VIRGINIA BOARD OF DENTISTRY

Invitation to an Open Forum on the Controlled Substances, Sedation and Anesthesia Regulations

Friday, December 1, 2017
Open Forum – 1:45pm to 3:15pm
Regulatory Advisory Panel meeting – 3:15pm to 4:30pm
Training Room 1, 2nd Floor, Perimeter Center
9960 Mayland Drive, Henrico, VA 23233

The Board of Dentistry (Board) is reviewing Part VI. of the Regulations Governing the Practice of Dentistry on Controlled Substances, Sedation and Anesthesia. This Open Forum begins the review process and is being convened by the appointed Regulatory Advisory Panel (RAP) which will review the comments received and develop recommendations for consideration by the Board's Regulatory/Legislative Committee (Committee).

The Open Forum is an opportunity for interested individuals, institutions and organizations to present their views on the current regulations and to make recommendations for improving the clarity and consistency of the requirements. Of particular interest to the Board is clarifying the requirements for pre-operative, peri-operative, and post-operative vital signs for each level of sedation and clarify the use of an end-tidal carbon dioxide monitor (capnography).

Speakers will be given up to seven minutes to express their views on the current regulations and to make recommendations for change. A transcript of the proceedings will be made to facilitate review by the RAP to identify changes it wishes to advance for consideration by the Committee.

Any policy action the Board decides to take will include the standard comment opportunities required to amend regulations.

Attached for your consideration are:
Part VI of the Regulations Governing the Practice of Dentistry
ADA Guidelines for the Use of Sedation and General Anesthesia by Dentists
ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students

Commonwealth of Virginia

REGULATIONS GOVERNING THE PRACTICE OF DENTISTRY

VIRGINIA BOARD OF DENTISTRY

Title of Regulations: 18 VAC 60-21-10 et seq.

Statutory Authority: § 54.1-2400 and Chapter 27 of Title 54.1 of the *Code of Virginia*

Effective Date: October 4, 2017

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Part VI. Controlled Substances, Sedation, and Anesthesia.

18VAC60-21-260. General provisions.

A. Application of Part VI. This part applies to prescribing, dispensing, and administering controlled substances in dental offices, mobile dental facilities, and portable dental operations and shall not apply to administration by a dentist practicing in (i) a licensed hospital as defined in § 32.1-123 of the Code, (ii) a state-operated hospital, or (iii) a facility directly maintained or operated by the federal government.

B. Registration required. Any dentist who prescribes, administers, or dispenses Schedules II through V controlled drugs must hold a current registration with the federal Drug Enforcement Administration.

C. Patient evaluation required.

1. The decision to administer controlled drugs for dental treatment must be based on a documented evaluation of the health history and current medical condition of the patient in accordance with the Class I through V risk category classifications of the American Society of Anesthesiologists (ASA) in effect at the time of treatment. The findings of the evaluation, the ASA risk assessment class assigned, and any special considerations must be recorded in the patient's record.

2. Any level of sedation and general anesthesia may be provided for a patient who is ASA Class I and Class II.

3. A patient in ASA Class III shall only be provided minimal sedation, conscious/moderate sedation, deep sedation, or general anesthesia by:

a. A dentist after he has documented a consultation with the patient's primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary;

b. An oral and maxillofacial surgeon who has performed a physical evaluation and documented the findings and the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary; or

c. A person licensed under Chapter 29 (§ 54.1-2900 et seq.) of Title 54.1 of the Code who has a specialty in anesthesia.

4. Minimal sedation may only be provided for a patient who is in ASA Class IV by:

a. A dentist after he has documented a consultation with the patient's primary care physician or other medical specialist regarding potential risks and special monitoring requirements that may be necessary; or

b. An oral and maxillofacial surgeon who has performed a physical evaluation and documented the findings and the ASA risk assessment category of the patient and any special monitoring requirements that may be necessary.

5. Conscious/moderate sedation, deep sedation, or general anesthesia shall not be provided in a dental office for patients in ASA Class IV and Class V.

D. Additional requirements for patient information and records. In addition to the record requirements in 18VAC60-21-90, when conscious/moderate sedation, deep sedation, or general anesthesia is administered, the patient record shall also include:

1. Notation of the patient's American Society of Anesthesiologists classification;

2. Review of medical history and current conditions, including the patient's weight and height or, if appropriate, the body mass index;

3. Written informed consent for administration of sedation and anesthesia and for the dental procedure to be performed;

4. Preoperative vital signs;

5. A record of the name, dose, and strength of drugs and route of administration including the administration of local anesthetics with notations of the time sedation and anesthesia were administered;

6. Monitoring records of all required vital signs and physiological measures recorded every five minutes; and

7. A list of staff participating in the administration, treatment, and monitoring including name, position, and assigned duties.

E. Pediatric patients. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dentist office or treatment facility.

F. Informed written consent. Prior to administration of any level of sedation or general anesthesia, the dentist shall discuss the nature and objectives of the planned level of sedation or general anesthesia along with the risks, benefits, and alternatives and shall obtain informed, written consent from the patient or other responsible party for the administration and for the treatment to be provided. The written consent must be maintained in the patient record.

G. Level of sedation. The determinant for the application of the rules for any level of sedation or for general anesthesia shall be the degree of sedation or consciousness level of a patient that should reasonably be expected to result from the type, strength, and dosage of medication, the method of administration, and the individual characteristics of the patient as documented in the patient's record. The drugs and techniques used must carry a margin of safety wide enough to render the unintended reduction of or loss of consciousness unlikely, factoring in titration and the patient's age, weight, and ability to metabolize drugs.

H. Emergency management.

1. If a patient enters a deeper level of sedation than the dentist is qualified and prepared to provide, the dentist shall stop the dental procedure until the patient returns to and is stable at the intended level of sedation.

2. A dentist in whose office sedation or anesthesia is administered shall have written basic emergency procedures established and staff trained to carry out such procedures.

I. Ancillary personnel. Dentists who employ unlicensed, ancillary personnel to assist in the administration and monitoring of any form of minimal sedation, conscious/moderate sedation, deep sedation, or general anesthesia shall maintain documentation that such personnel have:

1. Training and hold current certification in basic resuscitation techniques with hands-on airway training for health care providers, such as Basic Cardiac Life Support for Health Professionals or a clinically oriented course devoted primarily to responding to clinical emergencies offered by an approved provider of continuing education as set forth in 18VAC60-21-250 C; or

2. Current certification as a certified anesthesia assistant (CAA) by the American Association of Oral and Maxillofacial Surgeons or the American Dental Society of Anesthesiology (ADSA).

J. Assisting in administration. A dentist, consistent with the planned level of administration (i.e., local anesthesia, minimal sedation, conscious/moderate sedation, deep sedation, or general anesthesia) and appropriate to his education, training, and experience, may utilize the services of a dentist, anesthesiologist, certified registered nurse anesthetist, dental hygienist, dental assistant, or nurse to perform functions appropriate to such practitioner's education, training, and experience and consistent with that practitioner's respective scope of practice.

K. Patient monitoring.

1. A dentist may delegate monitoring of a patient to a dental hygienist, dental assistant, or nurse who is under his direction or to another dentist, anesthesiologist, or certified registered nurse anesthetist. The person assigned to monitor the patient shall be continuously in the presence of the patient in the office, operatory, and recovery area (i) before administration is initiated or immediately upon arrival if the patient self-administered a sedative agent, (ii) throughout the administration of drugs, (iii) throughout the treatment of the patient, and (iv) throughout recovery until the patient is discharged by the dentist.

2. The person monitoring the patient shall:

a. Have the patient's entire body in sight;

b. Be in close proximity so as to speak with the patient;

c. Converse with the patient to assess the patient's ability to respond in order to determine the patient's level of sedation;

d. Closely observe the patient for coloring, breathing, level of physical activity, facial expressions, eye movement, and bodily gestures in order to immediately recognize and bring any changes in the patient's condition to the attention of the treating dentist; and

e. Read, report, and record the patient's vital signs and physiological measures.

L. A dentist who allows the administration of general anesthesia, deep sedation, or conscious/moderate sedation in his dental office is responsible for assuring that:

1. The equipment for administration and monitoring, as required in subsection B of 18VAC60-21-291 or subsection C of 18VAC60-21-301, is readily available and in good working order prior to performing dental treatment with anesthesia or sedation. The equipment shall either be maintained by the dentist in his office or provided by the anesthesia or sedation provider; and

2. The person administering the anesthesia or sedation is appropriately licensed and the staff monitoring the patient is qualified.

18VAC60-21-270. Administration of local anesthesia.

A dentist may administer or use the services of the following personnel to administer local anesthesia:

1. A dentist;

2. An anesthesiologist;

3. A certified registered nurse anesthetist under his medical direction and indirect supervision;

4. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older under his indirect supervision;

5. A dental hygienist to administer Schedule VI topical oral anesthetics under indirect supervision or under his order for such treatment under general supervision; or

6. A dental assistant or a registered or licensed practical nurse to administer Schedule VI topical oral anesthetics under indirect supervision.

18VAC60-21-279. Administration of only inhalation analgesia (nitrous oxide).

A. Education and training requirements. A dentist who utilizes nitrous oxide shall have training in and knowledge of:

1. The appropriate use and physiological effects of nitrous oxide, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

2. The use and maintenance of the equipment required in subsection D of this section.

B. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dental office or treatment facility.

C. Delegation of administration.

1. A qualified dentist may administer or use the services of the following personnel to administer nitrous oxide:

a. A dentist;

b. An anesthesiologist;

c. A certified registered nurse anesthetist under his medical direction and indirect supervision;

d. A dental hygienist with the training required by 18VAC60-25-100 B and under indirect supervision; or

e. A registered nurse upon his direct instruction and under immediate supervision.

2. Preceding the administration of nitrous oxide, a dentist may use the services of the following personnel working under indirect supervision to administer local anesthesia to numb an injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

D. Equipment requirements. A dentist who utilizes nitrous oxide only or who directs the administration by another licensed health professional as permitted in subsection C of this section shall maintain the following equipment in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Blood pressure monitoring equipment;

2. Source of delivery of oxygen under controlled positive pressure;

3. Mechanical (hand) respiratory bag; and

4. Suction apparatus.

E. Required staffing. When only nitrous oxide/oxygen is administered, a second person in the operatory is not required. Either the dentist or qualified dental hygienist under the indirect supervision of a dentist may administer the nitrous oxide/oxygen and treat and monitor the patient.

F. Monitoring requirements.

1. Baseline vital signs, to include blood pressure and heart rate, shall be taken and recorded prior to administration of nitrous oxide analgesia and prior to discharge, unless extenuating circumstances exist and are documented in the patient's record.

2. Continual clinical observation of the patient's responsiveness, color, respiratory rate, and depth of ventilation shall be performed.

3. Once the administration of nitrous oxide has begun, the dentist shall ensure that a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I monitors the patient at all times until discharged as required in subsection G of this section.

4. Monitoring shall include making the proper adjustments of nitrous oxide/oxygen machines at the request of or by the dentist or by another qualified licensed health professional identified in subsection C of this section. Only the dentist or another qualified licensed health professional identified in subsection C of this section may turn the nitrous oxide/oxygen machines on or off.

5. Upon completion of nitrous oxide administration, the patient shall be administered 100% oxygen for a minimum of five minutes to minimize the risk of diffusion hypoxia.

G. Discharge requirements.

1. The dentist shall not discharge a patient until he exhibits baseline responses in a post-operative evaluation of the level of consciousness. Vital signs, to include blood pressure and heart rate, shall be taken and recorded prior to discharge.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. Pediatric patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-21-280. Administration of minimal sedation.

A. Education and training requirements. A dentist who utilizes minimal sedation shall have training in and knowledge of:

1. The medications used, the appropriate dosages, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

2. The physiological effects of minimal sedation, the potential complications of administration, the indicators for complications, and the interventions to address the complications.

3. The use and maintenance of the equipment required in subsection D of this section.

B. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dental office or treatment facility.

C. Delegation of administration.

1. A qualified dentist may administer or use the services of the following personnel to administer minimal sedation:

a. A dentist;

b. An anesthesiologist;

c. A certified registered nurse anesthetist under his medical direction and indirect supervision;

d. A dental hygienist with the training required by 18VAC60-25-100 C only for administration of nitrous oxide/oxygen with the dentist present in the operatory; or

e. A registered nurse upon his direct instruction and under immediate supervision.

2. Preceding the administration of minimal sedation, a dentist may use the services of the following personnel working under indirect supervision to administer local anesthesia to numb an injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics;

3. If minimal sedation is self-administered by or to a patient 13 years of age or older before arrival at the dental office or treatment facility, the dentist may only use the personnel listed in subdivision 1 of this subsection to administer local anesthesia.

D. Equipment requirements. A dentist who utilizes minimal sedation or who directs the administration by another licensed health professional as permitted in subsection C of this section

shall maintain the following equipment in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Blood pressure monitoring equipment;
2. Source of delivery of oxygen under controlled positive pressure;
3. Mechanical (hand) respiratory bag;
4. Suction apparatus; and
5. Pulse oximeter.

E. Required staffing. The treatment team for minimal sedation shall consist of the dentist and a second person in the operatory with the patient to assist the dentist and monitor the patient. The second person shall be a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I.

F. Monitoring requirements.

1. Baseline vital signs to include blood pressure, respiratory rate, and heart rate shall be taken and recorded prior to administration of sedation and prior to discharge.

2. Blood pressure, oxygen saturation, respiratory rate, and pulse shall be monitored continuously during the procedure.

3. Once the administration of minimal sedation has begun by any route of administration, the dentist shall ensure that a licensed health care professional or a person qualified in accordance with 18VAC60-21-260 I monitors the patient at all times until discharged as required in subsection G of this section.

4. If nitrous oxide/oxygen is used in addition to any other pharmacological agent, monitoring shall include making the proper adjustments of nitrous oxide/oxygen machines at the request of or by the dentist or by another qualified licensed health professional identified in subsection C of this section. Only the dentist or another qualified licensed health professional identified in subsection C of this section may turn the nitrous oxide/oxygen machines on or off.

5. If any other pharmacological agent is used in addition to nitrous oxide/oxygen and a local anesthetic, requirements for the induced level of sedation must be met.

G. Discharge requirements.

1. The dentist shall not discharge a patient until he exhibits baseline responses in a post-operative evaluation of the level of consciousness. Vital signs, to include blood pressure, respiratory rate, and heart rate shall be taken and recorded prior to discharge.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. Pediatric patients shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

18VAC60-21-290. Requirements for a conscious/moderate sedation permit.

A. After March 31, 2013, no dentist may employ or use conscious/moderate sedation in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply to an oral and maxillofacial surgeon who maintains membership in the American Association of Oral and Maxillofacial Surgeons (AAOMS) and who provides the board with reports that result from the periodic office examinations required by AAOMS. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. Automatic qualification. Dentists who hold a current permit to administer deep sedation and general anesthesia may administer conscious/moderate sedation.

C. To determine eligibility for a conscious/moderate sedation permit, a dentist shall submit the following:

1. A completed application form indicating one of the following permits for which the applicant is qualified:

a. Conscious/moderate sedation by any method;

b. Conscious/moderate sedation by enteral administration only; or

c. Temporary conscious/moderate sedation permit (may be renewed one time);

2. The application fee as specified in 18VAC60-21-40;

3. A copy of a transcript, certification, or other documentation of training content that meets the educational and training qualifications as specified in subsection D of this section, as applicable; and

4. A copy of current certification in advanced cardiac life support (ACLS) or pediatric advanced life support (PALS) as required in subsection E of this section.

D. Education requirements for a permit to administer conscious/moderate sedation.

1. Administration by any method. A dentist may be issued a conscious/moderate sedation permit to administer by any method by meeting one of the following criteria:

a. Completion of training for this treatment modality according to the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred, while enrolled in an accredited dental program or while enrolled in a post-doctoral university or teaching hospital program; or

b. Completion of a continuing education course that meets the requirements of 18VAC60-21-250 and consists of (i) 60 hours of didactic instruction plus the management of at least 20 patients per participant, (ii) demonstration of competency and clinical experience in conscious/moderate sedation, and (iii) management of a compromised airway. The course content shall be consistent with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred.

2. Enteral administration only. A dentist may be issued a conscious/moderate sedation permit to administer only by an enteral method if he has completed a continuing education program that meets the requirements of 18VAC60-21-250 and consists of not less than 18 hours of didactic instruction plus 20 clinically oriented experiences in enteral or a combination of enteral and nitrous oxide/oxygen conscious/moderate sedation techniques. The course content shall be consistent with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred. The certificate of completion and a detailed description of the course content must be maintained.

3. A dentist who self-certified his qualifications in anesthesia and moderate sedation prior to January 1989 may be issued a temporary conscious/moderate sedation permit to continue to administer only conscious/moderate sedation until May 7, 2015. After May 7, 2015, a dentist shall meet the requirements for and obtain a conscious/moderate sedation permit to administer by any method or by enteral administration only.

E. Additional training required. Dentists who administer conscious/moderate sedation shall:

1. Hold current certification in advanced resuscitation techniques with hands-on simulated airway and megacode training for health care providers, such as ACLS or PALS as evidenced by a certificate of completion posted with the dental license; and

2. Have current training in the use and maintenance of the equipment required in 18VAC60-21-291.

18VAC60-21-291. Requirements for administration of conscious/moderate sedation.

A. Delegation of administration.

1. A dentist who does not hold a permit to administer conscious/moderate sedation shall only use the services of a qualified dentist or an anesthesiologist to administer such sedation in a dental office. In a licensed outpatient surgery center, a dentist who does not hold a permit to administer conscious/moderate sedation shall use either a qualified dentist, an anesthesiologist, or a certified registered nurse anesthetist to administer such sedation.

2. A dentist who holds a permit may administer or use the services of the following personnel to administer conscious/moderate sedation:

a. A dentist with the training required by 18VAC60-21-290 D 2 to administer by an enteral method;

b. A dentist with the training required by 18VAC60-21-290 D 1 to administer by any method;

c. An anesthesiologist;

d. A certified registered nurse anesthetist under the medical direction and indirect supervision of a dentist who meets the training requirements of 18VAC60-21-290 D 1; or

e. A registered nurse upon his direct instruction and under the immediate supervision of a dentist who meets the training requirements of 18VAC60-21-290 D 1.

3. If minimal sedation is self-administered by or to a patient 13 years of age or older before arrival at the dental office, the dentist may only use the personnel listed in subdivision 2 of this subsection to administer local anesthesia. No sedating medication shall be prescribed for or administered to a patient 12 years of age or younger prior to his arrival at the dentist office or treatment facility.

4. Preceding the administration of conscious/moderate sedation, a permitted dentist may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

5. A dentist who delegates administration of conscious/moderate sedation shall ensure that:

a. All equipment required in subsection B of this section is present, in good working order, and immediately available to the areas where patients will be sedated and treated and will recover; and

b. Qualified staff is on site to monitor patients in accordance with requirements of subsection D of this section.

B. Equipment requirements. A dentist who administers conscious/moderate sedation shall have available the following equipment in sizes for adults or children as appropriate for the patient being treated and shall maintain it in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask or masks;

2. Oral and nasopharyngeal airway management adjuncts;

3. Endotracheal tubes with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway;

4. A laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades;

5. Pulse oximetry;

6. Blood pressure monitoring equipment;

7. Pharmacologic antagonist agents;

8. Source of delivery of oxygen under controlled positive pressure;

9. Mechanical (hand) respiratory bag;

10. Appropriate emergency drugs for patient resuscitation;

11. Electrocardiographic monitor if a patient is receiving parenteral administration of sedation or if the dentist is using titration;

12. Defibrillator;

13. Suction apparatus;

14. Temperature measuring device;

15. Throat pack; and

16. Precordial or pretracheal stethoscope.

17. An end-tidal carbon dioxide monitor (capnograph).

C. Required staffing. At a minimum, there shall be a two-person treatment team for conscious/moderate sedation. The team shall include the operating dentist and a second person to monitor the patient as provided in 18VAC60-21-260 K and assist the operating dentist as provided in 18VAC60-21-260 J, both of whom shall be in the operatory with the patient throughout the dental procedure. If the second person is a dentist, an anesthesiologist, or a certified registered nurse anesthetist who administers the drugs as permitted in 18VAC60-21-291 A, such person may monitor the patient.

D. Monitoring requirements.

1. Baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility and prior to discharge.

2. Blood pressure, oxygen saturation, end-tidal carbon dioxide, and pulse shall be monitored continually during the administration and recorded every five minutes.

3. Monitoring of the patient under conscious/moderate sedation is to begin prior to administration of sedation or, if pre-medication is self-administered by the patient, immediately upon the patient's arrival at the dental facility and shall take place continuously during the dental procedure and recovery from sedation. The person who administers the sedation or another licensed practitioner qualified to administer the same level of sedation must remain on the premises of the dental facility until the patient is evaluated and is discharged.

E. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge and vital signs have been taken and recorded.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number.

3. The patient shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

F. Emergency management. The dentist shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.

18VAC60-21-300. Requirements for a deep sedation/general anesthesia permit.

A. After March 31, 2013, no dentist may employ or use deep sedation or general anesthesia in a dental office unless he has been issued a permit by the board. The requirement for a permit shall not apply to an oral and maxillofacial surgeon who maintains membership in AAOMS and who provides the board with reports that result from the periodic office examinations required by AAOMS. Such an oral and maxillofacial surgeon shall be required to post a certificate issued by AAOMS.

B. To determine eligibility for a deep sedation/general anesthesia permit, a dentist shall submit the following:

1. A completed application form;

2. The application fee as specified in 18VAC60-21-40;

3. A copy of the certificate of completion of a CODA accredited program or other documentation of training content which meets the educational and training qualifications specified in subsection C of this section; and

4. A copy of current certification in Advanced Cardiac Life Support for Health Professionals (ACLS) or Pediatric Advanced Life Support for Health Professionals (PALS) as required in subsection C of this section.

C. Educational and training qualifications for a deep sedation/general anesthesia permit.

1. Completion of a minimum of one calendar year of advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level in a training program in conformity with the ADA's Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry in effect at the time the training occurred; or

2. Completion of an CODA accredited residency in any dental specialty that incorporates into its curriculum a minimum of one calendar year of full-time training in clinical anesthesia and related clinical medical subjects (i.e., medical evaluation and management of patients) comparable to those set forth in the ADA's Guidelines for Graduate and Postgraduate Training in Anesthesia in effect at the time the training occurred; and

3. Current certification in advanced resuscitative techniques with hands-on simulated airway and megacode training for health care providers, including basic electrocardiographic interpretations, such as courses in ACLS or PALS; and

4. Current training in the use and maintenance of the equipment required in 18VAC60-21-301.

18VAC60-21-301. Requirements for administration of deep sedation or general anesthesia.

A. Preoperative requirements. Prior to the appointment for treatment under deep sedation or general anesthesia the patient shall:

1. Be informed about the personnel and procedures used to deliver the sedative or anesthetic drugs to assure informed consent as required by 18VAC60-21-260 F.

2. Have a physical evaluation as required by 18VAC60-21-260 C.

3. Be given preoperative verbal and written instructions including any dietary or medication restrictions.

B. Delegation of administration.

1. A dentist who does not meet the requirements of 18VAC60-21-300 shall only use the services of a dentist who does meet those requirements or an anesthesiologist to administer deep sedation or general anesthesia in a dental office. In a licensed outpatient surgery center, a dentist shall use either a dentist who meets the requirements of 18VAC60-21-300, an anesthesiologist, or a certified registered nurse anesthetist to administer deep sedation or general anesthesia.

2. A dentist who meets the requirements of 18VAC60-21-300 may administer or use the services of the following personnel to administer deep sedation or general anesthesia:

a. A dentist with the training required by 18VAC60-21-300 C;

b. An anesthesiologist; or

c. A certified registered nurse anesthetist under the medical direction and indirect supervision of a dentist who meets the training requirements of 18VAC60-21-300 C.

3. Preceding the administration of deep sedation or general anesthesia, a dentist who meets the requirements of 18VAC60-21-300 may use the services of the following personnel under indirect supervision to administer local anesthesia to anesthetize the injection or treatment site:

a. A dental hygienist with the training required by 18VAC60-25-100 C to parenterally administer Schedule VI local anesthesia to persons 18 years of age or older; or

b. A dental hygienist, dental assistant, registered nurse, or licensed practical nurse to administer Schedule VI topical oral anesthetics.

C. Equipment requirements. A dentist who administers deep sedation or general anesthesia shall have available the following equipment in sizes appropriate for the patient being treated and shall maintain it in working order and immediately available to the areas where patients will be sedated and treated and will recover:

1. Full face mask or masks;

2. Oral and nasopharyngeal airway management adjuncts;

3. Endotracheal tubes with appropriate connectors or other appropriate airway management adjunct such as a laryngeal mask airway;

4. A laryngoscope with reserve batteries and bulbs and appropriately sized laryngoscope blades;

5. Source of delivery of oxygen under controlled positive pressure;

6. Mechanical (hand) respiratory bag;

7. Pulse oximetry and blood pressure monitoring equipment available and used in the treatment room;

8. Appropriate emergency drugs for patient resuscitation;

9. EKG monitoring equipment;

10. Temperature measuring devices;

11. Pharmacologic antagonist agents;

12. External defibrillator (manual or automatic);

13. An end-tidal carbon dioxide monitor (capnograph);

14. Suction apparatus;

15. Throat pack; and

16. Precordial or pretracheal stethoscope.

D. Required staffing. At a minimum, there shall be a three-person treatment team for deep sedation or general anesthesia. The team shall include the operating dentist, a second person to monitor the

patient as provided in 18VAC60-21-260 K, and a third person to assist the operating dentist as provided in 18VAC60-21-260 J, all of whom shall be in the operatory with the patient during the dental procedure. If a second dentist, an anesthesiologist, or a certified registered nurse anesthetist administers the drugs as permitted in subsection B of this section, such person may serve as the second person to monitor the patient.

E. Monitoring requirements.

1. Baseline vital signs shall be taken and recorded prior to administration of any controlled drug at the facility to include: temperature, blood pressure, pulse, oxygen saturation, and respiration.

2. The patient's vital signs, end-tidal carbon dioxide, and EKG readings shall be monitored, recorded every five minutes, and reported to the treating dentist throughout the administration of controlled drugs. When depolarizing medications are administered, temperature shall be monitored constantly.

3. Monitoring of the patient undergoing deep sedation or general anesthesia is to begin prior to the administration of any drugs and shall take place continuously during administration, the dental procedure, and recovery from anesthesia. The person who administers the anesthesia or another licensed practitioner qualified to administer the same level of anesthesia must remain on the premises of the dental facility until the patient has regained consciousness and is discharged.

F. Emergency management.

1. A secured intravenous line must be established and maintained throughout the procedure.

2. The dentist shall be proficient in handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.

G. Discharge requirements.

1. The patient shall not be discharged until the responsible licensed practitioner determines that the patient's level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge and vital signs have been taken and recorded.

2. Post-operative instructions shall be given verbally and in writing. The written instructions shall include a 24-hour emergency telephone number for the dental practice.

3. The patient shall be discharged with a responsible individual who has been instructed with regard to the patient's care.

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*.

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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 CLASSIFICATION[2]

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 GUIDELINES[3]

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; and
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

MODERATE SEDATION CONTINUED

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

C. **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.

ENDNOTES

1 Excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia*, 2014, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at **www.asahq.org**.

2 Excerpted from *Continuum of Depth of Sedation: Definition of General Anesthesia and Levels of Sedation/ Analgesia*, 2014, of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at **www.asahq.org**.

3 Excerpted from ASA Task Force on Practice Guidelines for Sedation and Analgesia by non-Anesthesiologists; *Anesthesiology*; 2005-2006. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at **www.asahq.org**.

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 Classification[2]

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 Guidelines[3]

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 CO_2 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 CO_2 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 CO_2 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 CO_2 must be continuously monitored and evaluated.
- Non-intubated patient: End-tidal CO_2 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 CO_2 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.

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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.