April 2025

Administrative Code dictates Board of Pharmacy's role

Iowa Administrative Code 481 - 557.1(2) states the Iowa Board of Pharmacy has the following responsibilities:

1. Licensing of individuals.
2. Licensing of practice locations.
3. Conducting compliance inspections, audits and investigations of any persons or entities licensed or registered with the board.
4. Instituting disciplinary actions, hearing contested cases, issuing decisions and orders, and enforcing the terms of filed disciplinary orders.

DIAL staff have responsibilities such as processing licensure applications that meet all of the requirements, conducting inspections, and investigating complaints. The realignment of the Board of Pharmacy under DIAL changed how the staff is organized and supervised to achieve the goals of simplifying, standardizing, and modernizing the work done by staff. Under DIAL, staff work within a team of individuals who are responsible for the same function for other professional licensing boards. For example, Board of Pharmacy licensing specialists work alongside licensing specialists for the Boards of Medicine and Nursing, among the many other professional licensing boards under DIAL. Board compliance officers work alongside health professions investigators who investigate complaints against other licensed professionals. This restructuring has provided opportunities for streamlining processes for consistency among operations. Ultimately, any determination about whether a licensee should be publicly disciplined is left solely to the board.

Board rules updates in progress

Gov. Kim Reynolds issued Executive Order 10 (EO 10) in January 2023, directing all state agencies to conduct a comprehensive review of all administrative rules (also

known as “red tape review”). The order identified a zero-based review preferable and required each agency to be assigned a calendar year in which to complete this work. The Board of Pharmacy was assigned 2024, and the board published the required regulatory analysis on all proposed new chapters last summer. Following the public comments received from the regulatory analysis, the board subsequently published the new chapters under Notices of Intended Action, which opened another period of public comment. The board held two public hearings as required by EO 10.

Two chapters republished

In response to comments received, the board voted to republish two of the chapters under "Amended Notices of Intended Action" to provide an additional opportunity for stakeholder input. The public comment period ended March 25, 2025, and the board will likely consider all new chapters for adoption at the board’s May regular meeting. Once the board adopts the new chapters, the chapters will be published in the Iowa Administrative Bulletin and will become effective 35 days after publication.

Board of Pharmacy rules moving to Agency ID 481

Due to the state government realignment that was enacted in 2023, the Board of Pharmacy rules will no longer be housed under Agency ID 657 in the Iowa Administrative Code. Since the licensing agencies were brought under the Department of Inspections, Appeals, and Licensing (DIAL), the board’s rules will be housed within DIAL’s established Agency ID of 481 Iowa Administrative Code. The board’s rules will be found in 481 Iowa Administrative Code, Chapters 550 through 557 when they are published as adopted. Simultaneously, all existing rules in 657 IAC will be rescinded.

Common chapters consolidated

Another result of the red tape review and state government realignment has been the consolidation of common chapters of the Iowa Administrative Code (rules). The board has long maintained chapters of rules that mirror or closely resemble chapters from other licensing boards. The following chapters of topics can or will be found (once published) under the following Administrative Code chapters:

- Sales of goods and services - rule 481 IAC 1.12(10A,68B)
- Petitions for rulemaking - 481 IAC Chapter 2
- Declaratory orders - 481 IAC Chapter 3
- Agency procedure for rulemaking - 481 IAC Chapter 4
- Public records and fair information practices - 481 IAC Chapter 5

- Waivers - 481 IAC Chapter 6
- Military service, veteran reciprocity, and spouses of active-duty service members - 481 IAC Chapter 7
- Licensing and child support noncompliance, student loan repayment noncompliance, and nonpayment of state debt - 481 IAC Chapter 8
- Model rules for board administrative processes - 481 IAC Chapter 500
- Use of criminal convictions in eligibility determinations and initial licensing decisions - 481 IAC Chapter 502
- Model rules for complaints and investigations - 481 IAC Chapter 503
- Discipline - 481 IAC Chapter 504
- Licensee review committee - 481 IAC Chapter 505
- Contested cases and informal settlement - 481 IAC Chapter 506

In future newsletters, this section will provide more information about the notable changes resulting from the red tape review and address some common questions received by the board.

Iowa Prescription Monitoring Program updates and information

A new limit of 30 delegates per provider will be implemented with the adoption and implementation of 481 IAC - Chapter 556. Users with more than 30 delegates will not experience any change in access to the PMP but will not be able to add or approve additional delegates until they have removed enough delegate users to reach the new threshold. **Delegates retain access to the PMP until the supervising provider removes them.** Providers are ultimately responsible for their delegates' access and use of the PMP and should regularly review and remove delegate users as appropriate. Manage delegate access by visiting the Delegate Management page of your user profile. For step-by-step instructions on managing delegates, visit the PMP AWARxE© Support Center for delegates and delegate supervisors.

Credentialed healthcare professionals directly involved in patient care can obtain their own delegate user accounts with an unlimited number of supervisors. Access is granted only when a supervising provider approves them as a delegate. All searches completed by delegates require them to designate the provider requesting the search and will appear in the search history log of the designated

provider. An account can be created by visiting iowa.pmpaware.net. Each delegate must provide the email associated with their supervising provider's PMP user account when registering. However, once a provider has reached the threshold of 30 delegates, they will not be allowed to add them as a supervisor.

Compliance Corner - Board inspections and investigations

Board staff are tasked with performing compliance inspections and audits of all licensed or registered persons or entities. These inspections and audits are conducted to ensure accountability for all controlled substances and to ensure compliance with laws regulating the practice of pharmacy and the distribution of prescription drugs and devices in Iowa.

Inspections are designed to be an educational and proactive opportunity for the board compliance officer to work with licensee staff to identify deficiencies before they become a problem. While exceedingly rare, an inspection can be escalated to an investigation, if efforts to remedy a deficiency are unsuccessful after multiple attempts or if the deficiency is remarkably serious or egregious in nature. Any licensee should be in full compliance of Iowa laws, rules, and regulations during any routine inspection. Nonresident pharmacies must provide an inspection report that was conducted by an approved entity of the board that was completed within two years, was conducted while the pharmacy was in operation, addresses all services that the pharmacy conducts, and satisfies requirements of Iowa Code Section 155A.13A.

Board compliance officers investigate complaints related to alleged violations of Iowa law and administrative rules related to the practice of pharmacy and the distribution of drugs in Iowa. The board is authorized to investigate complaints about licensees and registrants and to take disciplinary action against any licensee or registrant alleged to have violated Iowa law or the board's administrative rules. When a complaint is received, board staff review the information to determine if a potential rule violation exists prior to compliance officer assignment for investigation. The compliance officer's role is to gather evidence that the board will use to determine if a violation occurred and, if so, what action should be taken by the board to resolve the situation. In every investigation, any licensee identified in the complaint or during the course of the investigation as possibly violating a board rule has an opportunity to provide a response or statement relating to the alleged violation(s).

Iowa Practitioner Health Program - Pharmacy

The Iowa Professional Health Program (IPHP) - Pharmacy (formerly known as the Iowa Monitoring Program for Pharmacy Professionals or IMP3) is a safe place for licensees of the Board of Pharmacy to receive the assistance and support they need for mental health conditions, physical health conditions, and/or substance use disorders that could impact their ability to safely practice pharmacy.

IPHP is designed to protect the public by supporting and monitoring licensees of the Board of Pharmacy whose health conditions may impact their ability to practice pharmacy safely. This is done by promoting early intervention, diagnosis, treatment, and monitoring.

IPHP's goal is to encourage licensees to self-report to the program and receive assistance BEFORE the Board of Pharmacy becomes aware of any disciplinary issues or about a potential impairment that could impact the safety of the public. However, the program is available to all licensees despite their involvement with the Board of Pharmacy.

Participation in IPHP is confidential

A Board of Pharmacy licensee's participation in the IPHP is confidential to the public. Participant information is also confidential to the Iowa Board of Pharmacy, except in limited situations where communication is necessary. According to 481 Iowa Administrative Code 505.6, the following situations authorize the IPHP to provide information to the Board or appropriate board staff:

- A participant's medical practice poses a significant risk to the public.
- The participant is not compliant with their IPHP contract and is referred by the IPHP to the board.
- The participant is under investigation by the board and knowing if the participant is compliant with the program would be beneficial to the investigative process.

If you or someone you know is struggling with a mental health concern, substance abuse concern, and/or a physical health concern, please consider self-reporting to IPHP by filling out the online form or by emailing rebecca.carlson@dia.iowa.gov.

Is there a specific topic that you would like to see more information about? We would love to hear from you!

Warning issued for counterfeit Ozempic®

The National Association of Boards of Pharmacy has issued a warning regarding counterfeit Ozempic® (semaglutide) injection 1 mg in the U.S. drug supply chain.

Novo Nordisk, manufacturer of Ozempic, has identified several hundred units of counterfeit Ozempic that have been illicitly distributed outside of its secure and authorized supply chain within the U.S. The U.S. Food and Drug Administration (FDA) issued a public warning concerning this counterfeit product. The FDA confirmed the seizure of the identified counterfeit units on April 9, 2025. Despite this action, the potential for further circulation of these dangerous counterfeit products remains a serious concern.

The counterfeit products bear the lot number PAR0362 and a serial number beginning with the initial eight digits 51746517. While the lot number PAR0362 itself is authentic and associated with genuine Ozempic, it is exclusively when this specific lot number is found in combination with a serial number starting with "51746517" that the product is confirmed to be counterfeit and must be immediately removed from circulation and not dispensed under any circumstances.