



Tony Evers, Governor
Dawn B. Crim, Secretary

**TELECONFERENCE/VIRTUAL MEETING
DE 9 & 11 AD HOC COMMITTEE
DENTISTRY EXAMINING BOARD
Room N208, 4822 Madison Yards Way, 2nd Floor, Madison
Contact: Christian Albouras (608) 266-2112
August 2, 2019**

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

AGENDA

8:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A. Adoption of Agenda (1)**
- B. Approval of Minutes of May 1, 2019 (2)**
- C. DE 9, 11 Relating to Laboratory and Work Reports and Anesthesia – Discussion and Consideration (3-31)**
- D. Public Comments**

ADJOURNMENT

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

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

**DE 9 & 11 AD HOC COMMITTEE
DENTISTRY EXAMINING BOARD
MEETING MINUTES
MAY 1, 2019**

PRESENT: Leonardo Huck, D.D.S.; Herbert Kaske, D.D.S. (*arrived at 8:07 a.m.*); and Wendy Pietz, D.D.S.

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

CALL TO ORDER

Wendy Pietz, Chair, called the meeting to order at 8:05 a.m. A quorum of two (2) members was confirmed.

ADOPTION OF AGENDA

MOTION: Leonardo Huck moved, seconded by Wendy Pietz, to adopt the agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF NOVEMBER 7, 2018

MOTION: Leonardo Huck moved, seconded by Wendy Pietz, to approve the minutes of November 7, 2018 as published. Motion carried unanimously.

(Herbert Kaske arrived at 8:07 a.m.)

ADJOURNMENT

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

The meeting adjourned at 8:59 a.m.

DE 11.02 Definitions. In this chapter:

(1g) “ASA” means American Society of Anaesthesiologists.

(1t) “Class 2 permit” means a sedation permit enabling a dentist to administer moderate sedation.

(1u) “Class 3 permit” means a sedation permit enabling a dentist to administer moderate or deep sedation, or general anesthesia.

(2m) “Continual” means repeated regularly and frequently in a steady succession.

(2r) “Continuous” means prolonged without any interruption at any time.

(3) “Deep sedation” means a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function maybe impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

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

(4) “General anesthesia” means a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug induced depression of neuromuscular function. Cardiovascular function may be impaired.

(4d) “Immediately available” means physically located in the dental office or facility and ready for immediate use or response.

(4h) “Inhalation” means administration by which a gaseous or volatile agent is introduced into the pulmonary tree and whose primary effect is due to absorption through the pulmonary bed.

(4p) “Minimal sedation” means a minimally depressed level of consciousness, produced by a pharmacological method that retains the patient’s ability to independently and continuously maintain an airway and respond normally to tactile stimulation and verbal command. Although cognitive function and coordination may be modestly impaired, ventilatory and cardiovascular functions are unaffected.

(4t) “Moderate sedation” means a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. If more than one enteral drug is administered or if an enteral drug is administered at a dosage that exceeds the maximum recommended dose during a single appointment, such administration is considered moderate sedation.

(7g) “Parenteral” means administration by which the drug bypasses the gastrointestinal tract through intramuscular, intravenous, intranasal, submucosal, subcutaneous, or intraocular methods.

(7r) “Pediatric patient” means a patient who is 12 years old and under.

DE 11.025 Permit to administer anesthesia. (1) Minimal sedation does not require a permit.

(2) The board may issue an anesthesia permit at the following levels:

(a) Class 2 is for the administration of moderate sedation.

(b) Class 3 is for the administration of moderate or deep sedation, or general anesthesia.

(3) A dentist may apply to the board for an anesthesia permit by submitting all of the following:

- (a) Application and fee.
- (b) Verification of any permit or credential authorizing anesthesia or sedation held by the dentist.
- (c) Disclosure of any previous anesthesia or sedation related incident, morbidity, mortality or any Board investigation or discipline relating to the delivery of anesthesia or sedation.
- (d) Evidence of current licensure to practice dentistry in the state of Wisconsin.
- (e) Evidence of certification in Advanced Cardiovascular Life Support or Pediatric Advanced Life Support through a course that follows the American Heart Association guidelines. Pediatric Advanced Life Support is required if treating pediatric patients.
- (f) If applying for a Class 2 Permit, evidence of one of the following:
 - 1. Current board certification or a candidate for board certification by the American Board of Oral and Maxillofacial Surgery.
 - 2. Diplomate of the American Dental Board of Anesthesiology.
 - 3. Successful completion of a Board approved education program that provides comprehensive training meeting the requirements in 11.035.
- (g) If applying for a Class 3 Permit, evidence of one of the following:
 - 1. Current board certification or a candidate for board certification by the American Board of Oral and Maxillofacial Surgery.
 - 2. Diplomate of the American Dental Board of Anesthesiology.

(3) A dentist may not administer anesthesia or sedation without a permit at the appropriate level of anesthesia or sedation.

(4) Nitrous-oxide when used in combination with sedative agent may produce minimal, moderate or deep sedation. During the administration of moderate or nitrous-oxide oxygen sedation, if a patient enters a deeper level of sedation than the dentist is authorized by permit to provide, then the dentist must stop the sedation and dental procedures until the patient returns to the intended level of sedation.

DE 11.35 Board approved education program content. (1) Board approved education program that provides comprehensive training for a Class 2 Permit shall consist of a minimum of 60 hours in administration and management of moderate sedation, including the following course contact:

- (a) Historical, philosophical and psychological aspects of anxiety and pain control.
- (b) Patient evaluation and selection through review of medical history taking, physical diagnosis and psychological profiling.
- (c) Use of patient history and examination for ASA classification, risk assessment and pre-procedure fasting instruction.
- (d) Definitions and descriptions of physiological and psychological aspects of anxiety and pain.
- (e) Description of the sedation anesthesia continuum, with special emphasis on the distinction between the conscious and the unconscious state.
- (f) Review of adult respiratory and circulatory physiology and related anatomy.
- (g) Pharmacology of local anesthetics and agents used in moderate sedation, including drug interactions and contraindications.
- (h) Indications and contraindications for use of moderate sedation
- (i) Review of dental procedures possible under moderate sedation.

- (j) Patient monitoring using observation, monitoring equipment, with particular attention to vital signs, ventilation, breathing and reflexes related to consciousness.
- (k) Maintaining proper records with accurate chart entries recording medical history, physical examination, informed consent, time oriented anesthesia record, including the names of all drugs administered, doses and monitored physiological parameters.
- (L) Prevention, recognition and management of complications and emergencies.
- (m) Description, maintenance and use of moderate sedation monitors and equipment.
- (n) Discussion of abuse potential.
- (o) Intravenous access anatomy, equipment and technique.
- (p) Prevention, recognition and management of complications of venipuncture and other parenteral techniques.
- (q) Description and rationale for the technique to be employed.
- (r) Prevention, recognition and management of systemic complications of moderate sedation, with particular attention to airway maintenance and support of the respiratory and cardiovascular systems.
- (s) 20 individually managed cases.

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

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

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

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

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

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

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

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

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

- (c) Complete medical history and a focused physical evaluation.
- (d) Instruct the patient on specific dietary limitations based upon the sedative and anesthetic technique to be used and patient's physical status.
- (e) Provide pre-operative instructions to the patient, or as appropriate, to the patient's parent or legal guardian.
- (f) Notify and require a patient to arrive and leave with a vested escort.
- (g) Establish and secure, where clinically indicated, an intravenous line throughout the procedure, except as provided for pediatric or special needs patients.
- (h) Advise the patient of fasting requirements.

(3) MONITORING AND EVALUATION OF GENERAL ANESTHESIA, DEEP SEDATION OR MODERATE SEDATION. A dentist administering general anesthesia, deep sedation or moderate sedation shall continuously monitor and evaluate all of the following:

- (a) Level of consciousness.
- (b) Oxygenation saturation by pulse oximetry.
- (c) Chest excursions continually.
- (d) Ventilation monitored by end-tidal carbon dioxide.
- (e) Auscultation of breath sounds with precordial or pretracheal stethoscope.
- (f) Respiration rate.
- (g) Heart rate and rhythm via electrocardiogram (ECG).
- (h) Blood pressure.
- (i) Color of mucosa, skin or blood
- (j) Body temperature whenever triggering agents associated with malignant hyperthermia are administered.

(4) MONITORING AND EVALUATION OF MINIMAL SEDATION. A dentist administering minimal sedation shall continuously monitor and evaluate all of the following:

- (a) Level of consciousness.
- (b) Chest excursions.
- (c) Ventilation by either auscultation of breath sounds or by verbal communication with the patient.
- (d) Color of mucosa, skin or blood
- (e) Blood pressure, heart rate, and oxygenation saturation by pulse oximetry pre-operatively and post-operative and intraoperatively.

(5) RECOVERY AND DISCHARGE. A dentist shall maintain and implement recovery and discharge procedures which include all of the following:

- (a) Immediate availability of oxygen and suction equipment.
- (b) Monitor and document the patient's blood pressure, heart rate, oxygenation and level of consciousness during recovery.
- (c) Determine and document that blood pressure, heart rate, level of consciousness, oxygenation, ventilation, and circulation are satisfactory for discharge.
- (d) Post-operative verbal and written instructions provided.
- (e) If a reversal agent is administered before discharge criteria have been met, the patient must be monitored until recovery is assured.

(6) EQUIPMENT. A dentist administering anesthesia or sedation shall have immediately available and maintain equipment, appropriate for patients served, in good working order according to manufacturer's directions all the following equipment:

- (a) Alternative light source for use during power failure.

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

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

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

Chapter DE 11

ANESTHESIA

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) Provides proof of one of the following:

1. A board approved training course which includes:

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

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

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

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

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

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

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

(a) Provides proof of one of the following:

1. A board approved training course which includes:

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

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

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

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

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

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

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

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

(a) Provides proof of one of the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

TABLE OF CONTENTS

I. INTRODUCTION	1
II. DEFINITIONS	2
III. EDUCATIONAL REQUIREMENTS	6
IV. CLINICAL GUIDELINES	8
▶ MINIMAL SEDATION	8
▶ MODERATE SEDATION	10
▶ DEEP SEDATION OR GENERAL ANESTHESIA	12
ENDNOTES	15

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 AND GENERAL ANESTHESIA

deep sedation – a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.¹

general anesthesia – a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

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

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

ROUTES OF ADMINISTRATION

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

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

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

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

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

TERMS

analgesia – the diminution or elimination of pain.

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

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

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

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

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

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

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

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

continual – repeated regularly and frequently in a steady succession.

continuous – prolonged without any interruption at any time.

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

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

AMERICAN SOCIETY OF ANESTHESIOLOGISTS (ASA) PATIENT PHYSICAL STATUS CLASSIFICATION²

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

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

AMERICAN SOCIETY OF ANESTHESIOLOGISTS' FASTING GUIDELINES³

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

III. EDUCATIONAL REQUIREMENTS



A. Minimal Sedation

1. To administer minimal sedation the dentist must demonstrate competency by having successfully completed:
 - a. training in minimal sedation consistent with that prescribed in the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students*;
 - or*
 - b. comprehensive training in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced;
 - or*
 - c. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage minimal sedation commensurate with these guidelines;
 - and*
 - d. a current certification in Basic Life Support for Healthcare Providers.

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



B. Moderate Sedation

1. To administer moderate sedation, the dentist must demonstrate competency by having successfully completed:
 - a. a comprehensive training program in moderate sedation that satisfies the requirements described in the Moderate Sedation section of the *ADA Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students* at the time training was commenced;
 - or*
 - b. an advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage moderate sedation commensurate with these guidelines;
 - and*
 - c. 1) A current certification in Basic Life Support for Healthcare Providers and
2) Either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same recertification cycle that is required for ACLS.

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



C. Deep Sedation or General Anesthesia

1. To administer deep sedation or general anesthesia, the dentist must demonstrate competency by having completed:
 - a. An advanced education program accredited by the Commission on Dental Accreditation that affords comprehensive and appropriate training necessary to administer and manage deep sedation or general anesthesia, commensurate with Part IV.C of these guidelines;
and
 - b. 1) A current certification in Basic Life Support for Healthcare Providers and
2) either current certification in Advanced Cardiac Life Support (ACLS or equivalent) or completion of an appropriate dental sedation/anesthesia emergency management course on the same re-certification cycle that is required for ACLS.
2. Administration of deep sedation or general anesthesia by another qualified dentist or independently practicing qualified anesthesia healthcare provider requires the operating dentist and his/her clinical staff to maintain current certification in Basic Life Support (BLS) Course for the Healthcare Provider.

IV. CLINICAL GUIDELINES



A. Minimal sedation

1. Patient History and Evaluation

Patients considered for minimal sedation must be suitably evaluated prior to the start of any sedative procedure. In healthy or medically stable individuals (ASA I, II) this should consist of a review of their current medical history and medication use. In addition, patients with significant medical considerations (ASA III, IV) may require consultation with their primary care physician or consulting medical specialist.

2. Pre-Operative Evaluation and Preparation

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

3. Personnel and Equipment Requirements

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

Equipment:

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



4. Monitoring and Documentation

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

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

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

Ventilation:

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

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

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

5. Recovery and Discharge

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

6. Emergency Management

- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient returns to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of minimal sedation and providing the equipment and protocols for patient rescue.



B. Moderate Sedation

1. Patient History and Evaluation

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

2. Pre-operative Evaluation and Preparation

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

3. Personnel and Equipment Requirements

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

Equipment:

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

- An appropriate scavenging system must be available if gases other than oxygen or air are used.
- The equipment necessary to establish intravascular or intraosseous access should be available until the patient meets discharge criteria.

4. Monitoring and Documentation

Monitoring: A qualified dentist administering moderate sedation must remain in the operatory room to monitor the patient continuously until the patient meets the criteria for recovery. When active treatment concludes and the patient recovers to a minimally sedated level a qualified auxiliary may be directed by the dentist to remain with the patient and continue to monitor them as explained in the guidelines until they are discharged from the facility. The dentist must not leave the facility until the patient meets the criteria for discharge and is discharged from the facility. Monitoring must include:

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

Oxygenation: Oxygen saturation must be evaluated by pulse oximetry continuously.

Ventilation:

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

Circulation:

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

Documentation:

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

5. Recovery and Discharge

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

- Post-operative verbal and written instructions must be given to the patient, parent, escort, legal guardian or care giver.
- If a pharmacological reversal agent is administered before discharge criteria have been met, the patient must be monitored for a longer period than usual before discharge, since re-sedation may occur once the effects of the reversal agent have waned.

6. Emergency Management

- If a patient enters a deeper level of sedation than the dentist is qualified to provide, the dentist must stop the dental procedure until the patient is returned to the intended level of sedation.
- The qualified dentist is responsible for the sedative management, adequacy of the facility and staff, diagnosis and treatment of emergencies related to the administration of moderate sedation and providing the equipment, drugs and protocol for patient rescue.



C. Deep Sedation or General Anesthesia

1. Patient History and Evaluation

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

2. Pre-operative Evaluation and Preparation

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



3. Personnel and Equipment Requirements

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

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

Equipment:

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

4. Monitoring and Documentation

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

Oxygenation: Oxygenation saturation must be evaluated continuously by pulse oximetry.

Ventilation:

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

*Circulation:*

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

Temperature:

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

Documentation:

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

5. Recovery and Discharge

- Oxygen and suction equipment must be immediately available if a separate recovery area is utilized.
- The dentist or clinical staff must continually monitor the patient's blood pressure, heart rate, oxygenation and level of consciousness.
- The dentist must determine and document that level of consciousness; oxygenation, ventilation and circulation are satisfactory for discharge.
- Post-operative verbal and written instructions must be given to the patient, **and** parent, escort, guardian or care giver.

6. Special Needs Patients

Because many dental patients undergoing deep sedation or general anesthesia are mentally and/or physically challenged, it is not always possible to have a comprehensive physical examination or appropriate laboratory tests prior to administering care. When these situations occur, the dentist responsible for administering the deep sedation or general anesthesia should document the reasons preventing the recommended preoperative management.

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

7. Emergency Management

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

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 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*, 2011. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at www.asahq.org.
- 4 Standardized BMI category definitions can be obtained from the Centers for Disease Control and Prevention or the American Society of Anesthesiologists.

Report to the Wisconsin Dentistry Examining Board Ad Hoc Committee on Anesthesia

Subject: Updating Current Sedation Regulations in light of 2016 ADA guidelines

July 3, 2019

Presented by Michael D. Silverman, DMD, FICD, DICOI
President, DOCS Education

The public's safety is not at issue here.

- No clinical or research evidence that supports the conclusion that the additional training recommended by the ADA and its 2016 guidelines makes patients the least bit safer.
- In fact, those states that have adopted ADA 2016 guidelines-style regulations have reported no data that would suggest that the number of safety incidents has declined. Said another way, the states that have NOT adopted ADA 2016 guidelines-style regulations are not reporting incident rates any higher than those who have adopted the ADA guidelines.
- Here in Wisconsin, 1,100 oral conscious sedation permitted dentists, operating under the pre-2016 ADA sedation guidelines, have conservatively treated an estimated **165,000 patients**, safely and effectively. The clinical evidence in Wisconsin is overwhelmingly clear: the existing guidelines are already more than sufficient to protect public safety.

The real issue here is economics and the fear of some specialist dentists that too much of their business is being siphoned off by general dentists offering safe, effective oral sedation.

- When these specialist dentists prevail, their income goes up, while the public's access to care becomes significantly more expensive – and hence, fewer patients can obtain safe, effective oral health care. The safety of patients, evidence has shown, is unaffected by the stricter guidelines. More importantly, access to care will be severely restricted if the public cannot seek affordable alternatives to alleviate their dental fears.

- It has been implied that DOCS Education, as a for-profit education company, is motivated in its statements here by its financial interest. In fact, DOCS is arguing against its economic interest. Restrictions on sedation permits that increase the educational requirements will increase the money to be made by DOCS Education as a provider of the additional required education.

Oral sedation dentistry has an enviable 20+ year safety record. It eclipses the safety record of IV sedation over the same period by a substantial edge.

Dentists who fail to follow existing Wisconsin regulations and pre-2016 ADA guidelines may still – in rare circumstances – cause harm to a patient. But the fault is with careless, inept dentists – not their training or the regulations that govern them. All the regulations in the world won't prevent harm to a patient from a dentist who ignores the rules and proper protocols. For an exhaustive study of the impact of the 2016 ADA guidelines on patient safety, see *Proposed Guideline Revisions for Dental Sedation and General Anesthesia: Why Target the Safest Level of Sedation?* Dr. Raymond A. Dionne, quoted in part below with a link to the full article.

The 2016 ADA guidelines are a solution in search of a problem.

Ask the dentists in Wisconsin about their experiences with oral sedation in compliance with existing Wisconsin Dentistry Examining Board regulations, and they will tell you how truly unnecessary it is to tighten those rules. Indeed, if there were a safety issue surrounding the existing guidelines, the dentists of Wisconsin would be the very first to demand changes to protect their patients.

Those pushing for change are not the ones who use oral sedation. They are the specialists asking you to pass new regulations to govern other dentists.

In the end, the dental boards of each state should not be governed by what the ADA recommends for them. Instead, it is incumbent on each state dental board to assess the circumstances in its state and do what is right for its citizens and its professionals.

The ADA Center for Evidence-Based Dentistry, established in 2007, currently includes [89 critical summaries and systematic reviews](#) in its evidence database pertaining to Anesthesia, Oral Sedation and Pain Control. Not one of them even remotely provides an evidence-based rationale for regulating sedation based on the level of medication without consideration of the route of administration. Enteral administration has a buffer built into the physiology of absorption through the digestive system.

Likewise, *The Journal of Evidence-Based Dental Practice* and *Evidence-Based Dentistry* – both respected voices in evidence-based dentistry – have published no articles or summaries that would explain the need to revise or amend the previous ADA guidelines pertaining to sedation dentistry.

Where is the evidence then? There is none. The ADA guidelines not only failed to rely on any scientific evidence of a need to make changes, but it also failed to ascertain the impact on “patient needs and preferences” adequately.

Alternate Approach

The following states have updated their regulations to be congruent with the current definitions set by the American Society of Anesthesiologists (ASA), while maintaining access to care with enteral sedation permits: California, Arizona, Idaho, Texas, North Dakota, Kansas, Oklahoma, Missouri, Arkansas, Indiana, Kentucky, Tennessee, Mississippi, Alabama, Georgia, Maryland, New Jersey, Washington, Kansas, Missouri, and Maine. Updates such as these would bring Wisconsin’s definitions in line with the national medical community.

In summary, the Wisconsin Dentistry Examining Board is more than capable of assessing the risks and benefits of sedation dentistry regulation in Wisconsin. Wisconsin, as with all jurisdictions studied, has not seen any unreasonable level of risk under its current regulations. The Board can also see that there has been no increase in safety evidenced in states that have adopted regulations like the ADA 2016 guidelines. In service of the dental patients of Wisconsin, it is our hope that this Board maintains the access to care made possible by allowing dentists to continue providing safe sedation so necessary, particularly to those who will not seek dental care without sedation.

Proposed Guideline Revisions for Dental Sedation and General Anesthesia: Why Target the Safest Level of Sedation?

September 19, 2016

From the September 2016 Issue of “Compendium of Continuing Education in Dentistry.”

In the September 2016 *Compendium* article, **Dr. Raymond A. Dionne** describes changes proposed by **ADA Resolution 37** as “substantial,” warning that the new guidelines “may have far-reaching and unintended consequences.”

According to Dr. Dionne, since 2000, more than 22,000 dentists have been trained to provide conscious sedation to their patients for use in anxiety control in outpatient settings.

“If implemented, the proposed revisions of the [ADA] guidelines will not appreciably improve the safety of enteral sedation but may eventually limit the ability of general dentists to provide sedation services to patients who would otherwise avoid restorative and preventive dental procedures,” Dr. Dionne writes in *Compendium*.

Conclusion

Discussion of all potential risk factors that affect the safety of dentists providing anesthesia and sedation in outpatient settings is beyond the scope of this article, but it should be recognized that dictating clinical practice based on the concept of MRD and arbitrary assignment of training hours and clinical experiences are only a few of the many factors that determine the overall risk. Recognition of the need to adequately inform patients of the incidence of death associated with various types of anesthesia and sedation, for example, is now being recognized through legislative efforts in California and Florida and in the insurance liability profession.³⁷ The

dental profession and the public would be better served by development of an evidence-based comprehensive strategy to optimize the safety of outpatient anesthesia and sedation rather than attempting to restrict the use of enteral sedation through the proposed revisions to the ADA guidelines.

– See the full article at: <http://tinyurl.com/Dionne2016>