

DENTAL BOARD[650]

Notice of Intended Action

**Proposing rule making related to sedation and nitrous oxide
and providing an opportunity for public comment**

The Dental Board hereby proposes to rescind Chapter 29, “Sedation and Nitrous Oxide Inhalation Analgesia,” and adopt a new Chapter 29, “Sedation and Nitrous Oxide,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 147.76 and 153.33.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 153.33 and 153.33B.

Purpose and Summary

The primary purpose of this proposed rule making is to update the requirements for providing sedation and nitrous oxide in dental offices. The rule making was drafted based on updated recommendations from the American Dental Association and input from the Board’s Anesthesia Credentials Committee.

This rule making updates requirements for providing moderate sedation, deep sedation and general anesthesia in dental offices. This rule making specifies the conditions under which the administration of the sedation services may be delegated to another health care provider, such as an anesthesiologist or nurse anesthetist.

This rule making clarifies that training in the use of nitrous oxide during enrollment in an accredited school of dentistry or dental hygiene is approved for the purposes of these rules. This rule making also clarifies what a dental assistant is allowed to do or required to do, or both, while monitoring the administration of nitrous oxide.

This rule making establishes a requirement for training in the monitoring of patients under moderate sedation, deep sedation or general anesthesia. Due to the increased risk of these levels of sedation, the training could focus on additional training in observation of a patient under sedation and prepare staff to recognize signs of an adverse reaction or occurrence.

This rule making establishes a prohibition of the use of drugs intended for deeper levels of sedation from being employed for the purposes of moderate sedation. This rule making clarifies the facilities and locations subject to inspection and the equipment required to be maintained at each facility where moderate sedation, deep sedation or general anesthesia, or all three, are performed.

This rule making updates terminology to be more specific and to clarify the requirements for providing sedation or nitrous oxide inhalation analgesia. These amendments also reorder some of the rules for clearer understanding and reference.

Fiscal Impact

This rule making has no fiscal impact to the State of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 650—Chapter 7.

Public Comment

Any interested person may submit written or oral comments concerning this proposed rule making. Written or oral comments in response to this rule making must be received by the Board no later than 4:30 p.m. on May 15, 2019. Comments should be directed to:

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Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its [regular monthly meeting](#) or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

Rescind 650—Chapter 29 and adopt the following **new** chapter in lieu thereof:

CHAPTER 29 SEDATION AND NITROUS OXIDE

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:

“ACC” means the anesthesia credentials committee of the board.

“ASA” refers to the American Society of Anesthesiologists Patient Physical Status Classification System. Category I means normal healthy patients, and category II means patients with mild systemic disease. Category III means patients with severe systemic disease, and category IV means patients with severe systemic disease that is a constant threat to life.

“Board” means the Iowa dental board established in Iowa Code section 147.14(1)“d.”

“Capnography” means the monitoring of the concentration of exhaled carbon dioxide in order to assess physiologic status or determine the adequacy of ventilation during anesthesia.

“Current ACLS or PALS certification” means current certification in Advanced Cardiac Life Support (ACLS) or Pediatric Advanced Life Support (PALS). Current certification means certification by an organization on an annual basis or, if that certifying organization requires certification on a less frequent basis, evidence that the individual has been properly certified for each year covered by the renewal period. The course for the purposes of certification must include a clinical component.

“DAANCE” means the Dental Anesthesia Assistant National Certification Examination as offered by the American Association of Oral and Maxillofacial Surgeons (AAOMS).

“Deep sedation” means drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated painful stimulation. The ability to

independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

“*Facility*” means any dental office or clinic where sedation is used in the practice of dentistry. The term “facility” does not include a hospital.

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

“*Licensed sedation provider*” means a physician anesthesiologist currently licensed by the Iowa board of medicine or a certified registered nurse anesthetist (CRNA) currently licensed by the Iowa board of nursing.

“*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. A patient whose only response reflex is withdrawal from repeated painful stimuli is not considered to be in a state of minimal sedation.

“*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. A patient whose only response reflex is withdrawal from a painful stimulus is not considered to be in a state of moderate 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.

“*MRD*” means the manufacturer’s maximum recommended dose of a drug as printed in FDA-approved labeling.

“*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.

“*Patient monitor*” means a dental assistant, dental hygienist, nurse or dentist who is designated to continuously monitor a patient receiving moderate sedation, deep sedation or general anesthesia until the patient meets the criteria to be discharged to the recovery area.

“*Pediatric*” means patients aged 12 or under.

“*Permit holder*” means an Iowa licensed dentist who has been issued a moderate sedation or general anesthesia permit by the board.

“*Time-oriented anesthesia record*” means documentation at appropriate time intervals of drugs, doses and physiologic data obtained during patient monitoring.

650—29.2(153) Advertising. A dentist shall ensure that any advertisements related to the availability of antianxiety premedication or minimal sedation clearly reflect the level of sedation provided and are not misleading.

650—29.3(153) Nitrous oxide inhalation analgesia.

29.3(1) A dentist may use nitrous oxide inhalation analgesia sedation on an outpatient basis for dental patients provided the dentist has completed training and complies with the following:

- a. Has adequate equipment with fail-safe features.
- b. 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.

c. Ensures the patient is continually monitored by a patient monitor while receiving nitrous oxide inhalation analgesia.

29.3(2) A dentist shall provide direct supervision of the administration and monitoring of nitrous oxide and establish a written office protocol for taking vital signs, adjusting anesthetic concentrations, and addressing emergency situations that may arise. The dentist shall be responsible for dismissing the patient following completion of the procedure.

29.3(3) A dental hygienist may administer and monitor nitrous oxide inhalation analgesia provided the services have been prescribed by a dentist and the hygienist has completed training while a student in an accredited school of dental hygiene or a board-approved course of training.

29.3(4) A dental assistant may monitor a patient who is under nitrous oxide after the dentist has induced a patient and established the maintenance level, provided the dental assistant has completed a board-approved expanded function course. A dental assistant may make adjustments to decrease the nitrous oxide concentration while monitoring the patient or may turn off oxygen delivery at the completion of the dental procedure.

29.3(5) Record keeping. The patient chart must include the concentration administered and duration of administration, as well as any vital signs taken.

650—29.4(153) Minimal sedation standards.

29.4(1) A dentist shall evaluate a patient prior to the start of any sedative procedure. In healthy or medically stable patients (ASA I, II), the dentist should review the patient's current medical history and medication use. For a patient with significant medical considerations (ASA III, IV), a dentist may need to consult with the patient's primary care provider or consulting medical specialist. A dentist shall obtain informed consent from the patient or the patient's parent or legal guardian prior to providing minimal sedation.

29.4(2) Record keeping. A time-oriented anesthesia 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.

29.4(3) Minimal sedation for ASA I or II nonpediatric patients.

a. A dentist may prescribe or administer a single medication for minimal sedation via the enteral route that does not exceed the MRD for unmonitored home use. A dentist may administer a supplemental dose of the same drug provided the total aggregate dose does not exceed 1.5 times the MRD on the day of treatment. The dentist shall not administer a supplemental dose until the clinical half-life of the initial dose has passed.

b. A dentist may administer a single medication for minimal sedation via the enteral route that does not exceed the MRD for monitored use on the day of treatment.

c. A dentist may utilize nitrous oxide inhalation analgesia in combination with a single enteral drug.

29.4(4) Minimal sedation for ASA III, ASA IV or pediatric patients.

a. A dentist may prescribe or administer a single medication for minimal sedation via the enteral route for ASA III or IV patients or pediatric patients that does not exceed the MRD for unmonitored home use.

b. A dentist may administer a single medication for minimal sedation via the enteral route that does not exceed the MRD for monitored use on the day of treatment.

c. A dentist may administer nitrous oxide inhalation analgesia for minimal sedation of ASA III or IV patients or pediatric patients provided the concentration does not exceed 50 percent and is not used in combination with any other drug.

650—29.5(153) Shared standards for moderate sedation, deep sedation and general anesthesia.

29.5(1) Prior to administering moderate sedation, deep sedation or general anesthesia, a dentist must obtain a current moderate sedation permit or general anesthesia permit pursuant to rule 650—29.11(153).

29.5(2) A dentist administering moderate sedation, deep sedation or general anesthesia must maintain current ACLS certification. A dentist administering moderate sedation to pediatric patients may maintain current PALS certification in lieu of current ACLS certification.

29.5(3) A dentist shall evaluate a patient prior to the start of any sedative procedure. A dentist should review a patient's medical history, medication(s) and NPO (nothing by mouth) status. For a patient with significant medical considerations (ASA III, IV), a dentist may need to consult with the patient's primary care provider or consulting medical specialist. The dentist should consult the body mass index as part of the preprocedural workup.

29.5(4) A dentist who administers sedation or anesthesia shall ensure that each facility where sedation services are provided is appropriately staffed to reasonably handle emergencies incident to the administration of sedation. A patient monitor shall be present in the treatment room and continually monitor the patient until the patient returns to a level of minimal sedation.

29.5(5) The dentist must provide postoperative verbal and written instructions to the patient and caregiver prior to discharging the patient.

29.5(6) The dentist must not leave the facility until the patient meets the criteria for discharge.

29.5(7) 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.

29.5(8) The dentist must establish emergency protocols which comply with the following:

- a.* A dentist must establish a protocol for immediate access to backup emergency services;
- b.* A patient monitor shall employ initial life-saving measures in the event of an emergency and shall activate the EMS system for life-threatening complications;
- c.* A dentist who utilizes an immobilization device must avoid chest or airway obstruction when applying the device and shall allow a hand or foot to remain exposed; and
- d.* The recovery room for a pediatric patient must include a functioning suction apparatus as well as the ability to provide >90% oxygen and positive-pressure ventilation, along with age- and size-appropriate rescue equipment.

29.5(9) Record keeping. A time-oriented anesthesia record 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.

650—29.6(153) Moderate sedation standards.

29.6(1) Moderate sedation for ASA I or II nonpediatric patients.

- a.* A dentist may prescribe or administer a single enteral drug in excess of the MRD on the day of treatment.
- b.* A dentist may prescribe or administer a combination of more than one enteral drug.
- c.* A dentist may administer a medication for moderate sedation via the parenteral route.
- d.* A dentist may administer a medication for moderate sedation via the parenteral route in incremental doses.
- e.* A dentist shall ensure the drug(s) or techniques, or both, carry a margin of safety wide enough to render unintended loss of consciousness unlikely.
- f.* A dentist may administer nitrous oxide with more than one enteral drug.

29.6(2) Moderate sedation for ASA III, ASA IV or pediatric patients. A dentist who does not meet the requirements of paragraph 29.11(3) "c" is prohibited from administering moderate sedation to pediatric or ASA III or IV patients. The following constitutes moderate sedation:

- a.* The use of one or more enteral drugs in combination with nitrous oxide.
- b.* The administration of any intravenous drug.

29.6(3) A dentist administering moderate sedation in a facility shall have at least one patient monitor observe the patient while under moderate sedation. The patient monitor shall be capable of administering emergency support and shall complete one of the following:

- a. A minimum of three hours of on-site training in airway management that provides the knowledge and skills necessary for a patient monitor to competently assist with emergencies;
- b. Current ACLS or PALS certification; or
- c. Current DAANCE certification.

29.6(4) Use of capnography or pretracheal/precordial stethoscope is required for moderate sedation providers.

a. All moderate sedation permit holders shall use capnography to monitor end-tidal carbon dioxide unless the use of capnography is precluded or invalidated by the nature of the patient, procedure or equipment.

b. In cases where the use of capnography is precluded or invalidated for the reasons listed previously, a pretracheal or precordial stethoscope must be used to continually monitor the auscultation of breath sounds at all facilities where licensed sedation providers provide sedation.

650—29.7(153) Deep sedation or general anesthesia standards.

29.7(1) The administration of anesthetic sedative agents intended for deep sedation or general anesthesia, including but not limited to Propofol, Ketamine and Dilaudid, shall constitute deep sedation or general anesthesia.

29.7(2) A dentist shall have at least two patient monitors observe the patient while the patient is under deep sedation or general anesthesia. The patient monitors who observe patients under deep sedation or general anesthesia shall be capable of administering emergency support and shall have completed one of the following:

- a. Current ACLS or PALS certification; or
- b. Current DAANCE certification.

29.7(3) A dentist shall use capnography and a pretracheal/precordial stethoscope.

29.7(4) If the dentist has a recovery area separate from the operatory, the recovery area must have oxygen and suction equipment.

650—29.8(153) Facility and equipment requirements for moderate sedation, deep sedation or general anesthesia.

29.8(1) Change of address or addition of facility location(s). A permit holder shall notify the board office in writing within 60 days of a change in location or the addition of a sedation facility.

29.8(2) Facilities shall be permanently equipped. A dentist who administers moderate sedation, deep sedation or general anesthesia in a facility is required to be trained in and maintain, at a minimum, the following equipment to be properly equipped:

- a. Electrocardiogram (EKG) monitor;
- b. Positive pressure oxygen;
- c. Suction;
- d. Laryngoscope and blades;
- e. Endotracheal tubes;
- f. Magill forceps;
- g. Oral airways;
- h. Stethoscope;
- i. Blood pressure monitoring device;
- j. Pulse oximeter;
- k. Emergency drugs;
- l. Defibrillator;
- m. Capnography machine to monitor end-tidal carbon dioxide;
- n. Pretracheal or precordial stethoscope; and
- o. Any additional equipment necessary to establish intravascular or intraosseous access, which shall be available until the patient meets discharge criteria.

29.8(3) The board or designated agents of the board may conduct facility inspections. 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 specified in 650—Chapter 15.

650—29.9(153) Use of another licensed sedation provider or permit holder.

29.9(1) A permit holder may use a licensed sedation provider or another permit holder to administer moderate sedation, deep sedation or general anesthesia in a dental facility. A dentist who does not hold a sedation permit is prohibited from using a licensed sedation provider or permit holder to provide moderate sedation, deep sedation or general anesthesia.

29.9(2) A permit holder who has a licensed sedation provider or another permit holder administer moderate sedation, deep sedation or general anesthesia must remain present in the treatment room for the duration of the dental procedure.

29.9(3) A permit holder who has a licensed sedation provider or another permit holder administer moderate sedation, deep sedation or general anesthesia services must maintain a permanently and properly equipped facility pursuant to the provisions of this chapter.

29.9(4) A permit holder shall assess the need and the patient suitability for sedation services.

650—29.10(153) Reporting of adverse occurrences related to sedation or nitrous oxide.

29.10(1) All licensed dentists must submit a report to the board office within a period of seven days of any mortality related to sedation or nitrous oxide or any other incident related to sedation or nitrous oxide which results in temporary or permanent physical or mental injury requiring inpatient treatment at a hospital or clinic. The report shall include a complete copy of the patient record and include responses to 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.

29.10(2) Failure to report an adverse occurrence, when the occurrence is related to the use of sedation or nitrous oxide, may result in disciplinary action.

650—29.11(153) Requirements for issuance of a moderate sedation or general anesthesia permit.

29.11(1) No dentist shall administer moderate sedation, deep sedation or general anesthesia for dental patients unless the dentist possesses a current permit issued by the board.

29.11(2) A dentist who intends to obtain a sedation permit must submit a completed application and pay the fee specified in 650—Chapter 15.

29.11(3) To qualify for a moderate sedation permit, the applicant shall have successfully completed the following education and training:

a. 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 experience in moderate sedation.

b. Training that includes rescuing patients from a deeper level of sedation than intended, including managing the airway, intravascular or intraosseous access, and reversal medications.

c. For a dentist who intends to utilize moderate sedation 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.

29.11(4) To qualify for a general anesthesia permit, the applicant shall have successfully completed the following education and training:

- a. An advanced education program accredited by the Commission on Dental Accreditation that provides training in deep sedation and general anesthesia.
- b. 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 ACC.
- c. Formal training in airway management.
- d. Current ACLS certification.

29.11(5) Prior to issuance of a new permit, all facilities where the applicant intends to provide sedation services must have passed inspection by the board or designated agent.

29.11(6) The applicant may be required to complete a peer review evaluation, if requested by the ACC, prior to issuance of a permit.

650—29.12(153) ACC.

29.12(1) The ACC 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 ACC shall hold deep sedation/general anesthesia or moderate sedation permits issued under this chapter.

29.12(2) The ACC shall perform the following duties:

- a. Review all permit applications and take action as authorized.
- b. Perform peer reviews as needed and report the results to the board.
- c. Other duties as delegated by the board.

650—29.13(153) Review of permit applications.

29.13(1) *Referral to the ACC.* All applications will be referred to the ACC for review at its next scheduled meeting.

29.13(2) *Review by the ACC.* Following review and consideration of an application, the ACC may take any of the following actions:

- a. Request additional information;
- b. Request that the applicant appear for an interview;
- c. Approve issuance of the permit;
- d. Approve issuance of the permit under certain terms and conditions or with certain restrictions;
- e. Recommend denial of the permit;
- f. Refer the permit application to the board for review and consideration with or without recommendation; or
- g. Request a peer review evaluation.

29.13(3) *Review by board.* The board shall consider applications and recommendations referred by the ACC. The board may take any of the following actions:

- a. Request additional information;
- b. Request that the applicant appear for an interview;
- c. Grant the permit;
- d. Grant the permit under certain terms and conditions or with certain restrictions; or
- e. Deny the permit.

29.13(4) *Appeal process for denials.* If a permit application is denied, an applicant may file an appeal of the final decision using the process described in rule 650—11.10(147).

650—29.14(153) Renewal. A permit to administer deep sedation/general anesthesia or moderate sedation shall be renewed biennially at the time of license renewal. Permits expire August 31 of every even-numbered year.

29.14(1) To renew a permit, a licensee must submit the following:

- a. Evidence of renewal of current ACLS certification or of current PALS certification if the permit holder provides sedation services for pediatric patients.

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.

29.14(2) Failure to renew the permit prior to November 1 following its expiration shall cause the permit to lapse and become invalid for practice.

29.14(3) A permit that has been lapsed may be reinstated upon submission of a new application for a permit in compliance with the provisions of this chapter and payment of the application fee as specified in 650—Chapter 15.

650—29.15(147,153,272C) Grounds for nonrenewal. A request to renew a permit may be denied on any of the following grounds:

29.15(1) After proper notice and hearing, for a violation of these rules or Iowa Code chapter 147, 153, or 272C during the term of the last permit renewal.

29.15(2) Failure to pay required fees.

29.15(3) Failure to obtain required continuing education.

29.15(4) Failure to provide documentation of current ACLS or PALS certification.

29.15(5) Failure to provide documentation of maintaining a properly equipped facility.

29.15(6) Receipt of a certificate of noncompliance from the college student aid commission or the child support recovery unit of the department of human services in accordance with 650—Chapter 33 or 650—Chapter 34.

650—29.16(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.

These rules are intended to implement Iowa Code sections 153.13, 153.33, and 153.33B.