Regulatory Analysis

Notice of Intended Action to be published: Iowa Administrative Code 481—Chapter 557
"Board of Pharmacy Operations"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 17A.3, 21, 124, 124B, 147.80, 155A, 272C

State or federal law(s) implemented by the rulemaking: Iowa Code chapters 17A, 21, 124, 124B, 155A and 272C and section 147.80

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
3:30 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
Iowa Department of Inspections, Appeals, and Licensing
6200 Park Avenue, Suite 100
Des Moines, Iowa 50321
Email: sue.mears@iowa.gov

Purpose and Summary

The purpose of this proposed rulemaking is to provide information about Board of Pharmacy operations and responsibilities, including Board meetings, administrative fees, and references to other applicable rules of the Department that will be adopted by reference.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

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

Individuals seeking information or documentation from the Board or applicants who have submitted a payment of up to $10 more than required for the application or administrative service requested will bear the costs of the administrative fees identified in the proposed rulemaking.

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

The general public will benefit from the proposed rulemaking by having information about the Board, including its authority, responsibilities, and meetings and access to publicly available information.

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 administrative fees that are proposed are intended simply to recoup the administrative cost of providing the listed service (license/registration verification, reprinting of an original pharmacist license certificate, etc.). It is anticipated that, within the Department, there will continue to be an evaluation of administrative service fees and consolidation of processes to provide consistency of such fees within the Department.

- Qualitative description of impact:

The impact to the general public is significant since information about the Board's operation and how to participate in the public process allows the general public to see how the Board does its work to the legal extent that it can.

3. Costs to the State:

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

The costs to the Board include the Board's six annual meetings to handle public matters (handling requests and petitions, voting on rulemaking, etc.) as well as closed-session matters (investigative reports or other matters requiring licensee confidentiality). The cost of the meetings includes a $50 per diem for the Board members along with reimbursement of travel expenditures. Hybrid meetings are available as a convenience for all participants.

- Anticipated effect on state revenues:

There is no anticipated impact to state revenues. The administrative service fees would be retained in the Licensing and Regulation Fund as established by 2023 Iowa Acts, Senate File 557.

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

Inaction would appear to mean that the Board would not meet to discuss its statutory regulatory authority over the practice of pharmacy, the handling of controlled substances, and the distribution of drugs in the drug supply chain. In such case, such inaction would result in an increased risk of public harm by way of licensees experiencing no negative impact of violating the law or rules or failing to meet the accepted standard of care.

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

As it relates to a written license or registration verification, a less costly method exists for any interested party. The Board's online licensing database provides a mechanism for online verification of any license, registration, or permit at no charge. The administrative service fee identified in these proposed rules would be an option for individuals who seek the same level of documentation provided by Board staff.

6. Alternative methods considered by the agency:

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

At this time, the Board has not contemplated alternative methods (fees) for the administrative services listed. As noted previously, it is anticipated that administrative fees across the Department will continue to be evaluated and adjusted as deemed appropriate.

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

It is presumed that a Department-wide effort will be undertaken to assess the provision for administrative services and the appropriate charge for such services.

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 noted in these proposed rules, ultimately any business licensee can petition the Board for a waiver to the Board's rules in accordance with 481—Chapter 6, including for the administrative fees identified herein. In each petition, the petitioner can identify the unique circumstances under which the Board's rule impacts the petitioner's situation or finances and can seek relief via a waiver.

Text of Proposed Rulemaking

ITEM 1. Adopt the following **new** 481—Chapter 557:

CHAPTER 557
BOARD OF PHARMACY OPERATIONS

481—557.1(17A,147,155A,272C) Board of pharmacy operations.

557.1(1) *Authority.* The board's authority for regulating the practice of pharmacy and the legal distribution and dispensing of prescription drugs and devices, including controlled substances, in the state of Iowa is found in Iowa Code chapters 124, 124B, 126, 147, 155A, 205, and 272C.

557.1(2) *Responsibilities.* The responsibilities of the board include but are not limited to:

a. Licensing of individuals. Licensing or registering qualified individuals in the practice of pharmacy and handling or prescribing of controlled substances.

b. Licensing of practice locations. Licensing or registering authorized entities engaged in the legal distribution or dispensing of prescription drugs, devices and controlled substances within or into Iowa.

c. Conducting compliance inspections, audits and investigations of any person or entity licensed or registered with the board.

d. Instituting disciplinary actions, hearing contested cases, issuing decisions and orders, and enforcing the terms of filed disciplinary orders.

557.1(3) *Meetings.* All meetings of the board will be open to the public except as authorized by the Iowa Code. Meeting notices will be routinely posted on the department of inspections, appeals, and licensing's website.

557.1(4) *Administrative fees.* The following nonrefundable fees will be assessed for the following administrative services:

a. Written license or registration verification: $15.

b. Provision of licensee data files: variable, $35 minimum.

c. Returned payment: $20.

d. Original pharmacist license certificate: $20.

e. Certification of pharmacist-intern internship hours: $15.

f. Petition for eligibility determination: $25.

557.1(5) *Overpayment of fees.* Payment for any administrative service or license fee in excess of the required fee amount of $10 or less will not be refunded.

557.1(6) *Adoption of agency rules by reference.* The board adopts by reference the following rules of the department:

a. Public records and fair information practices as found in 481—Chapter 5.

b. Petitions for rulemaking as found in 481—Chapter 2.
c. Declaratory orders as found in 481—Chapter 3.
d. Agency procedure for rulemaking as found in 481—Chapter 4.
e. Sales of goods and services as found in rule 481—1.12(10A,68B).
f. Licensee review committee as found in 481—Chapter 505.
g. Waivers as found in 481—Chapter 6.

This rule is intended to implement Iowa Code chapters 17A, 21, 124, 124B, 155A and 272C and section 147.80.