

DENTAL BOARD[650]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Dental Board hereby amends Chapter 29, “Deep Sedation/General Anesthesia, Conscious Sedation and Nitrous Oxide Inhalation Analgesia,” Iowa Administrative Code.

The amendments make various changes to the rules on the use of sedation and antianxiety premedication. The intent of these changes is to clarify the different levels of sedation and to clarify when a dentist must hold a sedation permit. In 2008, the American Dental Association (ADA) revised its guidelines for the use of sedation and adopted new definitions concerning sedation. The ADA adopted new definitions for “minimal sedation” and “moderate sedation,” which was previously referred to as “conscious sedation.” The Board is adopting these new definitions, along with additional guidance for dentists on what constitutes minimal sedation or antianxiety premedication.

The training requirements for obtaining a moderate sedation or deep sedation permit in Iowa have not changed; however, the Board is incorporating the specific requirements in its rules. To qualify for a moderate sedation permit, a dentist must complete a Board-approved course in moderate (conscious) sedation that consists of a minimum of 60 hours of instruction and management of at least 20 patients. The Board does not differentiate between an enteral sedation permit or a parenteral sedation permit. All dentists who administer moderate sedation, regardless of the route of administration, must meet the same training requirements.

The amendments also require that a dentist utilizing moderate sedation on pediatric (patients aged 12 and under) or American Society of Anesthesiologists (ASA) category 3 or 4 patients must have completed additional postgraduate training approved by the Board. This requirement is consistent with the ADA guidelines that require dentists to have completed additional training in pediatric and medically compromised patients in order to provide sedation to these patients. This change will impact all current permit holders as well as new applicants. The Board surveyed existing permit holders to determine the level of impact. Two-thirds of permit holders responded to the survey. Only one person who responded to the survey would be negatively impacted. The permit holder would be eligible to apply for a waiver of this subrule.

These amendments are subject to waiver at the sole discretion of the Board in accordance with 650—Chapter 7.

Notice of Intended Action was published in the December 16, 2009, Iowa Administrative Bulletin as **ARC 8370B**. A public hearing on the proposed amendments was held on January 5, 2010. Four written comments on the proposed amendments were received. In response to these comments, the following changes were made.

In Item 4, the definition of “ASA” has been changed and a new definition for “maximum recommended dose (MRD)” has been added.

In Item 7, paragraph “c” has been amended to clarify that a dentist may also be eligible for a moderate sedation permit if the dentist completes an accredited residency program that includes formal training and clinical experience in moderate sedation.

In Item 13, the time period for reporting mortality or hospitalization incidents due to the use of sedation has been changed from 30 days to 7 days.

A new Item 14 has been added in response to comments from the Iowa Dental Association requesting that record-keeping requirements for each level of sedation be specified in accordance with ADA guidelines.

These amendments were approved at the January 26, 2010, teleconference meeting of the Iowa Dental Board.

These amendments will become effective on April 14, 2010.

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

The following amendments are adopted.

ITEM 1. Amend **650—Chapter 29**, title, as follows:
~~DEEP SEDATION/GENERAL ANESTHESIA, CONSCIOUS SEDATION
AND NITROUS OXIDE INHALATION ANALGESIA~~

ITEM 2. Amend rule 650—29.1(153), introductory paragraph, as follows:

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

ITEM 3. Amend rule **650—29.1(153)**, definitions of “Antianxiety premedication” and “Conscious sedation,” as follows:

~~“Antianxiety premedication” is the prescription/administration of pharmacologic substances for the relief of anxiety and apprehension which does not result in a depressed level of consciousness means minimal sedation. A dentist providing minimal sedation must meet the requirements of rule 650—29.7(153).~~

~~“Conscious sedation” is a depressed level of consciousness produced by the administration of pharmacologic substances, that retains the patient’s ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command means moderate sedation.~~

ITEM 4. Adopt the following new definitions of “ASA,” “Maximum recommended dose (MRD),” “Minimal sedation,” “Moderate sedation” and “Pediatric” in rule **650—29.1(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.

“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.

“Pediatric” means patients aged 12 or under.

ITEM 5. Strike “conscious” wherever it appears in rules **650—29.2(153)** to **650—29.7(153)**, **650—29.11(153)** and **650—29.12(153)** and insert “moderate” in lieu thereof.

ITEM 6. Amend paragraph **29.3(1)“a”** as follows:

a. ~~Has successfully completed Part II of the American Dental Association Council on Dental Education Guidelines~~ an advanced education program accredited by the Commission on Dental Accreditation that provides training in deep sedation and general anesthesia; and

ITEM 7. Amend subrule 29.4(1) as follows:

29.4(1) A permit may be issued to a licensed dentist to use ~~conscious moderate~~ moderate sedation ~~on an outpatient basis~~ for dental patients provided the dentist meets the following requirements:

a. Has successfully completed a training program approved by the board that meets ~~Parts I and III of the American Dental Association Council on Dental Education 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. No change.

c. Has submitted evidence of successful completion of ~~conscious sedation experience at the graduate level~~ an accredited residency program that includes formal training and clinical experience in moderate sedation, which is approved by the board.

ITEM 8. Adopt the following **new** subrule 29.4(9):

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.

ITEM 9. Amend subrule 29.5(8) as follows:

29.5(8) Permit holders shall follow the American Dental Association's guidelines for the use of ~~conscious sedation, deep~~ sedation and general anesthesia for dentists, except as otherwise specified in these rules.

ITEM 10. Adopt the following **new** subrule 29.5(9):

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.

ITEM 11. Amend rule 650—29.7(153) as follows:

650—29.7(153) Antianxiety premedication Minimal sedation.

29.7(1) ~~Antianxiety premedication is the prescription or administration of pharmacologic substances for the relief of anxiety and apprehension. The term “minimal sedation” also means “antianxiety premedication” or “anxiolysis.”~~

29.7(2) ~~The regulation and monitoring of this modality of treatment are the responsibility of the ordering dentist.~~

29.7(3) ~~29.7(2)~~ If a dentist intends to achieve a state of ~~conscious moderate~~ sedation from the administration of ~~an antianxiety premedication~~ minimal sedation, the rules for ~~conscious moderate~~ sedation shall apply.

29.7(4) ~~29.7(3)~~ A dentist utilizing ~~antianxiety premedication~~ 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.

ITEM 12. Amend rule 650—29.9(153), catchwords, as follows:

650—29.9(153) Reporting of adverse occurrences related to ~~deep sedation/general anesthesia, conscious sedation, nitrous oxide inhalation analgesia, and antianxiety premedication.~~

ITEM 13. Amend subrules 29.9(1) and 29.9(2) as follows:

29.9(1) Reporting. All licensed dentists in the practice of dentistry in this state must submit a report within a period of ~~30~~ 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, ~~conscious sedation or deep sedation/general anesthesia related thereto~~ sedation. The report shall include responses to at least the following:

a. to f. No change.

29.9(2) Failure to report. Failure to comply with subrule 29.9(1), when the occurrence is related to the use of ~~deep sedation/general anesthesia, conscious sedation, nitrous oxide inhalation analgesia, or antianxiety premedication,~~ may result in the dentist's loss of authorization to administer ~~deep sedation/general anesthesia, conscious sedation, nitrous oxide inhalation analgesia, or antianxiety premedication~~ or in ~~other sanctions~~ any other sanction provided by law.

ITEM 14. Amend rule 650—29.13(153) as follows:

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. Intermittent vital signs shall be taken and recorded in the patient chart during procedures and 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.* ~~For nitrous oxide inhalation analgesia, the~~ The patient chart must include the concentration administered and duration of administration, as well as any vital signs taken.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 3/10/10.