Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 578
"Prescribing, Administering, and Dispensing Drugs"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124, 153A, 153.33 and 155A
State or federal law(s) implemented by the rulemaking: Iowa Code section 153.20

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 578 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 section 153.20 by providing Iowans, licensees and their employers with information relevant to the authority and requirements of licensed dentists who are prescribing, administering, or dispensing prescription drugs. This chapter also provides requirements for recordkeeping, labels and containers, and use of the Prescription Monitoring Program (PMP).

Analysis of Impact

1. Persons affected by the proposed rulemaking:

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

There are no costs incurred by the public to comply with this rulemaking, other than a copay if one is required with a prescription. Licensees who prescribe may be required to pay for technology in order to comply with prescription rules. Licensees who are dispensing opioids are also responsible for the cost to register with the federal Drug Enforcement Administration (DEA) and the Iowa Board of Pharmacy.

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

The public will benefit from this rulemaking since it provides guidelines for prescribing, administering and dispensing prescription drugs, providing protection for the licensee and the public. It provides detail as to who licensees can prescribe for, what type of conditions they can prescribe for, and how to document these prescriptions.

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 no costs incurred by the public to comply with this rulemaking, other than a copay if one is required with a prescription. Licensees who prescribe may be required to pay for technology in order to comply with prescription rules. Licensees who are dispensing opioids are also responsible for the cost to register with the DEA and the Iowa Board of Pharmacy.

- Qualitative description of impact:

In order to regulate the profession as directed in the Iowa Code, the requirements that have been created to regulate this profession are necessary to protect the public. The 6.0 full-time equivalent (FTE) positions dedicated to this function play a critical role in issuing licenses, conducting investigations, providing administrative support to the Dental Board (Board), monitoring compliance and supporting the board monitoring programs. This work is done with a focus on protecting the health and safety of the public who receive services and/or care from licensed professionals. Due to the state government realignment, boards are evaluating ways to streamline and simplify processes and procedures.

3. Costs to the State:

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

The only cost to the agency to implement and enforce this chapter is the cost to staff personnel to ensure compliance. 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 rulemaking 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 believes all current requirements ensure public safety and ensure a minimum competency of care is provided to Iowans. The Department's Licensing Division continues to assess and implement opportunities to increase efficiencies and standardize board processes across all licensing boards. Through the realignment, 31 boards were moved under the Licensing Division within the Department.

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

Professionals who prescribe, administer and dispense drugs are also regulated by the DEA and the Iowa Board of Pharmacy. They are also required to utilize the PMP. This is all in an attempt to provide protection to the public, and a less restrictive alternative is not available.

6. Alternative methods considered by the agency:

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

The Board has not been able to identify any less restrictive alternatives to these rules, which provide specific guidelines for prescribing and dispensing. The DEA and the Iowa Board of Pharmacy also articulate requirements for prescribers and monitor compliance.

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

Professionals who prescribe, administer and dispense drugs are also regulated by the DEA and the Iowa Board of Pharmacy. They are also required to utilize the PMP. This is all in an attempt to provide protection to the public, and a less restrictive alternative is not available.

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 rules relate to high-stakes public safety concerns that are present whether the business is a small business or a large corporation. While some dental professionals may work in a smaller dental office, some also work for large corporations, hospitals, and other dental facilities. To exempt small businesses from adhering to this chapter would jeopardize any member of the public who sought services from that small business. The risk to the public is greater than the potential harm or cost to the small business.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 578:

CHAPTER 578
PRESCRIBING, ADMINISTERING, AND DISPENSING DRUGS

481—578.1(153) Scope of authority and prescribing requirements.

578.1(1) A license to practice dentistry issued by this board permits the licensee to prescribe, administer, or dispense prescription drugs if the use is directly within the scope of the dentist-patient relationship. Registration with the federal Drug Enforcement Administration and the board of pharmacy extends this privilege to controlled substances.

578.1(2) A licensed dentist may only prescribe, administer or dispense a prescription drug for a diagnosed dental condition that is included in the treatment plan and entered into the patient record. A dental examination and medical history must be completed and entered into the patient record before a dentist prescribes, administers, or dispenses a prescription drug to a patient. Fluoride may also be dispensed under protocols approved by the dental and oral health program of the department of health and human services.

578.1(3) On each occasion when a dentist prescribes, administers, or dispenses a prescription drug to a patient, the patient's dental record will be updated to include the following information:

a. Name, quantity, and strength of the prescription drug.
b. Directions for its use.
c. Date of issuance.
d. Conditions for which the prescription drug was used.

578.1(4) A dentist may only prescribe, administer, or dispense prescription drugs in accordance with all applicable state and federal laws.

578.1(5) A dentist may only purchase, administer, or dispense controlled substances if the dentist maintains records and accountability in accordance with 481—Chapter 553 and all other applicable state and federal laws.

578.1(6) A dentist cannot self-prescribe or self-administer controlled substances.

578.1(7) A dentist may only prescribe, administer, or dispense controlled substances to members of the licensee's immediate family in the case of an acute dental condition or on an emergency basis for a dental condition after the licensee conducts an examination, establishes a patient record, and maintains proper documentation.

481—578.2(153) Dispensing—requirements for containers and labeling.

578.2(1) *Containers.* A prescription drug shall be dispensed in a suitable container designed to protect its integrity in accordance with all applicable federal and state laws.

578.2(2) *Labeling.* A label shall be affixed to the container in which a prescription drug is dispensed bearing the following information:

a. Name and address of the dentist.

b. Name of the patient.

c. Date dispensed.

d. Directions for use.

e. Name, quantity, and strength of medication.

f. If the prescription drug is a Schedule II, III, or IV controlled substance, the federal transfer warning statement must appear on the label as follows: "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed."

g. Cautionary statements, if any.

481—578.3(153) Prescription requirements.

578.3(1) A dentist shall take adequate measures to prevent prescription forgery from occurring. Dentists may only transmit prescription drug orders, including prescriptions for controlled substances, electronically unless exempted. A dentist who fails to comply with the electronic prescription mandate may be subject to a nondisciplinary administrative penalty of $250 per violation, up to a maximum of $5,000 per calendar year.

578.3(2) A dentist may delegate to a licensed dental hygienist or registered dental assistant the preparation of a prescription for the review, authorization, and manual or electronic signature of the dentist, but the dentist is responsible for the accuracy, completeness, and validity of the prescription.

578.3(3) A dentist shall securely maintain the unique authentication credentials issued to the dentist for utilization of the electronic prescription application and authentication of the dentist's electronic signature. Unique authentication credentials issued to any individual may not be shared with or disclosed to any other individual.

481—578.4(153) Required use of the prescription monitoring program (PMP).

578.4(1) A dentist may only prescribe or dispense an opioid if the dentist or authorized delegate queries the PMP. The query for each patient may not be performed more than 48 hours prior to each instance of an opioid prescription being authorized, issued, or dispensed.

578.4(2) A dentist who dispenses a controlled substance is required to report the dispensing to the PMP within one business day in accordance with 481—Chapter 556.

These rules are intended to implement Iowa Code section 153.20.