ARC 8370B

DENTAL BOARD[650]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)"b."

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147.76, the Dental Board hereby gives Notice of Intended Action to amend 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. Last year, 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 proposing to adopt 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 proposed 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.

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

Any interested person may make written comments or suggestions on the proposed amendments on or before January 5, 2010. Such written comments should be directed to Jennifer Hart, Executive Officer, Iowa Dental Board, 400 SW 8th Street, Suite D, Des Moines, Iowa 50309-4687. E-mail may be sent to Jennifer.Hart@iowa.gov.

Also, there will be a public hearing on January 5, 2010, beginning at 10 a.m. in the Board Conference Room, 400 SW 8th Street, Suite D, Des Moines, Iowa. At the hearing, persons will be asked to give their names and addresses for the record and to confine their remarks to the subject of the amendments. Any person who plans to attend the public hearing and who may have special requirements, such as those related to hearing or mobility impairments, should contact the Board and advise of specific needs.

These amendments were approved at the October 27, 2009, regular meeting of the Iowa Dental Board. These amendments are intended to implement Iowa Code sections 153.33 and 153.34. The following amendments are proposed.

ITEM 1. Amend **650—Chapter 29**, title, as follows: <u>DEEP SEDATION/GENERAL ANESTHESIA, CONSCIOUS</u> 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, <u>conscious moderate</u> sedation, <u>minimal sedation</u>, 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 <u>new</u> definitions of "ASA," "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 with no functional limitations. Category 3 means patients with moderate systemic disease with functional limitations, and category 4 means patients with severe systemic disease that is a constant threat to life.

"*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 <u>conscious moderate</u> sedation <u>on an</u> <u>outpatient basis</u> 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. and c. No change.

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 **<u>new</u>** 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 <u>conscious moderate</u> sedation from the administration of <u>an antianxiety premedication</u> <u>minimal sedation</u>, the rules for conscious moderate sedation shall apply.

29.7(4) <u>29.7(3)</u> 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.

<u>c.</u> For adult patients, a dentist may also utilize nitrous oxide inhalation analgesia in combination with a single enteral drug.

<u>d.</u> <u>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 the dentist must hold a moderate sedation permit.</u>

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.

<u>b.</u> 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 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 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.