

STATE OF WISCONSIN
DENTISTRY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : DENTISTRY EXAMINING BOARD
DENTISTRY EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE 04-095)

ORDER

An order of the Dentistry Examining Board to repeal DE 11.02 (5), 11.11 and 11.12; to amend DE 11.02 (1) to (4); to repeal and recreate DE 11.03 to 11.10; and to create DE 11.02 (1m) and (6) to (11), relating to the requirements for administering the office facilities and equipment for safe and effective administration and the applicable standards of care, and to provide for reporting of adverse occurrences related to anesthesia administration.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statute interpreted:

Section 447.02 (2) (b), Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) and 447.02 (2) (b), Stats.

Explanation of agency authority:

The Dentistry Examining Board has the authority under s. 447.02, Wis. Stats., to establish the standards, conditions, and any educational requirements that must be met by a dentist in order to induce anesthesia in connection with the practice of dentistry. Presently, those standards are set forth in Chapter DE 11. The proposed rules better identify the different levels of anesthesia, including nitrous oxide, anxiolysis, conscious sedation-enteral, conscious sedation-parenteral, deep sedation, and general anesthesia, and the requirements for each level. This proposal is intended to ensure that practitioners are adequately trained before they induce anesthesia and that the public is sufficiently protected.

Related statute or rule:

There are no related statutes or rules other than those listed above.

Plain language analysis:

The purpose of this rule is to establish and modify the training, certification staffing requirements for administering sedation and anesthesia at all levels performed in the course of dental practice. A system of permits issued by the Department of Regulation and Licensing, which designates by class the various levels of sedation and anesthesia practice, is hereby

established. Office facility and equipment prerequisites for safe and effective administration are delineated, the applicable standards of care are specified, and the procedure necessary for reporting adverse occurrences related to anesthesia administration is described.

These requirements emerged from recent efforts by state licensing boards to regulate “oral conscious sedation.” Oral conscious sedation drugs are being marketed to dentists for the purpose of managing patient anxiety surrounding dental work in patients that remain conscious throughout the procedure.

SECTIONS 1, 2 and 3 add new definitions for “analgesia,” “anxiolysis,” “conscious sedation,” and “deep sedation.”

SECTION 4 amends the definition of “general anesthesia.”

SECTION 5 repeals the definition of “parenteral sedation,” which is defined elsewhere in the rule.

SECTION 6 adds new definitions for “nitrous oxide inhalation,” “operative supervision,” “qualified staff,” “routes of administration,” and “time-oriented anesthesia record.”

SECTION 7 establishes and modifies requirements for administering nitrous oxide inhalation, anxiolysis, conscious sedation-enteral, conscious sedation-parenteral, deep sedation and general anesthesia. No permit is required to administer nitrous oxide inhalation or to perform anxiolysis. Basic life support certification must be completed. A class 1 permit is required to administer enteral conscious sedation. The permit attests that a board approved training course has been completed with 18 hours of didactic instruction and 20 clinical cases, or graduate level training approved by the board inclusive of at least the same didactic and clinical requirements, in addition to certification in basic life support, airway management, and where applicable, certification in pediatric advanced life support. It also requires qualified staff to be present with the dentist throughout the procedure. A class 2 permit is required to administer parenteral conscious sedation, including successful completion of 60 hours of didactic instruction and 20 clinical cases, or graduate level training approved by the board inclusive of at least the same didactic and clinical requirements, or a minimum of five years licensed experience utilizing conscious sedation parenteral, and advanced cardiac life support including, where applicable, certification in pediatric advanced life support. The same staff presence is also required. To perform deep sedation and general anesthesia, a class 3 permit must be obtained. The class 3 permit certifies successful completion of either a board approved postdoctoral training program, a postdoctoral program in anesthesiology approved by the Accreditation Council for Graduate Medical Education, at least one year of advanced clinical training in anesthesiology provided it meets the objectives set forth in part 2 of the American Dental’s Association’s “Guidelines for Teaching the Comprehensive Control of Anxiety and Pain in Dentistry,” or 5 years of experience utilizing general anesthesia. The life support training is the same as for the class 2 permit. The staff presence requirement is modified to allow a dentist to work with a Certified Registered Nurse Anesthetist (CRNA) or licensed physician on the anesthesiology staff at a hospital so long as the CRNA or physician remains on the premises of the dental facility until the patient regains consciousness.

This section further establishes the requirements for conforming the office facilities and equipment required for safe and effective administration and the applicable standards of care, e.g. emergency preparedness, in addition to providing for reporting of adverse occurrences related to anesthesia administration. Finally, the section adds a reporting requirement for dentists for any mortality or other incident resulting in any physical or mental injury that requires hospitalization if that event occurred as a result of anesthesia administration regulated by this chapter.

SECTION 8 repeals ss. DE 11.11 and 11.12, the current rule sections relating to office facilities and equipment and reports of death or injury to the Dentistry Examining Board.

Summary of, and comparison with, existing or proposed federal regulation:

No proposed or existing federal regulation intended to address oral conscious sedation currently exists.

Comparison with rules in adjacent states:

Illinois

The Illinois Dental Practice Act contains specific provisions governing anesthesia. Permits are required for the administration of conscious sedation. Dentists are required to have specialized training and office facilities must contain certain equipment. Adverse occurrences are also required to be reported. Permits must be renewed biennially. Additional information is available at the Illinois website: <http://www.ildpr.com/WHO/ARprospd/WEBdentrules.pdf>

Indiana

The Indiana State Board of Dentistry requires dentists to obtain a permit prior to administering general anesthesia, deep sedation, or light parenteral conscious sedation. Education and training are required to obtain such permits. Permits must be renewed biennially. Five hours of continuing education are required for permit renewal. Certain emergency equipment is also required. Additional information is available at Indiana's website: <http://www.ai.org/legislative/iac/T08280/A00030.PDF>

Iowa

The Iowa Board of Dental Examiners requires a permit for the administration of deep sedation, general anesthesia, and conscious sedation. Dentists are required to have specialized training and office facilities must contain certain equipment. Adverse occurrences are also required to be reported. Six hours of continuing education are required for permit renewals. Additional information is available at Iowa's website: <http://www.legis.state.ia.us/Rules/Current/iac/650iac/65029/65029.pdf>

Michigan

The Michigan Board of Dentistry has rules governing general anesthesia and intravenous conscious sedation. The Michigan Board is currently contemplating a rules' revision to include specific rules for conscious sedation. Additional information is available at Michigan's website:

http://www.state.mi.us/orr/emi/admincode.asp?AdminCode=Single&Admin_Num=33811101&Dpt=CH&RngHigh

Minnesota

The Minnesota Board of Dentistry has rules governing general anesthesia and conscious sedation. Education and training are required for both. However, no special permit is issued. Additional information is available at Minnesota's website:

<http://www.revisor.leg.state.mn.us/arule/3100/3600.html>

Summary of factual data and analytical methodologies:

The Dentistry Examining Board gathered information from various entities involved in promoting oral conscious sedation and others experienced in regulating the practice. Dr. Joseph Best, Clinical Assistant Professor at Marquette University School of Dentistry, presented information to the board in March, 2003. Dr. Jason Goodchild, representing The Dental Organization for Conscious Sedation, delivered a presentation to the board in May, 2003. Initially, the board decided its focus in regulating oral conscious sedation should be on how it is advertised, how it is titrated so that overdosing is prevented, and how many hours of adequate training and what level of clinical experience should be required to administer it. The subject was further discussed at the American Association of Dental Examiners' 2003 annual meeting in San Francisco. The board held open session discussions as the rules process advanced, and legal counsel reviewed the rules of other states. Eventually the focus of the board broadened, resulting in revision of the board's anesthesia rule with sedation levels identified and a system of permits required for various levels of anesthesia.

Determination of significant fiscal effect on the private sector:

The Department of Regulation and Licensing has determined that this rule has no significant fiscal effect on the private sector.

Fiscal estimate: See attached.

Effect on small business:

These proposed rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats. The Department's Regulatory Review Coordinator may be contacted by email at larry.martin@drl.state.wi.us, or by calling (608) 266-8608.

Agency contact person:

Pamela Haack, Department of Regulation and Licensing, Office of Legal Counsel, 1400 East Washington Avenue, Room 171, P.O. Box 8935, Madison, Wisconsin 53708-8935. Telephone: (608) 266-0495. Email: pamela.haack@drl.state.wi.us.

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

Comments may be submitted to the addresses listed above. Comments must be received on or before November 15, 2004 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. DE 11.02 (1) is amended to read:

DE 11.02 (1) "Analgesia" means the diminution or elimination of pain in ~~the~~ a conscious patient.

SECTION 2. DE 11.02 (1m) is created to read:

DE 11.02 (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.

SECTION 3. DE 11.02 (2) and (3) are amended to read:

DE 11.02 (2) "Conscious sedation" means a ~~minimally~~ depressed level of consciousness ~~that retains the patient's~~ 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 ~~inability~~ 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.

SECTION 4. 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 loss of protective reflexes, including ~~inability~~ 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.

SECTION 5. DE 11.02 (5) is repealed.

SECTION 6. DE 11.02 (6) to (11) are created to read:

DE 11.02 (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 physiologic data obtained during patient monitoring.

SECTION 7. DE 11.03 to 11.10 are repealed and recreated to read:

DE 11.03 Requirements for nitrous oxide inhalation. (1) A dentist may use nitrous oxide inhalation on an outpatient basis for dental patients provided that he or she has 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.

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.

DE 11.05 Requirements for conscious sedation–enteral. (1) Beginning on January 1, 2007, no dentist may administer conscious sedation via an enteral route without having first obtained a class one permit from the board, unless a dentist has been granted a permit under s. DE 11.06 or 11.07. A class one permit enables a dentist to utilize conscious sedation enterally. The board shall grant a class one permit to administer conscious sedation enterally to a dentist who 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 subds. 1.a. and 1.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.

DE 11.06 Requirements for conscious sedation–parenteral. (1) Beginning on January 1, 2007, no dentist may administer conscious sedation via a parenteral route without having first obtained a class 2 permit from the board, unless a dentist has been granted a permit under s. DE 11.07. A class 2 permit enables a dentist to utilize conscious sedation–enteral, and conscious sedation–parenteral. The board shall grant a class 2 permit to administer conscious sedation–parenterally to a dentist who does all of 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.

DE 11.07 Requirements for deep sedation and general anesthesia. (1) Beginning on January 1, 2007, no dentist may administer deep sedation or general anesthesia without having first obtained a class 3 permit from the board. A class 3 permit enables a dentist to utilize conscious sedation-enteral, conscious sedation-parenteral, deep sedation, and general anesthesia. The board shall grant a class 3 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.

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.

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 anxiolysis 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.

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.

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.

SECTION 8. DE 11.11 and 11.12 are repealed.

(END OF TEXT OF RULE)

These proposed rules shall take effect on January 1, 2007.

Dated _____

Agency _____

Chairperson
Dentistry Examining Board

Ch DE 11 CR04-095 (Conscious Sedation) Final Draft for Adoption 5-16-06

FISCAL ESTIMATE

Implementing the provisions of these rule changes will cost the Department of Regulation and Licensing the value of salary and fringe and supplies costs for one time of \$21,498 and on-going annually \$38,181.

Assumptions:

One time Costs:

Develop Course List for Specialty Code

	Staff costs	Supplies	Total
Forms development -- 60 hours PA Time @ 17 hr including fringe	1,020		
Database Update -- 50 hrs (1 hr/wk)	850		
Intake, correspondence -- 600 hrs (1 hr per course)	10,200		
Calls @ 10 min ea, 2/crse -- 200 hrs	3,400		
 Total -- 910 hrs Program Assistant	 15,470		

Changes to IT systems for new permit

80 hours IT programmer time @ \$35/hour including fringe	2,800		
16 hours programmer @ \$48 per hour including overhead		768	

Credentialing--develop forms and applications

20 Credentialing program manger @ 36 hr including fringe	720		
40 hours PA 3 @ \$17 including fringe	680		
20 hours legal counsel @ \$53 including fringe	1,060		
	2,460		

Total One Time	20,730	768	21,498
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On-going Costs:

Credentialing review new specialty on renewals

		Annual cost
3,300 dentists every 2 years		
PA 20 minutes for each times 3,300 divided by 2 for annual estimate		8,415

Increased Complaint Costs approx 10 additional complaints per year

All staff hourly amounts

include fringe @ 40.64%

	<u>2 complaints to full hearing</u>	
Screen	4 hrs prog asst @ 17 hr X 2	136
	1hr leg couns @ 53 X 2	106

Investigate	6 hrs invest @ 26 X 2	312
Formal action	32 hrs pros @53 X 2 40 rs alj @51 X 2	3,392 4,080
Close	1 hr pa3 @ \$17 hr X 2	34
	<u>8 other through invest</u>	
Screen	4 hrs prog asst @ 17 hr X 8 1hr leg couns @ 53 X 8	544 424
Investigate	6 hrs invest @ 26 X 8	1,248
Close	1 hr pa3 @ \$17 hr X 8	136
Subtotal Enforcement		10,412
Total On-going		18,827