

Clearinghouse Rule 19-132

STATE OF WISCONSIN
DENTISTRY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : DENTISTRY EXAMINING BOARD
DENTISTRY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Dentistry Examining Board to repeal DE 11.02(1), (1m), (2), (7), (8), and (9), 11.04, 11.05, 11.06, 11.07, 11.08 and 11.10 (intro.); to renumber DE 11.10 (1), (2), (3), (4), (5), (6), and (7); to amend DE 9.015 (2), 11.02 (1s), (1t), and (1u), 11.02 (3), 11.02 (4), 11.02 (6) and 11.10 (title); to repeal and recreate DE 9.02, 11.025, 11.03 and 11.09; and to create DE 11.02 (1g), (2g), (2r), (3m), (43), (4m), (4s), (6g) and (6r), 11.035, 11.075, 11.085 and 11.10 (1), (2) and (3)(intro.) relating to laboratory work authorizations, sedation and anesthesia.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: ss. 447.02 (2) (b), and 447.03 (3) (f) 1., Stats.

Statutory authority: ss. 15.08 (5) (b) and 447.02 (2) (b), Stats.

Explanation of agency authority:

Each Examining Board shall promulgate rules for its own guidance and for the guidance of the profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular profession. [s. 15.08 (5) (b), Stats.]

The Examining Board shall promulgate rules specifying the standards, conditions and any educational requirements that are in addition to the requirements specified in s. 447.04 (1) that must be met by a dentist to be permitted to induce general anesthesia or conscious sedation in connection with the practice of dentistry. [s. 447.02 (2) (b), Stats.]

Related statute or rule: N/A

Plain language analysis:

Section 1 simplifies the definition to just an official, signed request from a dentist to a laboratory.

Section 2 eliminates the prescribed format for the dental laboratory work authorization and simplifies the requirements to include the patient's name or id number, the dentist's name and the prescription information.

Sections 3, 5, 7, and 15 repeal definitions no longer utilized in the chapter.

Section 4 defines ASA as the American Society of Anesthesiologists.

Section 6 amends the definitions for Class 1, Class 2 and Class 3 permits. Currently the permits are issued based upon method of sedation and this proposed rule bases the permits on level of sedation which is in line with the American Dental Association's guidelines. A Class 1 is no longer being issued or valid as minimal sedation is being considered as part of the scope of dentistry that does not require a sedation permit. A Class 2 permit allows the dentist to do moderate sedation. A Class 3 permit allows a dentist to do deep sedation or general anesthesia.

Section 8 defines continual to mean repeated regularly and frequently in a steady succession and continual to mean prolonged without interruption.

Section 9 redefines deep sedation as a drug induced depression of consciousness. A patient cannot be easily aroused but respond to repeated painful stimulation. A patient may require assistance in maintaining an airway and spontaneous ventilation may be inadequate. Cardiovascular function usually is maintained.

Section 10 creates a definition for enteral for agents which are absorbed through the gastrointestinal tract or through the oral, rectal or nasal mucous membranes.

Section 11 redefines general anesthesia as a drug-induced loss of consciousness. The patient is not arousable. The patient often requires assistance to maintain an airway and ventilation is required. Cardiovascular function may be impaired.

Section 12 defines immediately available as the person is actually in the dental office or facility and can immediately available to respond.

Minimal sedation is defined as a depressed level of consciousness allowing the patient to maintain an airway and respond to stimulation or command. Ventilatory and cardiovascular functions are unaffected.

Moderate sedation is defined as a drug-induced depression of consciousness which the patient can respond to oral commands either alone or with a light stimulation. No interventions are necessary to maintain airway or ventilation. Cardiovascular function is maintained. If more than one enteral drug is administered or it is administered at a dosage that exceeds the maximum recommended dose during one appointment, it is considered moderate sedation instead of minimal.

Section 13 revises the term being defined to "nitrous oxide" and defines it as a combination of nitrous oxide and oxygen in a patient.

Section 14 creates a definition for parenteral which means the administration of a drug which bypasses the gastrointestinal tract. It is administered into a muscle, vein, nasal structures, areolar connective tissue lying beneath a mucous membrane, interocular, or under the skin. The definition of a pediatric patient is a patient who is 12 years or younger.

Section 16 indicates a permit is not required for minimal sedation. A Class 2 is required for moderate sedation and a Class 3 is required for moderate or deep sedation or general anesthesia. A person applies for a permit by submitting the following: an application; fee; verification of any permit or credential for anesthesia or sedation held by the application; disclosure of any previous adverse incident involving anesthesia or sedation; evidence of current Wisconsin dentistry licensure; evidence of certification in advanced cardiovascular life support or pediatric advanced life support; and approved education. Class 2 permit requires one of the following: board certification or a candidate for board certification by the American Board of Oral and Maxillofacial Surgery; diplomate or candidate of the American Dental Board of Anesthesiology; or successful completion of a Board approved education program. Class 3 permit requires one of the following: board certification or a candidate for board certification by the American Board of Oral and Maxillofacial Surgery; diplomate or candidate of the American Dental Board of Anesthesiology; or postdoctoral residency in an accredited dental program in dental anesthesiology.

Section 17 clarifies that nitrous oxide when used in combination with a sedative agent may produce minimal, moderate or deep sedation. If a patient enters a deeper level of sedation than the dentist is authorized to provide, the dentist must stop the sedation and procedures until the patient returns to the intended level of sedation.

Section 18 provides the education requirements approved by the Board for Class 2 permit. The program shall be at least 60 hours in administration and management of moderate sedation and include:

- Aspects of anxiety and pain control.
- Patient evaluation and selection based upon review of medical history, physical diagnosis and psychological profiling.
- Use of patient history and examination for ASA classification, risk assessment and fasting instructions.
- Definitions and descriptions of physiological psychological aspects of anxiety and pain.
- Description of the sedation anesthesia continuum.
- Review of adult respiratory and circulatory physiology and related anatomy.
- Pharmacology of local anesthetics and agents used in moderate sedation.
- Indications and contraindications for use of moderate sedation.
- Review of dental procedures possible under moderate sedation.
- Patient monitoring using observation and monitoring equipment.
- Maintaining proper records with accurate chart entries.
- Prevention, recognition and management of complications and emergencies.
- Description, maintenance and use of moderate sedation monitors and equipment.
- Discussion of abuse potential.
- Intravenous access anatomy, equipment and technique.

- Prevention, recognition and management of complications of venipuncture and other parenteral techniques.
- Description and rationale for the technique to be employed.
- Prevention, recognition and management of systemic complications of moderate sedation.
- 20 individually managed cases.

Section 19 repeals the sections on requirements for anxiolysis, conscious sedation-enteral, conscious sedation-parenteral, and deep sedation and general anesthesia due to being obsolete.

Section 20 creates a requirement for a dentist holding a sedation permit must complete 2 hours of continuing education on the topic of sedation and anesthesia each biennium. The continuing education can count toward the general continuing education requirements for dentists.

Section 21 repeals the office facilities and equipment section as it is addressed under the standards of care section.

Section 22 requires auxiliary personnel to be certified in basic life support for the health care provider. A dentist administering moderate sedation must have one additional person present during the procedure and another person on the premises and available to respond to a patient emergency. A dentist administering general anesthesia or deep sedation must have two additional persons present during the procedure. If the dentist is both performing the dental procedures administering moderate or deep sedation, or general anesthesia, then an auxiliary person must be designated to only monitor the patient.

Section 23 delineates the standards of care. A dentist administering anesthesia or sedation must be in the room to continuously monitor the patient until the patient meets the criteria for transfer to recovery. The dentist 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.

Preoperative preparation includes:

- Determine the adequacy of the oxygen supply and equipment necessary.
- Take and record the patient's baseline vital signs.
- Complete medical history and a focused physical evaluation.
- Instruct the patient on specific dietary limitations based upon the sedative and anesthetic technique to be used and patient's physical status.
- Provide pre-operative instructions to the patient.
- Notify and require a patient to arrive and leave with a vested escort.
- Establish and secure, an intravenous line throughout the procedure.
- Advise the patient of fasting requirements.

Utilizing moderate or deep sedation or general anesthesia, a dentist must continuously monitor and evaluate:

- Level of consciousness.
- Oxygenation saturation by pulse oximetry.
- Chest excursions.
- Ventilation monitored by end-tidal carbon dioxide.

- Auscultation of breath sounds by precordial or pretracheal stethoscope.
- Respiration rate.
- Heart rate and rhythm via electrocardiogram.
- Blood pressure.
- Color of mucosa, skin or blood.
- Body temperature whenever triggering agents associated with malignant hyperthermia are administered.

Utilizing minimal sedation, a dentist must continuously monitor and evaluate:

- Level of consciousness.
- Chest excursions.
- Ventilation by either auscultation of breath sounds or by verbal communication with the patient.
- Color of mucosa, skin or blood.
- Blood pressure, heart rate, and oxygenation saturations by pulse oximetry pre-operatively and postoperative and intraoperatively.

A dentist shall maintain and implement recovery and discharge procedures which must include:

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

A dentist administering anesthesia or sedation shall have immediately available and maintain in good working order the following equipment:

- Alternative light source for use during power failure.
- Automated external defibrillator.
- Disposable syringes in assorted sizes.
- Oxygen in a portable cylinder E tank capable of administering positive pressure ventilation via a bag-valve-mask system.
- Sphygmomanometer and stethoscope for pediatric and adult patients.
- Suction and backup system.
- An operating chair capable of withstanding cardiopulmonary resuscitation or a back board.
- Emergency airway equipment.

A dentist administering sedation or anesthesia shall maintain and properly store drugs in current and unexpired condition (and properly dispose of expired drugs). The emergency drug kit shall include:

- Non-enteric coated aspirin.
- Ammonia inhalants.
- Antihistamine
- Antihypoglycemic agent.
- Bronchodilator.
- Epinephrine.

- Oxygen.
- Nitroglycerin.
- Reversal agents.
- Muscle relaxant.

A dentist administering anesthesia or sedation must be responsible for the management, diagnosis and treatment of emergencies and for ensuring the equipment, drugs and protocols for patient rescue are immediately available.

A dentist must maintain an anesthesia record that documents all events related to the administration of the sedative or anesthetic agent.

Sections 24, 25, 26, and 27 require a dentist to report to the board any anesthesia or sedation related mortality within two business days and any morbidity which may result in permanent physical or mental injury within 30 days.

Summary of, and comparison with, existing or proposed federal regulation: None

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: Illinois does not have rules related to laboratory work authorizations. Illinois does not require a permit for minimal sedation. Moderate sedation requires a Permit A. To receive a Permit A, a dentist must complete an anesthesiology training program that includes 75 hours of didactic and clinical study in moderate sedation (conscious sedation), physical evaluation, venipuncture, advanced airway management, technical administration, recognition and management of complications and emergencies, and monitoring with additionally supervised experience in providing moderate sedation to 20 patients. The following personnel are required to remain in the treatment room for moderate sedation: the dentist who holds the Permit A; a dental hygienist or dental assistant who has completed training; and one additional hygienist or dental assistant. Deep sedation or general anesthesia requires a Permit B. To receive a Permit B, a dentist must be a diplomate of the American board of Oral and Maxillofacial Surgery, or complete 2 years of advanced training in anesthesiology or have a specialty license in oral and maxillofacial surgery. The following equipment is required: sphygmomanometer; stethoscope; oxygen delivery system; emergency drugs; suction equipment; emergency backup lighting system; pulse oximeter; laryngoscope; advanced airway devices; tonsillar or pharyngeal suction tips; nasal and oral airways; defibrillator; equipment for the establishment of an intravenous infusion; operating chair or table; and recovery area with available oxygen, lighting, suction and electrical outlets. Adverse reactions are required to be reported to the Board. Nine hours of continuing education is required per renewal cycle.

Iowa: Iowa does not have rules related to laboratory work authorizations Iowa requires a moderate sedation permit or general anesthesia permit if the dentist is doing moderate sedation, deep sedation or general anesthesia. To qualify for a moderate sedation permit, the applicant shall complete a training program approved by the board that consists of a minimum of 60 hours

of instruction and management of at least 20 patients or an accredited residency program that includes: formal training and clinical experiences in moderate sedation; a training that includes rescuing patients from a deeper level of sedation than intended; and if intends to utilize on pediatric or ASA III or IV patients, an accredited residency program that includes formal training in anesthesia and clinical experience in managing pediatric or ASA III or IV patients. To qualify for a general anesthesia permit, the applicant shall complete an advanced education program accredited by the Commission on Dental Accreditation that provides training in deep sedation and general anesthesia; a minimum of one year of advanced training in anesthesiology and related academic subjects in a training program approved by the anesthesia credentials committee of the board; formal training in airway management; and current ACLS certification. The dentist must evaluate a patient prior to the start of any sedative procedure. The dentist must not leave the facility until the patient meets the criteria for discharge and the dentist or another designated permit holder or licensed sedation provider must be available for postoperative aftercare for a minimum of 48 hours following the administration of sedation. A dentist who administers moderate sedation, deep sedation or general anesthesia is required to have the following equipment: electrocardiogram monitor; positive pressure oxygen; suction; laryngoscope and blades; endotracheal tubes; magill forceps; oral airways; stethoscope; blood pressure monitoring device; pulse oximeter; emergency drugs; defibrillator; capnography machine to monitor end-tidal carbon dioxide; pretracheal or precordial stethoscope; and any additional equipment necessary to establish intravascular or intraosseous access. Dentists must report any adverse occurrence related to sedation or nitrous oxide within a period of 7 days. Permits expire every 2 years.

Michigan: Michigan does not have rules related to laboratory work authorizations Michigan adopts the standards for advanced training in anesthesia and pain control and training in intravenous conscious sedation and related subjects set forth by the Commission on Dental Education of the American Dental Association in the publication entitled “Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students” (October 2012). Michigan adopts the standards for enteral sedation course as outlined in the Dental Education of the American Dental Association in the publication entitled “Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students” (October 2012). Michigan adopts the standards regarding the equipment within a facility set forth by the American Association of Oral and Maxillofacial Surgeons in the publication entitled “Office Anesthesia Evaluation Manual” (8th edition). Dentists must report morbidity reports within 30 days after the incident and mortality report within 5 days after the incident.

Minnesota: Minnesota does not have rules related to laboratory work authorizations Minnesota requires the following education for deep sedation or general anesthesia: a didactic and clinical program at a dental school, hospital, or graduate medical or dental program accredited by the Commission on Dental Accreditation equivalent to a program for advanced specialty education in oral and maxillofacial surgery or a one year residency in general anesthesia at an institution certified by the American Society of Anesthesiology, the American Medical Association, or the Joint Commission on Hospital Accreditation consisting of a minimum of 390 hours of didactic study, 1,040 hours of clinical anesthesiology and 260 cases of administration of general anesthesia to an ambulatory outpatient. The dentist has ACLS or PALS certification and CPR certification. Minnesota requires the following education for moderate sedation: a course

consisting of a minimum of 60 hours of didactic education in both enteral and parenteral administration, personally administering and managing at least 10 individual supervised cases of parenteral moderate sedation (5 may be on a simulated manikin); ACLS or PALS certification and CPR certification. A dentist who is administering general anesthesia, deep sedation, or moderate sedation, or is administering nitrous oxide inhalation analgesia shall inform the board of that fact on forms provided by the board. A dentist who has a current license to practice dentistry in Minnesota may administer minimal sedation or analgesia. Adverse incidents must be reported to the board. Dentists administering general anesthesia, deep sedation, or moderate sedation need the following equipment: defibrillator; positive pressure oxygen delivery system; suction device; auxiliary lighting; a gas storage facility; recovery area; a method to monitor respiratory function; and board approved emergency cart or kit.

Summary of factual data and analytical methodologies: The Dentistry Examining Board conducted a comprehensive review of chapters DE 9 and 11 to ensure the chapters are statutorily compliant, current with professional standards and practices and removed obsolete or unnecessary provisions. The Dentistry Examining Board reviewed the American Dental Association Guidelines for the Use of Sedation and General Anesthesia by Dentists (October 2016) and other state requirements.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Effect on small business:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Daniel.Hereth@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-2377; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Sharon Henes, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received at or before the public hearing to be held on November 6, 2019 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. DE 9.015 (2) is amended to read:

DE 9.015 (2) "Work authorization" means an official, signed request to a dental workroom or laboratory from a licensed dentist ~~that clearly and thoroughly transmits at least the date of request, the doctor's name, license number, and contact information, the patient information, choice of base material, choice of metal alloy or type of porcelain to be used for the prosthesis, choice of margin and pontic design of the prosthesis, impressions or measurements, and shade description.~~

SECTION 2. DE 9.02 is repealed and recreated to read:

DE 9.02 Work authorizations. Work authorizations shall include all of the following:

- (1) The patient's name or identification number.
- (2) The dentist's name.
- (3) Prescription information.

SECTION 3. DE 11.02 (1) is repealed.

SECTION 4. DE 11.02 (1g) is created to read:

DE 11.02 (1g) "ASA" means American Society of Anesthesiologists.

SECTION 5. DE 11.02 (1m) is repealed.

SECTION 6. DE 11.02 (1s), (1t) and (1u) are amended to read:

DE 11.02 (1s) "Class I permit" means a sedation permit ~~enabling a dentist to administer oral conscious sedation enteral~~ issued prior to [LRB insert effective date]. This permit is no longer valid.

(1t) "Class II permit" means a sedation permit enabling a dentist to administer ~~conscious sedation parenteral and conscious sedation enteral~~ moderate sedation.

(1u) "Class III permit" means a sedation permit enabling a dentist to administer moderate or deep sedation, or general anesthesia, ~~conscious sedation parenteral, and conscious sedation enteral.~~

SECTION 7. DE 11.02 (2) is repealed.

SECTION 8. DE 11.02 (2g) and (2r) are created to read:

DE 11.02 (2g) "Continual" means repeated regularly and frequently in a steady succession.

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

SECTION 9. DE 11.02 (3) is amended to read:

DE 11.02 (3) “Deep sedation” means a ~~controlled state drug-induced depression 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~~ during which a pharmacologic patient cannot be easily aroused but respond purposefully following repeated or non-pharmacologic method, or a combination of pharmacologic and non-pharmacologic methods painful stimulation. The ability to independently maintain ventilatory function may be impaired. A patient may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function in usually maintained.

SECTION 10. DE 11.02 (3m) is created to read:

DE 11.02 (3m) “Enteral” means administration by which the agent is absorbed through the gastrointestinal tract or through the oral, rectal, or nasal mucosa.

SECTION 11. DE 11.02 (4) is amended to read:

DE 11.02 (4) “General anesthesia” means a ~~controlled state of unconsciousness accompanied by partial or complete drug-induced loss of protective reflexes, including the ability to independently maintain an airway and respond purposefully to physical stimulation or verbal command, produced by~~ consciousness during which a pharmacologic or non-pharmacologic method, or a combination of pharmacologic and non-pharmacologic methods patient is not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. A patient often requires 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.

SECTION 12. DE 11.02 (4e) (4m) and (4s) are created to read:

DE 11.02 (4e) “Immediately available” means physically located in the dental office or facility and ready for immediate use or response.

(4m) “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.

(4s) “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.

SECTION 13. DE 11.02 (6) is amended to read:

DE 11.02 (6) “Nitrous oxide ~~inhalation~~” means ~~analgesia by administration of~~ a combination of nitrous oxide and oxygen ~~in a patient~~.

SECTION 14. DE 11.02 (6g) and (6r) are created to read:

DE 11.02 (6g) “Parenteral” means administration by which the drug bypasses the gastrointestinal tract through intramuscular, intravenous, intranasal, submucosal, subcutaneous, or intraocular methods.

(6r) “Pediatric patient” means a patient who is 12 years old and under.

SECTION 15. DE 11.02 (7), (8) and (9) are repealed.

SECTION 16. DE 11.025 is repealed and recreated to read:

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 or candidate 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 or candidate of the American Dental Board of Anesthesiology.

3. Postdoctoral residency in an accredited dental program in dental anesthesiology.

(h) Notwithstanding par. (f) or (g), a dentist holding a Class I Permit on [effective date of rule to be inserted by LRB] shall be granted a Class 2 Permit upon evidence of 20 cases within the last 5 years of providing moderate sedation.

NOTE: As of [LRB insert effective date], a Class 1 Permit is no longer valid and moderate sedation requires a Class 2 Permit.

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

SECTION 17. DE 11.03 is repealed and recreated to read:

DE 11.03 Requirements for nitrous oxide in combination with sedative agent. 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 shall stop the sedation and dental procedures until the patient returns to the intended level of sedation.

SECTION 18. DE 11.035 is created to read:

DE 11.035 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 content:

- (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.

SECTION 19. DE 11.04, 11.05, 11.06 and 11.07 are repealed.

SECTION 20. DE 11.075 is created to read:

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

SECTION 21. DE 11.08 is repealed

SECTION 22. DE 11.085 is created to read:

DE 11.085 Auxiliary Personnel. (1) Auxiliary personnel shall be certified in basic life support for the health care provider.

(2) A dentist administering moderate sedation shall have one additional individual present during the procedure and another individual on the premises and available to respond to a patient emergency.

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

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

SECTION 23. DE 11.09 is repealed and recreated to read:

DE 11.09 Standards of Care. (1) GENERAL. A dentist administering anesthesia or sedation shall be 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's 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.
 - (d) Ventilation monitored by end-tidal carbon dioxide.
 - (e) Auscultation of breath sounds by precordial or pretracheal stethoscope.
 - (f) Respiration rate.
 - (g) Heart rate and rhythm via electrocardiogram.
 - (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.
 - (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.
 - (b) 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.
 - (c) The duration of the procedure
 - (d) The individuals present during the procedure.

SECTION 24. DE 11.10 (title) is amended to read:

DE 11.10 Reporting of adverse occurrences related to sedation or anesthesia administration.

SECTION 25. DE 11.10 (intro.) is repealed.

SECTION 26. DE 11.10 (1), (2), (3), (4), (5), (6), and (7) are renumbered to DE 11.10 (3) (a), (b), (c), (d), (e), (f) and (g).

SECTION 27. DE 11.10 (1), (2) and (3) (intro.) are created to read:

DE 11.10 (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.

(3) The report shall include all of the following:

SECTION 28. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)
