CHAPTER 29 SEDATION AND NITROUS OXIDE INHALATION ANALGESIA

[Prior to 5/18/88, Dental Examiners, Board of [320]]

650—29.1(153) Definitions. For the purpose of these rules, relative to the administration of deep sedation/general anesthesia, moderate sedation, minimal sedation, and nitrous oxide inhalation analgesia by licensed dentists, the following definitions shall apply:

"Antianxiety premedication" means minimal sedation. A dentist providing minimal sedation must meet the requirements of rule 650—29.7(153).

"ASA" refers to the American Society of Anesthesiologists Patient Physical Status Classification System. Category 1 means normal healthy patients, and category 2 means patients with mild systemic disease. Category 3 means patients with moderate systemic disease, and category 4 means patients with severe systemic disease that is a constant threat to life.

"Conscious sedation" means moderate sedation.

"Deep sedation/general anesthesia" is a controlled state of unconsciousness, produced by a pharmacologic agent, accompanied by a partial or complete loss of protective reflexes, including inability to independently maintain an airway and respond purposefully to physical stimulation or verbal command.

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

"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. The term "minimal sedation" also means "antianxiety premedication" or "anxiolysis." A dentist providing minimal sedation shall meet the requirements of rule 650—29.7(153).

"Moderate sedation" means a drug-induced depression of consciousness, either by enteral or parenteral means, 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. Prior to January 1, 2010, moderate sedation was referred to as conscious sedation.

"Monitoring nitrous oxide inhalation analgesia" means continually observing the patient receiving nitrous oxide and recognizing and notifying the dentist of any adverse reactions or complications.

"Nitrous oxide inhalation analgesia" refers to the administration by inhalation of a combination of nitrous oxide and oxygen producing an altered level of consciousness that retains the patient's ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command.

"Pediatric" means patients aged 12 or under. [ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.2(153) Prohibitions.

29.2(1) *Deep sedation/general anesthesia*. Dentists licensed in this state shall not administer deep sedation/general anesthesia in the practice of dentistry until they have obtained a permit as required by the provisions of this chapter.

29.2(2) *Moderate sedation.* Dentists licensed in this state shall not administer moderate sedation in the practice of dentistry until they have obtained a permit as required by the provisions of this chapter.

29.2(3) *Nitrous oxide inhalation analgesia*. Dentists licensed in this state shall not administer nitrous oxide inhalation analgesia in the practice of dentistry until they have complied with the provisions of rule 650—29.6(153).

29.2(4) Antianxiety premedication. Dentists licensed in this state shall not administer antianxiety premedication in the practice of dentistry until they have complied with the provisions of rule 650—29.7(153).

[ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.3(153) Requirements for the issuance of deep sedation/general anesthesia permits.

- **29.3(1)** A permit may be issued to a licensed dentist to use deep sedation/general anesthesia on an outpatient basis for dental patients provided the dentist meets the following requirements:
- a. Has successfully completed an advanced education program accredited by the Commission on Dental Accreditation that provides training in deep sedation and general anesthesia; and
 - b. Has formal training in airway management; and
- c. Has completed a minimum of one year of advanced training in anesthesiology and related academic subjects beyond the undergraduate dental school level in a training program approved by the board
- **29.3(2)** A dentist using deep sedation/general anesthesia shall maintain a properly equipped facility. The dentist shall maintain and be trained on the following equipment at each facility where sedation is provided: anesthesia or analgesia machine, EKG monitor, positive pressure oxygen, suction, laryngoscope and blades, endotracheal tubes, magill forceps, oral airways, stethoscope, blood pressure monitoring device, pulse oximeter, emergency drugs, defibrillator. A licensee may submit a request to the board for an exemption from any of the provisions of this subrule. Exemption requests will be considered by the board on an individual basis and shall be granted only if the board determines that there is a reasonable basis for the exemption.
- **29.3(3)** The dentist shall ensure that each facility where sedation services are provided is staffed with trained auxiliary personnel capable of reasonably handling procedures, problems and emergencies incident to the administration of general anesthesia. Auxiliary personnel shall maintain current certification in basic life support and be capable of administering basic life support.
- **29.3(4)** A dentist administering deep sedation/general anesthesia must document and maintain current, successful completion of an Advanced Cardiac Life Support (ACLS) course.
- **29.3(5)** A dentist who is performing a procedure for which deep sedation/general anesthesia was induced shall not administer the general anesthetic and monitor the patient without the presence and assistance of at least two qualified auxiliary personnel in the room who are qualified under subrule 29.3(3).
- **29.3(6)** A dentist qualified to administer deep sedation/general anesthesia under this rule may administer moderate sedation and nitrous oxide inhalation analgesia provided the dentist meets the requirements of rule 650—29.6(153).
- **29.3(7)** A licensed dentist who has been utilizing deep sedation/general anesthesia in a competent manner for the five-year period preceding July 9, 1986, but has not had the benefit of formal training as outlined in this rule, may apply for a permit provided the dentist fulfills the provisions set forth in 29.3(2), 29.3(3), 29.3(4), and 29.3(5). [ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.4(153) Requirements for the issuance of moderate sedation permits.

- **29.4(1)** A permit may be issued to a licensed dentist to use moderate sedation for dental patients provided the dentist meets the following requirements:
- a. Has successfully completed a training program approved by the board that meets the American Dental Association Guidelines for Teaching Pain Control and Sedation to Dentists and Dental Students and that consists of a minimum of 60 hours of instruction and management of at least 20 patients; and
 - b. Has formal training in airway management; or
- c. Has submitted evidence of successful completion of an accredited residency program that includes formal training and clinical experience in moderate sedation, which is approved by the board.
- **29.4(2)** A dentist utilizing moderate sedation shall maintain a properly equipped facility. The dentist shall maintain and be trained on the following equipment at each facility where sedation is provided: anesthesia or analgesia machine, EKG monitor, positive pressure oxygen, suction, laryngoscope and blades, endotracheal tubes, magill forceps, oral airways, stethoscope, blood pressure monitoring device, pulse oximeter, emergency drugs, defibrillator. A licensee may submit a request to the board for an exemption from any of the provisions of this subrule. Exemption requests will be considered by the

board on an individual basis and shall be granted only if the board determines that there is a reasonable basis for the exemption.

- **29.4(3)** The dentist shall ensure that each facility where sedation services are provided is staffed with trained auxiliary personnel capable of reasonably handling procedures, problems and emergencies incident to the administration of general anesthesia. Auxiliary personnel shall maintain current certification in basic life support and be capable of administering basic life support.
- **29.4(4)** A dentist administering moderate sedation must document and maintain current, successful completion of an Advanced Cardiac Life Support (ACLS) course.
- **29.4(5)** A dentist who is performing a procedure for which moderate sedation is being employed shall not administer the pharmacologic agents and monitor the patient without the presence and assistance of at least one qualified auxiliary personnel in the room who is qualified under subrule 29.4(3).
- **29.4(6)** A licensed dentist who has been utilizing moderate sedation on an outpatient basis in a competent manner for five years preceding July 9, 1986, but has not had the benefit of formal training as outlined in this rule, may apply for a permit provided the dentist fulfills the provisions set forth in subrules 29.4(2), 29.4(3), 29.4(4) and 29.4(5).
- **29.4(7)** Dentists qualified to administer moderate sedation may administer nitrous oxide inhalation analgesia provided they meet the requirement of rule 650—29.6(153).
- **29.4(8)** If moderate sedation results in a general anesthetic state, the rules for deep sedation/general anesthesia apply.
- **29.4(9)** A dentist utilizing moderate sedation on pediatric or ASA category 3 or 4 patients must have completed an accredited residency program that includes formal training in anesthesia and clinical experience in managing pediatric or ASA category 3 or 4 patients. A dentist who does not meet the requirements of this subrule is prohibited from utilizing moderate sedation on pediatric or ASA category 3 or 4 patients.

[ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.5(153) Permit holders.

- **29.5(1)** No dentist shall use or permit the use of deep sedation/general anesthesia or moderate sedation in a dental office for dental patients, unless the dentist possesses a current permit issued by the Iowa board of dental examiners. A dentist holding a permit shall be subject to review and facility inspection as deemed appropriate by the board.
- **29.5(2)** An application for a deep sedation/general anesthesia permit must include the appropriate fee as specified in 650—Chapter 15, as well as evidence indicating compliance with rule 650—29.3(153).
- **29.5(3)** An application for a moderate sedation permit must include the appropriate fee as specified in 650—Chapter 15, as well as evidence indicating compliance with rule 650—29.4(153).
- **29.5(4)** If an applicant will be practicing at a facility that has been previously inspected and approved by the board, a provisional permit may be granted to the applicant upon the recommendation of the anesthesia credentials committee after review of the applicant's credentials.
- **29.5(5)** Permits shall be renewed biennially at the time of license renewal following submission of proper application and may involve board reevaluation of credentials, facilities, equipment, personnel, and procedures of a previously qualified dentist to determine if the dentist is still qualified. The appropriate fee for renewal as specified in 650—Chapter 15 of these rules must accompany the application.
- **29.5(6)** Upon the recommendation of the anesthesia credentials committee that is based on the evaluation of credentials, facilities, equipment, personnel and procedures of a dentist, the board may determine that restrictions may be placed on a permit.
- **29.5**(7) The actual costs associated with the on-site evaluation of the facility shall be the primary responsibility of the licensee. The cost to the licensee shall not exceed the fee as specified in 650—Chapter 15.
- **29.5(8)** Permit holders shall follow the American Dental Association's guidelines for the use of sedation and general anesthesia for dentists, except as otherwise specified in these rules.

29.5(9) A dentist utilizing moderate sedation on pediatric or ASA category 3 or 4 patients must have completed an accredited residency program that includes formal training in anesthesia and clinical experience in managing pediatric or ASA category 3 or 4 patients. A dentist who does not meet the requirements of this subrule is prohibited from utilizing moderate sedation on pediatric or ASA category 3 or 4 patients.

[ARC 8614B, IAB 3/10/10, effective 4/14/10; ARC 0265C, IAB 8/8/12, effective 9/12/12]

650—29.6(153) Nitrous oxide inhalation analgesia.

- **29.6(1)** A dentist may use nitrous oxide inhalation analgesia sedation on an outpatient basis for dental patients provided the dentist:
 - a. Has completed a board approved course of training; or
- b. Has training equivalent to that required in 29.6(1) "a" while a student in an accredited school of dentistry, and
- c. Has adequate equipment with fail-safe features and minimum oxygen flow which meets FDA standards.
- d. Has routine inspection, calibration, and maintenance on equipment performed every two years and maintains documentation of such, and provides documentation to the board upon request.
- e. Ensures the patient is continually monitored by qualified personnel while receiving nitrous oxide inhalation analgesia.
- **29.6(2)** A dentist utilizing nitrous oxide inhalation analgesia shall be trained and capable of administering basic life support, as demonstrated by current certification in a nationally recognized course in cardiopulmonary resuscitation.
- **29.6(3)** A licensed dentist who has been utilizing nitrous oxide inhalation analgesia in a dental office in a competent manner for the 12-month period preceding July 9, 1986, but has not had the benefit of formal training outlined in paragraph 29.6(1) "a" or 29.6(1) "b," may continue the use provided the dentist fulfills the requirements of paragraphs 29.6(1) "c" and "d" and subrule 29.6(2).
- **29.6(4)** A dental hygienist may administer nitrous oxide inhalation analgesia provided the administration of nitrous oxide inhalation analgesia has been delegated by a dentist and the hygienist meets the following qualifications:
 - a. Has completed a board-approved course of training; or
- b. Has training equivalent to that required in 29.6(4) "a" while a student in an accredited school of dental hygiene.
- **29.6(5)** A dental hygienist or registered dental assistant may monitor a patient under nitrous oxide inhalation analgesia provided all of the following requirements are met:
- a. The hygienist or registered dental assistant has completed a board-approved course of training or has received equivalent training while a student in an accredited school of dental hygiene or dental assisting;
- b. The task has been delegated by a dentist and is performed under the direct supervision of a dentist:
 - c. Any adverse reactions are reported to the supervising dentist immediately; and
 - d. The dentist dismisses the patient following completion of the procedure.
- **29.6(6)** A dentist who delegates the administration of nitrous oxide inhalation analgesia in accordance with 29.6(4) shall provide direct supervision and establish a written office protocol for taking vital signs, adjusting anesthetic concentrations, and addressing emergency situations that may arise.
- **29.6(7)** If the dentist intends to achieve a state of moderate sedation from the administration of nitrous oxide inhalation analgesia, the rules for moderate sedation apply. [ARC 8369B, IAB 12/16/09, effective 1/20/10; ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.7(153) Minimal sedation.

- **29.7(1)** The term "minimal sedation" also means "antianxiety premedication" or "anxiolysis."
- **29.7(2)** If a dentist intends to achieve a state of moderate sedation from the administration of minimal sedation, the rules for moderate sedation shall apply.

29.7(3) A dentist utilizing minimal sedation and the dentist's auxiliary personnel shall be trained in and capable of administering basic life support.

29.7(4) Minimal sedation for adults.

- a. Minimal sedation for adults is limited to a dentist's prescribing or administering a single enteral drug that is no more than 1.0 times the maximum recommended dose (MRD) of a drug that can be prescribed for unmonitored home use. A single supplemental dose of the same drug may be administered, provided the supplemental dose is no more than one-half of the initial dose and the dentist does not administer the supplemental dose until the dentist has determined the clinical half-life of the initial dose has passed.
 - b. The total aggregate dose shall not exceed 1.5 times the MRD on the day of treatment.
- c. For adult patients, a dentist may also utilize nitrous oxide inhalation analgesia in combination with a single enteral drug.
- d. Combining two or more enteral drugs, excluding nitrous oxide, prescribing or administering drugs that are not recommended for unmonitored home use, or administering any intravenous drug constitutes moderate sedation and requires that the dentist must hold a moderate sedation permit.
 - **29.7(5)** Minimal sedation for ASA category 3 or 4 patients or pediatric patients.
- a. Minimal sedation for ASA category 3 or 4 patients or pediatric patients is limited to a dentist's prescribing or administering a single dose of a single enteral drug that can be prescribed for unmonitored home use and that is no more than 1.0 times the maximum recommended dose.
- b. A dentist may administer nitrous oxide inhalation analgesia for minimal sedation of ASA category 3 or 4 patients or pediatric patients provided the concentration does not exceed 50 percent and is not used in combination with any other drug.
- c. The use of one or more enteral drugs in combination with nitrous oxide, the use of more than a single enteral drug, or the administration of any intravenous drug in ASA category 3 or 4 patients or pediatric patients constitutes moderate sedation and requires that the dentist must hold a moderate sedation permit.
- **29.7(6)** A dentist providing minimal sedation shall not bill for non-IV conscious or moderate sedation.
- **29.7(7)** A dentist shall ensure that any advertisements related to the availability of antianxiety premedication, anxiolysis, or minimal sedation clearly reflect the level of sedation provided and are not misleading.

[ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.8(153) Noncompliance. Violations of the provisions of this chapter may result in revocation or suspension of the dentist's permit or other disciplinary measures as deemed appropriate by the board.

650—29.9(153) Reporting of adverse occurrences related to sedation, nitrous oxide inhalation analgesia, and antianxiety premedication.

29.9(1) Reporting. All licensed dentists in the practice of dentistry in this state must submit a report within a period of seven days to the board of any mortality or other incident which results in temporary or permanent physical or mental injury requiring hospitalization of the patient during, or as a result of, antianxiety premedication, nitrous oxide inhalation analgesia, or sedation. The report shall include responses to at least the following:

- a. Description of dental procedure.
- b. Description of preoperative physical condition of patient.
- c. List of drugs and dosage administered.
- d. Description, in detail, of techniques utilized in administering the drugs utilized.
- e. Description of adverse occurrence:
- 1. Description, in detail, of symptoms of any complications, to include but not be limited to onset, and type of symptoms in patient.
 - 2. Treatment instituted on the patient.
 - 3. Response of the patient to the treatment.

- f. Description of the patient's condition on termination of any procedures undertaken.
- **29.9(2)** Failure to report. Failure to comply with subrule 29.9(1), when the occurrence is related to the use of sedation, nitrous oxide inhalation analgesia, or antianxiety premedication, may result in the dentist's loss of authorization to administer sedation, nitrous oxide inhalation analgesia, or antianxiety premedication or in any other sanction provided by law.

 [ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.10(153) Anesthesia credentials committee.

- **29.10(1)** The anesthesia credentials committee is a peer review committee appointed by the board to assist the board in the administration of this chapter. This committee shall be chaired by a member of the board and shall include at least six additional members who are licensed to practice dentistry in Iowa. At least four members of the committee shall hold deep sedation/general anesthesia or conscious sedation permits issued under this chapter.
- **29.10(2)** The anesthesia credentials committee shall perform the following duties at the request of the board:
- a. Review all permit applications and make recommendations to the board regarding those applications.
- b. Conduct site visits at facilities under subrule 29.5(1) and report the results of those site visits to the board. The anesthesia credentials committee may submit recommendations to the board regarding the appropriate nature and frequency of site visits.
 - c. Perform professional evaluations and report the results of those evaluations to the board.
 - d. Other duties as delegated by the board or board chairperson.
- **650—29.11(153) Renewal.** A permit to administer deep sedation/general anesthesia or moderate sedation shall be renewed biennially at the time of license renewal. Prior to July 1, 2008, permits expired on June 30 of every even-numbered year. A permit due to expire June 30, 2008, shall be automatically extended until August 30, 2008, and expire August 31, 2008. Beginning July 1, 2008, permits expire August 31 of every even-numbered year.
 - **29.11(1)** To renew a permit, a licensee must submit the following:
 - a. Evidence of renewal of ACLS certification.
- b. A minimum of six hours of continuing education in the area of sedation. These hours may also be submitted as part of license renewal requirements.
 - c. The appropriate fee for renewal as specified in 650—Chapter 15.
- **29.11(2)** Failure to renew the permit prior to November 1 following its expiration shall cause the permit to lapse and become invalid for practice.
- **29.11(3)** A permit that has been lapsed may be reinstated upon submission of a new application for a permit in compliance with rule 29.5(153) and payment of the application fee as specified in 650—Chapter 15.

[ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.12(153) Rules for denial or nonrenewal. A dentist who has been denied a deep sedation/general anesthesia or moderate sedation permit or renewal may appeal the denial and request a hearing on the issues related to the permit or renewal denial by serving a notice of appeal and request for hearing upon the executive director not more than 30 days following the date of the mailing of the notification of the permit or renewal denial, or not more than 30 days following the date upon which the dentist was served notice if notification was made in the manner of service of an original notice. The hearing shall be considered a contested case proceeding and shall be governed by the procedures set forth in 650 IAC 51.

[ARC 8614B, IAB 3/10/10, effective 4/14/10]

650—29.13(153) Record keeping.

29.13(1) Minimal sedation. An appropriate sedative record must be maintained and must contain the names of all drugs administered, including local anesthetics and nitrous oxide, dosages, time

administered, and monitored physiological parameters, including oxygenation, ventilation, and circulation.

29.13(2) *Moderate or deep sedation.* The patient chart must include preoperative and postoperative vital signs, drugs administered, dosage administered, anesthesia time in minutes, and monitors used. Pulse oximetry, heart rate, respiratory rate, and blood pressure must be recorded continually until the patient is fully ambulatory. The chart should contain the name of the person to whom the patient was discharged.

29.13(3) *Nitrous oxide inhalation analgesia.* The patient chart must include the concentration administered and duration of administration, as well as any vital signs taken. [ARC 8369B, IAB 12/16/09, effective 1/20/10; ARC 8614B, IAB 3/10/10, effective 4/14/10]

These rules are intended to implement Iowa Code sections 153.33 and 153.34.

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[♦] Two or more ARCs

Effective date of 29.6(4) to 29.6(6) delayed 70 days by the Administrative Rules Review Committee at its meeting held June 9, 1998.

Effective date of 29.6(4) to 29.6(6) delayed until the end of the 2000 Session of the General Assembly by the Administrative Rules Review Committee at its meeting held September 15, 1999. Subrules 29.6(4) and 29.6(5) were rescinded IAB 2/9/00, effective 3/15/00; delay on subrule 29.6(6) lifted by the Administrative Rules Review Committee at its meeting held January 4, 2000, effective January 5, 2000.