Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 556
"Iowa Prescription Monitoring Program"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 124, subchapter VI (sections 124.550 through 124.558)

State or federal law(s) implemented by the rulemaking: Iowa Code chapter 124, subchapter VI (sections 124.550 through 124.558)

Public Hearing

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

August 29, 2024	6200 Park Avenue, Suite 100
3 p.m.	Des Moines, Iowa

Virtual participation for the public hearing will be available on the Department of Inspections, Appeals, and Licensing website.

Public Comment

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

Sue Mears
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Purpose and Summary

The purpose of this proposed rulemaking is to establish the functional requirements for the Iowa Prescription Monitoring Program (PMP) Advisory Committee (Committee), requirements for practitioners to register for the PMP, reporting requirements, PMP security, and requirements for access to and reporting of PMP information. The citation to 481—Chapter 550 refers to that chapter as proposed in a Regulatory Analysis published herein (IAB 8/7/24).

Analysis of Impact

1. Persons affected by the proposed rulemaking:

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

Pharmacies and practitioners who dispense reportable controlled substances will bear the cost of such required reporting, which will vary depending on the entity's submission method and utilization of a software vendor for facilitation of reporting. Controlled Substances Act registrants would bear the cost of a registration surcharge (up to 25 percent) if that is implemented as a means to fund the PMP.

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

Iowa patients will benefit from controlled substance dispensing information being available to the patients' practitioners as an educational tool in furtherance of the practitioners' care of their patients. In addition to the basic patient dispensing information being available to practitioners, the PMP's issuance of prescriber activity reports and proactive notifications provides additional educational value in the provision of patient care.

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:

The impact of the proposed rulemaking includes periodic meetings of the Committee, no-cost practitioner registration for the PMP, submission of reportable prescriptions to the PMP (as noted above, with varying cost associated), and issuance of prescriber activity reports ($25,000 annually) and proactive notifications (no extra cost).

- Qualitative description of impact:

The impact of the proposed rulemaking includes the near-instantaneous availability of patient-controlled substance utilization information to practitioners seeking to provide comprehensive health care to that patient.

3. Costs to the State:

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

There is no anticipated implementation cost since the requirements and standards are in existence in the Board of Pharmacy's current rules. Enforcement costs include one full-time PMP Administrator and potentially include a portion of compliance officer staff time to investigate complaints of violations.

- Anticipated effect on state revenues:

There is no anticipated impact on state revenues. If implemented, the up-to-25-percent registration surcharge would be deposited into the PMP fund for use on program activities.

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

While the costs are variable, the cost of inaction would be a significant impact on patient care. Without access to a patient's controlled substance dispensing history, a practitioner would not have the ability to identify when a patient is misusing or abusing the patient's prescribed medication, which would inevitably lead to poor patient outcomes, including increased patient deaths.

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

Less costly methods may include elimination of the NarxCare program ($186,000 annually) and integration with electronic health records systems (not required and cost is variable), which methods are currently funded nearly entirely by grant funding. Should the grant funding be eliminated, these opportunities may also be eliminated, which may result in less efficient utilization of the PMP for practitioners, which may lead to less utilization overall.

6. Alternative methods considered by the agency:

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

At this time, no alternative methods were seriously considered.

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

No alternative methods were considered at this time due to current adequate funding for the PMP and enhancements that make access more efficient for program registrants.

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?

While not specifically identified in this proposed rulemaking, any registrant would be authorized to petition the Board for a waiver of Board rules that are not also required by the Iowa Code (in accordance with 481—Chapter 6). This opportunity is available to any business entity regardless of its size. A petition for waiver of one or more Board rules would include information that would demonstrate how the petitioner would continue to protect the public by alternate means if the rule is waived, in whole or in part.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 556:

CHAPTER 556
IOWA PRESCRIPTION MONITORING PROGRAM

481—556.1(124,155A) Definitions. The definitions found in 481—Chapter 550 are incorporated by reference into these rules.

481—556.2(124) PMP advisory committee.

556.2(1) *Membership.* The membership of the PMP advisory committee will include prescribing practitioners as identified in Iowa Code section 124.555(1) as amended by 2024 Iowa Acts, Senate File 2385, and may include a multidisciplinary coalition of authorized users who routinely interact with the PMP and one member of the public who is not eligible to register with the PMP.

556.2(2) *Term of appointment.* Committee members will be appointed by the board for a three-year term and may be reappointed by the board for no more than two additional terms. Each term will expire on June 30 of the third year of the term.

556.2(3) *Quorum.* A quorum will be a majority of the appointed members.

556.2(4) *Termination of appointment.* A committee member who is no longer eligible or able to serve on the committee will submit a written resignation to the board. A committee member who fails to attend three consecutive regular committee meetings is deemed to have resigned.

481—556.3(124) Registration.

556.3(1) *Registration.* Authorized access to PMP information pursuant to Iowa Code section 124.553 will be available only to registered users, except as provided herein.

556.3(2) *Registration not needed.* Individuals seeking their own individual prescription records need not register with the PMP.

556.3(3) *Practitioner's delegates.* A practitioner may authorize an adequate number of credentialed health care professionals not exceeding 30 to access PMP information. The practitioner is responsible for the PMP information access of the delegates.

481—556.4(124) Reporting requirements.

556.4(1) *Reportable data.*

a. The following will be reported to the PMP in accordance with Iowa Code sections 124.551, 124.552, and 124.554(1)*"g"*:

(1) Controlled substances dispensed to a patient for self-administration.

(2) Opioid antagonists dispensed or administered by a practitioner, including:

1. To an emergency department patient, and
2. To a patient upon discharge from a hospital, correctional facility, or care facility.

b. If the pharmacy did not dispense or administer any reportable prescriptions during a reporting period, a zero report.

556.4(2) *Required data elements.*

a. In addition to the information required in Iowa Code section 124.552(1), the following elements will be reported:

(1) Form of transmission of prescription origin.
(2) Refill number.
(3) Number of refills authorized.

b. In an exceptional circumstance, a practitioner may request an extension of time for transmitting program information.

556.4(3) *Exemptions—practitioners.* The following are exempt from reporting controlled substances:

a. A licensed veterinarian in the normal course of professional practice.

b. A DEA-registered narcotic treatment program that is subject to the recordkeeping provisions of 21 CFR §1304.24 as amended June 28, 2021.

556.4(4) *Board notification.* A pharmacy that does not engage in any reportable dispensing or administration will notify the board at the time of licensure.

556.4(5) *Submission format.* Data will be transmitted via the PMP's current version of data upload or electronic submission.

556.4(6) *Submission errors.* Upon notification of a potential error in program information, the reporting practitioner will promptly correct the error.

481—556.5(124) Security.

556.5(1) *Board.* The board will collect, store, and disseminate program information using technology that utilizes encryption as defined in Iowa Code section 715C.1.

556.5(2) *Integrated systems.* A practitioner, pharmacy, or health care system utilizing an integrated system to connect its electronic health record or data processing system with the PMP will:

a. Ensure the maintenance of user access logs for four years from the date of access, including the identification of the practitioner for which a delegate accessed program information.

b. Ensure the maintenance of adequate security to prevent unauthorized access, disclosure, or theft of program information.

c. Notify the board within 72 hours of any breach in the electronic health record or data processing system that may have included program information.

481—556.6(124) Access to and reporting of PMP information.

556.6(1) *Patient requests.* An individual patient or a patient's authorized representative may request the individual's own program information via submission of a completed PMP patient request form via personal, mail, or commercial delivery. A patient's authorized representative includes an individual with medical power of attorney for the patient, the patient's attorney, an executor of the patient's estate, or the patient's next of kin as defined in Iowa Code section 523A.102.

556.6(2) *Authorized user requests.* An individual authorized to receive program information may request program information pursuant to and in accordance with Iowa Code section 124.553 via the program platform, which request will include verification of the requestor's authorization to receive the information.

556.6(3) *Statistical data.* The board or its designee may provide summary, statistical, or aggregate data to public or private entities for statistical, public research, public policy, or educational purposes.

556.6(4) *Prescriber activity reports.* At least annually, the board will electronically issue to each prescriber whose prescribed controlled substances were reported to the program during the preceding reporting period an activity report in accordance with Iowa Code section 124.554(3)*"a."*

556.6(5) *Proactive notifications.* When a patient meets or exceeds the criteria and thresholds determined by the board and the advisory committee, the board will issue a notification to a practitioner that the patient may be at risk of abusing or misusing a controlled substance and suggest review of the patient's program information.

These rules are intended to implement Iowa Code chapter 124, subchapter VI.