition, the participation of highly qualified individuals in related fields, such as anesthesiologists, pharmacologists, internists, and cardiologists and psychologists, should be encouraged. The faculty should provide a mechanism whereby the participant can evaluate the performance of those individuals who present the course material.

F. Facilities: Competency courses must be presented where adequate facilities are available for proper patient care, including drugs and equipment for the management of emergencies.

V. Teaching Administration of Moderate Sedation

These *Guidelines* present a basic overview of the requirements for a competency course in moderate sedation. These include courses in enteral and parenteral moderate sedation. The teaching guidelines contained in this section on moderate sedation differ slightly from documents in medicine to reflect the differences in delivery methodologies and practice environment in dentistry.

Completion of a pre-requisite nitrous oxide-oxygen competency course is required for participants combining moderate sedation with nitrous oxide-oxygen.

A. Course Objectives: Upon completion of a course in moderate sedation, the dentist must be able to:

1. List and discuss the advantages and disadvantages of moderate sedation.
2. Discuss the prevention, recognition and management of complications associated with moderate sedation.
3. Administer moderate sedation to patients in a clinical setting in a safe and effective manner.
4. Discuss the abuse potential, occupational hazards and other untoward effects of the agents utilized to achieve moderate sedation.
5. Describe and demonstrate the technique of intravenous access, intramuscular injection and other parenteral techniques.
6. Discuss the pharmacology of the drug(s) selected for administration.
7. Discuss the precautions, indications, contraindications and adverse reactions associated with the drug(s) selected.
8. Administer the selected drug(s) to dental patients in a clinical setting in a safe and effective manner.
9. List the complications associated with techniques of moderate sedation.
10. Describe a protocol for management of emergencies in the dental office and list and discuss the emergency drugs and equipment required for the prevention and management of emergency situations.
11. Discuss principles of advanced cardiac life support or an appropriate dental sedation/anesthesia emergency course equivalent.
12. Demonstrate the ability to manage emergency situations.
13. Demonstrate the ability to diagnose and treat emergencies related to the next deeper level of anesthesia than intended.

B. Moderate Sedation Course Content:

1. Historical, philosophical and psychological aspects of anxiety and pain control.
2. Patient evaluation and selection through review of medical history taking, physical diagnosis and psychological considerations.
3. Use of patient history and examination for ASA classification, risk assessment and pre-procedure fasting instructions.
4. Definitions and descriptions of physiological and psychological aspects of anxiety and pain.
5. Description of the sedation anesthesia continuum, with special emphasis on the distinction between the conscious and the unconscious state.
6. Review of adult respiratory and circulatory physiology and related anatomy.

7. Pharmacology of local anesthetics and agents used in moderate sedation, including drug interactions and contraindications.
8. Indications and contraindications for use of moderate sedation.
9. Review of dental procedures possible under moderate sedation.
10. Patient monitoring using observation and monitoring equipment, with particular attention to vital signs, ventilation/breathing and reflexes related to consciousness.
11. Maintaining proper records with accurate chart entries recording medical history, physical examination, informed consent, time-oriented anesthesia record, including the names of all drugs administered including local anesthetics, doses, and monitored physiological parameters.
12. Prevention, recognition and management of complications and emergencies.
13. Description, maintenance and use of moderate sedation monitors and equipment.
14. Discussion of abuse potential.
15. Intravenous access: anatomy, equipment and technique.
16. Prevention, recognition and management of complications of venipuncture and other parenteral techniques.
17. Description and rationale for the technique to be employed.
18. Prevention, recognition and management of systemic complications of moderate sedation, with particular attention to airway maintenance and support of the respiratory and cardiovascular systems.

Moderate Sedation Course Duration and Documentation:

The Course must include:

- A minimum of 60 hours of instruction plus administration of sedation for at least 20 individually managed patients.
- Certification of competence in moderate sedation technique(s).
- Certification of competence in rescuing patients from a deeper level of sedation than intended including managing the airway, intravascular or intraosseous access, and reversal medications.
- Provision by course director or faculty of additional clinical experience if participant competency has not been achieved in time allotted.
- Records of instruction and clinical experiences (i.e., number of patients managed by each participant in each modality/route) that are maintained and available for participant review.

D. Documentation of Instruction: The course director must certify the competency of participants upon satisfactory completion of training in each moderate sedation technique, including instruction, clinical experience, managing the airway, intravascular/intraosseous access, and reversal medications.

E. Faculty: The course should be directed by a dentist or physician qualified by experience and training. This individual should possess a current permit or license to administer moderate or deep sedation and general anesthesia in at least one state, have had at least three years of experience, including formal postdoctoral training in anxiety and pain control. Dental faculty with broad clinical experience in the particular aspect of the subject under consideration should participate. In addition, the participation of highly qualified individuals in related fields, such as anesthesiologists, pharmacologists, internists, cardiologists and psychologists, should be encouraged.

A participant-faculty ratio of not more than four-to-one when moderate sedation is being taught allows for adequate supervision during the clinical phase of instruction. A one-to-one ratio is recommended during the early stage of participation.

The faculty should provide a mechanism whereby the participant can evaluate the performance of those individuals who present the course material.

F. Facilities: Competency courses in moderate sedation must be presented where adequate facilities are available for proper patient care, including drugs and equipment for the management of emergencies. These facilities may include dental and medical schools/offices, hospitals and surgical centers.

1 Excerpted from Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/Analgesia, 2014, of the American Society of Anesthesiologists (ASA)

2 ASA Physical Status Classification System is reprinted with permission of the American Society of Anesthesiologists, Updated by ASA House of Delegates, October 15, 2014.

3 American Society of Anesthesiologists: Practice Guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration: application to healthy patients undergoing elective procedures. Anesthesiology 114:495. 2011. Reprinted with permission.