Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 579
"Sedation and Nitrous Oxide"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 153.33

State or federal law(s) implemented by the rulemaking: Iowa Code sections 153.13, 153.33 and 153.33B

Public Hearing

A public hearing at which persons may present their views orally or in writing will be held as follows:

October 22, 2024 12 noon	6200 Park Avenue Des Moines, Iowa Via videoconference call: meet.google.com/nuk-xcby-nyf Or dial: 541.838.0234 PIN: 917 400 078#

Public Comment

Any interested person may submit written or oral comments concerning this Regulatory Analysis. Written or oral comments in response to this Regulatory Analysis must be received by the Department of Inspections, Appeals, and Licensing no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

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Purpose and Summary

This proposed rulemaking promulgates Chapter 579 and implements Iowa Code chapter 153 in accordance with the goals and directives of Executive Order 10 (January 10, 2023). Iowa Code section 153.33 provides that rulemaking authority.

This rulemaking implements Iowa Code sections 153.13, 153.33 and 153.33B by providing Iowans, licensees and their employers with information relevant to sedation permits. This chapter provides definitions relevant to the administration of deep sedation, general anesthesia, moderate sedation, minimal sedation, and nitrous oxide inhalation analgesia by licensed dentists or dental hygienists. This chapter provides information relevant to training, requirements for the facility, patient evaluations, supervision requirements, permittable levels of sedation, reporting adverse reactions and requirements for obtaining a permit.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

There are often costs associated with licensing and practice standards, since there is often time, effort and money associated with compliance, as is true for any service-oriented industry. Members of

the public would have costs associated with the services they are seeking to receive, which may include an office visit payment or copayment. Licensees would be responsible for the necessary training, the cost of the permit and the continuing education needed to renew this biennially. The licensees are also responsible for the cost of necessary staff and required equipment. The Dental Board does not have a mechanism for estimating what these total costs might be to the public and to the licensee.

- Classes of persons that will benefit from the proposed rulemaking:

The benefit to the public is being achieved since the chapter provides guidelines for the administration of sedation and anesthesia for licensees, therefore providing protection for the licensee and the public.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

There are often costs associated with licensing and practice standards, since there is often time, effort and money associated with compliance, as is true for any service-oriented industry. Members of the public would have costs associated with the services they are seeking to receive, which may include an office visit payment or copayment. Licensees would be responsible for the necessary training, the cost of the permit and the continuing education needed to renew this biennially. The licensees are also responsible for the cost of necessary staff and required equipment.

- Qualitative description of impact:

There are approximately 2,500 licensees who administer sedation or anesthesia to Iowans. The Board believes that the costs are justified by the benefits achieved because the rules provide required guardrails for providing sedation safely to Iowans. If this was not regulated, it could mean that lower-skilled individuals would provide this service to Iowans, which would be of concern to the Board because it could cause more adverse reactions or even deaths.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

Costs to the agency are for the staff time needed to manage Board activities, which includes oversight of practice standards and requirements for permits. The time needed to manage this provision is generally in the form of responding to questions related to practice standards, processing permit applications and conducting meetings of the Anesthesia Credential Committee to approve these applications. It takes roughly 6.0 full-time equivalent (FTE) positions to support the work of this Board. Staff salaries to support the work of the Board are covered by the Licensing and Regulation Fund established in 2023 Iowa Acts, Senate File 557.

- Anticipated effect on state revenues:

This rule has no anticipated impact on state revenues. Staff salaries to support the work of the Board are covered by the fund. Licensing fees go to the fund to cover the operations of the regulated professional licensing boards.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

The Board has not identified a more cost-effective alternative to the current process. Sedation requires adequate training and skill and careful monitoring to ensure the safety of Iowans. Licensees with this permit require ongoing monitoring for compliance and meeting practice standards.

The Department’s Licensing Division continues to assess and implement opportunities to increase efficiencies and standardize board processes across all professional licensing boards. These rule edits support this effort.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

The Board has not identified a more cost-effective alternative to the current process. Sedation requires adequate training and skill and careful monitoring to ensure the safety of Iowans. Licensees with this permit require ongoing monitoring for compliance and meeting practice standards. If this was not regulated, it could mean that lower-skilled individuals would provide this service to Iowans, which would be of concern to the Board because it could cause more adverse reactions or even deaths.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

The Board has not identified a less restrictive alternative to permitting those who provide sedation. The Board believes all current requirements ensure public safety and ensure a minimum competency of care is provided to Iowans. Requirements could be reduced or eliminated for the purpose of lowering the bar to be permitted, but the Board would be concerned about the public safety of Iowans in that scenario.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

There are approximately 2,500 licensees who administer sedation or anesthesia to Iowans. The Board believes that the costs are justified by the benefits achieved because the rules provide required guardrails for providing sedation safely to Iowans. If this were not regulated, it could mean that lower-skilled individuals would provide this service to Iowans, which would be of concern to the Board because it could cause more adverse reactions or even deaths.

Small Business Impact

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.
- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

The proposed rulemaking relates to high-stakes public safety concerns that are present whether the business is a small business or a large organization. The rulemaking is meant to ensure public safety in terms of licensing requirements for dentists and dental hygienists. While some dentists and dental hygienists likely are running a small business of their own, some also work for large corporations, hospitals, and other medical facilities. To exempt small businesses from adhering to this rulemaking would jeopardize any member of the public who sought services from those small businesses. The risk to the public is greater than the potential harm or cost to small businesses.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 579:

CHAPTER 579
SEDATION AND NITROUS OXIDE

481—579.1(153) Nitrous oxide inhalation analgesia.

579.1(1) A dentist may use nitrous oxide inhalation analgesia 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 inspection and maintenance performed on equipment as needed to ensure its proper performance, maintains documentation of such, and provides the documentation to the board upon request.

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

579.1(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 is responsible for the dismissal of the patient following completion of the procedure.

579.1(3) A dental hygienist may administer and monitor nitrous oxide inhalation analgesia when the services have been prescribed by a dentist and the hygienist has completed board-approved training.

579.1(4) A dental assistant who has completed a board-approved expanded function course or holds a current Dental Anesthesia Assistant National Certification Examination (DAANCE) certification may monitor a patient who is receiving nitrous oxide after the dentist has induced the patient and established the maintenance level. 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.

481—579.2(153) Minimal sedation standards.

579.2(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 may only provide minimal sedation after obtaining informed consent from the patient or the patient's parent or legal guardian.

579.2(2) 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 maximum recommended dose (MRD) for unmonitored home use. A dentist may only administer a supplemental dose of the same drug if the clinical half-life of the initial dose has passed and the total aggregate dose does not exceed 1.5 times the MRD on the day of treatment.

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.

579.2(3) 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 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 only 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.

481—579.3(153) Shared standards for moderate sedation, deep sedation and general anesthesia.

579.3(1) A dentist may only administer moderate sedation, deep sedation or general anesthesia if the dentist holds a current moderate sedation permit or general anesthesia permit pursuant to rule 481—572.11(153).

579.3(2) A dentist administering sedation anesthesia must maintain current advanced cardiac life support (ACLS) certification. A dentist administering moderate sedation to pediatric patients may maintain current pediatric advanced life support (PALS) certification in lieu of current ACLS certification.

579.3(3) A dentist may only start a sedative procedure after evaluating a patient. 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.

579.3(4) A dentist may only administer sedation or anesthesia if the following requirements are met:

a. Facilities are appropriately staffed to reasonably handle emergencies;

b. A patient monitor remains present in the treatment room to continually monitor the patient until the patient returns to a level of minimal sedation;

c. The dentist provides postoperative verbal and written instructions to the patient and caregiver prior to discharging the patient;

d. The dentist remains in the facility until the patient meets the criteria for discharge;

e. The dentist or another designated permit holder or licensed sedation provider is available for appropriate postoperative aftercare for a minimum of 48 hours following the administration of sedation; and

f. The dentist establishes emergency protocols that comply with the following:

(1) Establishment of a procedure for immediate access to backup emergency services;

(2) Employment of initial life-saving measures by a patient monitor in the event of an emergency, including activation of the emergency medical service (EMS) system for life-threatening complications;

(3) Avoidance of chest or airway obstruction when applying an immobilization device and allowance for the ongoing exposure of a hand or foot; and

(4) Availability of 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 in the recovery room for pediatric patients.

481—579.4(153) Moderate sedation standards.

579.4(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 nitrous oxide with more than one enteral drug.

d. A dentist may administer a medication for moderate sedation via the parenteral route in single or incremental doses.

e. A dentist may only administer drug(s) or techniques, or both, provided there is a margin of safety wide enough to render unintended loss of consciousness unlikely.

579.4(2) Moderate sedation for ASA III, ASA IV or pediatric patients. A dentist who does not meet the requirements of 481—subparagraph 573.11(1)*"b"*(3) may not administer moderate sedation, deep sedation or general anesthesia to pediatric or ASA III or IV patients. The following constitute moderate sedation:

a. The use of one or more enteral drugs in combination with nitrous oxide.

b. The administration of any intravenous drug.

579.4(3) A dentist may administer moderate sedation in a facility provided the following requirements are met:

a. Have at least one patient monitor observe the patient while the patient is under moderate sedation; and

b. Utilize capnography or a pretracheal/precordial stethoscope as stipulated below:

(1) 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.

(2) 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.

481—579.5(153) Deep sedation or general anesthesia standards.

579.5(1) The administration of anesthetic sedative agents intended for deep sedation or general anesthesia, including but not limited to Propofol, Ketamine and Dilaudid, is deemed to constitute deep sedation or general anesthesia.

579.5(2) A dentist may administer deep sedation or general anesthesia provided the following requirements are met:

a. Have at least two patient monitors observe the patient while the patient is under deep sedation or general anesthesia;

b. Utilize capnography and a pretracheal/precordial stethoscope; and

c. If the dentist has a recovery area separate from the operatory, the recovery area has oxygen and suction equipment.

481—579.6(153) Training and certification requirements for patient monitors. Patient monitors must be capable of administering emergency support and complete training as required by this rule.

579.6(1) Patient monitors who will observe patients receiving deep sedation or general anesthesia must comply with one of the following:

a. Have a current certification in ACLS or PALS or have a current DAANCE certification.

b. Have successfully completed expanded function training in the placement, management and removal of an intravenous (IV) infusion line for moderate sedation, deep sedation or general anesthesia pursuant to 481—Chapter 577.

c. Have successfully completed training in the area of assistance in dental anesthesia in conjunction with a moderate sedation continuing education course approved by the anesthesia credentials committee (ACC).

579.6(2) A patient monitor who will only observe patients receiving moderate sedation may meet one of the requirements listed in subrule 579.6(1) or complete on-site training for a minimum of three hours in airway management that provides the knowledge and skills necessary to competently assist with emergencies, including but not limited to recognizing apnea and airway obstruction.

481—579.7(153) Recordkeeping requirements for nitrous oxide, sedation or anesthesia. In addition to the recordkeeping requirements specified in rule 481—574.9(153,272C), the patient record must include the following information as applicable when administering nitrous oxide, sedation or anesthesia.

579.7(1) The concentration of nitrous oxide administered; dosage of medication administered, including any prescription for at-home unmonitored use, if applicable; duration of administration; and vital signs taken.

579.7(2) When administering moderate sedation, deep sedation or general anesthesia, a time-oriented anesthesia record that contains preoperative and postoperative vital signs; the names of all drugs administered, including local anesthetics and nitrous oxide, dosages, anesthesia time in minutes, and monitors used; and monitored physiological parameters, including oxygenation, ventilation, and

circulation. When administering deep sedation or general anesthesia, pulse oximetry, heart rate, respiratory rate, and blood pressure must be recorded continually until the patient is fully ambulatory.

579.7(3) When administering moderate sedation, deep sedation or general anesthesia, the record should include the name of the person to whom the patient was discharged.

481—579.8(153) Facility and equipment requirements for moderate sedation, deep sedation or general anesthesia.

579.8(1) 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.

579.8(2) A dentist may only administer moderate sedation or anesthesia in a facility that is permanently and properly equipped. A dentist is required to be trained in and maintain, at a minimum, the following equipment:

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;
n. Pretracheal or precordial stethoscope; and
o. Any additional equipment necessary to establish intravascular or intraosseous access, which will be available until the patient meets discharge criteria.

579.8(3) The board or its designated agents may conduct facility inspections. A facility inspection may be required before a sedation permit is issued or before sedation services are provided at a new or updated facility. The actual costs associated with the on-site evaluation of the facility are the primary responsibility of the licensee. The cost to the licensee will not exceed the fee specified in 481—Chapter 571.

481—579.9(153) Use of another licensed sedation provider or permit holder.

579.9(1) A dentist may only use the services of a licensed sedation provider or another permit holder to administer moderate sedation, deep sedation or general anesthesia in a dental facility if the following requirements are met:

a. The dentist holds a current moderate sedation or general anesthesia permit. A permit holder who does not meet the training requirement to administer moderate sedation to pediatric or ASA III or IV patients as stipulated in 481—subparagraph 572.11(1)*"b"*(3) may use another licensed sedation provider or qualified permit holder to administer moderate sedation to pediatric or ASA III or IV patients.

b. The dentist remains present in the treatment room for the duration of any dental treatment.

c. The facility is a permanently and properly equipped facility pursuant to the provisions of this chapter.

d. The permit holder assesses the need and patient suitability for sedation services. A permit holder may not interfere with any independent assessment performed by a licensed sedation provider.

579.9(2) When a licensed sedation provider or another permit holder is used to administer moderate sedation, deep sedation or general anesthesia, that provider constitutes one patient monitor for the purpose of complying with rule 481—579.6(153).

579.9(3) 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.

481—579.10(153) Advertising. A dentist will 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.

481—579.11(153) Noncompliance. Violations of the provisions of this chapter may result in disciplinary measures as deemed appropriate by the board.

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