JUNE 2022

IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Telepharmacy Practice – Rules Adopted

The Iowa Board of Pharmacy has adopted rulemaking that was the result of an overall five-year review of Chapter 13, "Telepharmacy practice," of 657 Iowa Administrative Code (IAC). The rulemaking reduces the notification period to terminate a written agreement between a managing pharmacy and a telepharmacy site from 90 days to 45 days. The rulemaking also expands the personnel who can work at a telepharmacy site to include pharmacy support persons (PSPs). PSPs will be able to engage in nontechnical functions in the operation of a telepharmacy site under the remote supervision of a pharmacist. The rulemaking removes reiteration of several rules, which are provided in other Board chapters. Finally, the rulemaking authorizes the Board to establish a committee to consider requests for an exemption to the technician practice experience requirements when exceptional circumstances exist that may otherwise result in the closure of the telepharmacy site. The rulemaking became effective on April 27, 2022.

Collaborative Pharmacy Practice Agreements – Rules Adopted

In response to the enactment of Senate File (SF) 296, the Board has adopted rulemaking that updates the Board's rule relating to collaborative practice agreements (CPAs) between pharmacists and Iowa-licensed prescribers who have independent prescribing authority. The rulemaking identifies the minimum required elements of such agreements. SF 296 defines "collaborative pharmacy practice" agreements as a practice of pharmacy and allows prescribers to enter CPAs with one or more pharmacists. The prescriber would be required to comply with applicable rules, if adopted, of its professional license regulatory authority. Pharmacists should be

reminded that physician assistants (PAs) are not independent practitioners and, as such, are not authorized to delegate activities within a CPA to a pharmacist. A pharmacist could, however, enter a CPA with the PA's supervising physician. The rulemaking became effective on March 16, 2022.

Pharmacy-Related Action Taken by the Iowa Legislature During 2022 Session

The Board introduced two bills for consideration by the Iowa Legislature in 2022. The Board put forth its annual controlled substance (CS) bill to align the Iowa Controlled Substances Act (CSA) with the federal CSA. The bill also proposed to amend the composition and appointment of the Iowa Prescription Monitoring Program (PMP) Advisory Council. The bill changed the advisory council from governor-appointed to Board-appointed; removed the minimum number of council members; modified the composition of the council; directed the Board to adopt rules on matters pertaining to council membership, including terms of appointment and quorum; required the Board to consult with professional organizations and licensing boards for council membership; and expanded the responsibility of the council to monitor and ensure that patient confidentiality, best interests, and civil liberties are protected at all times and preserved during the existence of the PMP. The bill was enacted by the legislature and signed by Governor Kim Reynolds. While the CS provisions take effect upon enactment, the changes relating to the PMP will take effect on July 1, 2022, and the Board will promulgate rules in the coming months.

The Board's second bill seeks to reduce the regulatory burden on nurses engaged in the practice of nursing by an order of a pharmacist, such as administration of an immunization or implementation of a statewide protocol. The code change would authorize the practice of nursing under the order of a pharmacist without requiring separate registration by the Board. The bill also removes a requirement that all nonresident pharmacy license applicants provide evidence of a toll-free telephone number at which a pharmacist with access to patient records can be reached at least six days and 40 hours per week on its labeling. The Board seeks removal of this requirement in the law so that it can more effectively address the requirement in the rule to be more targeted to the nonresident pharmacies that are shipping prescription drugs into this state and exclude the requirement for those nonresident pharmacies that are not directly shipping prescription drugs to Iowans. The governor signed this bill on June 13, 2022 with an effective date of July 1, 2022, and the Board will promulgate rules relating to the nonresident pharmacies that will be required to provide evidence of a toll-free telephone number at which a pharmacist with access to patient records can be reached during the pharmacy's regular business hours.

Civil Liability Protections for COVID-19-Related Pharmacy Practice

Iowa Code 686D, the "COVID-19 Response and Back-to-Business Limited Liability Act," enacted by the Iowa Legislature in 2020, provides liability from civil damages for health care providers for "causing or contributing, directly or indirectly, to the death or injury of an individual as a result of the health care provider's acts or omissions while providing or arranging health care in support of the state's response

to COVID-19." The liability protections cover, among others, "prescribing, administering, or dispensing a pharmaceutical for off-label use to treat a patient with a suspected or confirmed case of COVID-19." The act, however, does not "relieve any person of liability for civil damages for any act or omission which constitutes recklessness or willful misconduct."

Pharmacy Reporting of Compounding Data to the NABP Information Sharing Network

On January 19, 2022, Board Rule 657—20.24 became effective, requiring pharmacies in Iowa that distribute compounded preparations interstate to report compounding data to the National Association of Boards of Pharmacy® (NABP®) Information Sharing Network to meet the requirements of a memorandum of understanding (MOU) between the Board and Food and Drug Administration (FDA).

In February 2022, FDA issued notice that it intended to reconsider the MOU, as published, and publish a new document for public comment in the future. The United States District Court for the District of Columbia remanded the MOU back to FDA and required the agency to certify it will not have a significant economic effect on small business or prepare a regulatory flexibility analysis. As a result, FDA considers the MOU originally published in October 2020 to be suspended and unenforceable.

Although FDA does not currently require the reporting as detailed in Rule 657—20.24, the Board will continue to require compliance with this rule. The reporting framework is in place utilizing the NABP Information Sharing Network and it is currently accessible to licensees. The information is valuable to Board staff in understanding the scope of services that pharmacies provide and will be utilized by compliance staff as needed. The Board anticipates that the same or similar information will be included as a requirement of a future MOU, once drafted and approved.

Please note the deadline to submit applicable information to NABP for 2021 calendar year data was April 1, 2022. If your facility does not distribute prescriptions interstate, this requirement does not apply.

Please note: Information must be submitted to NABP via its established process (the Information Sharing Network). Please do not send data directly to the Board or to a compliance officer. Compliance with this rule may be assessed at future inspections. Waivers submitted requesting delays in compliance or exemption to this rule will be considered by the Board, if needed. Questions about reporting of compounding data pursuant to the Board's rule may be directed to your compliance officer.

COVID-19 Vaccine Administration and Testing Authority in Pharmacies

Following the February 15, 2022 expiration of the governor's public health disaster emergency proclamation, pharmacies continue to have separate and distinct pathways from which to administer coronavirus disease 2019 (COVID-19) vaccinations and tests.

For vaccinations, authority for pharmacies originate from:

- Board statewide protocol (ordering practitioner: pharmacist)
- Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (PREP Act, ordering practitioner: pharmacist)
- Statewide standing order (ordering practitioner: Dr David Stilley)

For testing, authority for pharmacies originate from:

- Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19 (PREP Act, ordering practitioner: pharmacist)
- Statewide standing order (ordering practitioner: Dr Stilley)

Pharmacists are encouraged to prepare for a future repeal of one or both statewide standing orders issued by Dr Stilley. In the event of a repeal of either of the orders, the remaining orders require the pharmacist to act as the ordering practitioner. Pharmacists are encouraged to obtain a national provider identification number and complete any requirements needed to be recognized by patient third-party payers.

Scope of Practice for Prescribing Psychologists

Iowa law authorizes licensed psychologists who have completed additional training in psychopharmacology to prescribe psychotropic medications to patients with mental disorders. To have this prescribing authority, a psychologist must have either a "conditional prescription certificate" or a "prescription certificate" issued by the Iowa Board of Psychology, within the Iowa Department of Public Health, Division of Professional Licensing and Regulation. A pharmacist can search for a licensed psychologist using the Iowa Board of Psychology website and can contact the Iowa Board of Psychology office to confirm a conditional prescription certificate or a prescription certificate.

645 IAC Chapter 244 describes the requirements to qualify for each type of certificate and the rules governing prescribing psychologists. A conditional prescription certificate is issued for a period of four years to allow the conditional prescribing psychologist to complete a minimum of two years of supervised practice in prescribing psychotropic medications to become eligible for a full prescription certificate.

A psychologist with prescriptive authority is limited to prescribing psychotropic medications for the treatment of mental disorders and is prohibited from prescribing narcotics. A prescription issued by a psychologist must identify the prescriber as a "psychologist certified to prescribe" and must include the Iowa license number of the psychologist. In addition, a prescription issued by a psychologist with a conditional prescription certificate must contain the name of the supervising physician overseeing the care of the patient. A psychologist with prescriptive authority is authorized to prescribe nonnarcotic CS provided the psychologist has active CSA and Drug

Enforcement Administration registrations. A pharmacist can validate an Iowa CSA registration at *https://ibop.igovsolution.net/online/Lookups/Lookup_Individual.aspx.*

Updated Rules for Pharmacy Security and CS Accountability

The Board has updated its rules for minimum pharmacy security standards and CS accountability requirements. At its May 2022 meeting, the Board voted to adopt and file these rules, providing an effective date of **July 6, 2022.**

Notable changes to minimum physical/technology security requirements include:

- Basic alarm system (delayed compliance, July 6, 2023)
- Video surveillance system (delayed compliance, July 6, 2023)
- Controlled access to computer records
- Designated location for employees' personal effects that can be monitored and is separate from the drug storage and handling areas

Notable changes to minimum requirements for CS accountability include:

- To the extent possible, a separation of duties related to the purchasing, receiving, stocking, dispensing, and reconciling of CS inventory
- Required reconciliation of Schedule II CS by either:
    - Verifying and documenting that the on-hand physical inventory matches the perpetual inventory following each transaction (receipt, disbursement, returned to stock, etc)
    - Performing a physical count of each Schedule II CS that has not been reconciled after each transaction (or if no transactions took place) and reconciling the count with the perpetual inventory once per year
- Reporting reconciliation discrepancies to the pharmacist-in-charge (PIC) within one business day following the discovery
- For inventories, all counts of solid dosage forms must be exact. Estimates are only permitted for liquid products packaged in nonincremented containers
- Required CS inventories whenever there is a change in PIC, including the assignment of a temporary PIC or an interim PIC, with the following caveats:
    - If there is no lapse between PIC assignments, the exiting PIC inventory may serve as the incoming PIC inventory

- Any lapse in PIC assignments will require two inventories to be conducted: one for the exiting PIC and one for the incoming PIC
- A PIC change inventory will **not** be required when an interim PIC is assigned and the pharmacy maintains a perpetual inventory of all CS

- Schedule III-V accountability. A pharmacy must do one or more of the following:
  - Maintain a perpetual inventory log (which may be electronic) in compliance with 657 IAC 10.18
  - Document an audit and reconciliation of all CS every six months
  - Document routine cycle counts of substances, so long as all CS are counted every 90 days and discrepancies are investigated and documented
- Establishment of an action plan following a loss, which must include any directives provided by a Board compliance officer

The Board's compliance team has educated licensees on these new requirements during routine inspections and will continue to do so. A copy of the entire rulemaking can be found here.

Get to Know Your Board of Pharmacy Members – Kathy Stone

The June Board member highlight is Kathy Stone, RPh. She is a pharmacist, critical access pharmacy manager, and current chair member. She is also her health system's pharmacy compliance manager for sterile compounding. What brought Kathy to the Board was the Iowa Pharmacy Association's Leadership Pharmacy retreat. "That week really helped me refocus on the profession and how I wanted to contribute," says Kathy. Her favorite part about serving on the Board is that it is uniquely focused on the public and patients, which is very important to her. One misconception she thinks people might have about the Board is that it is "out to get you," when in reality, it is there to help! "We help pharmacists, technicians, and pharmacy support persons to find their way to be compliant based on their practice. Our compliance officers should be your best friends! I think there is also the misconception about who we are here to ultimately serve. Our oath is to serve and protect the public, so our decisions are grounded in that goal." In her spare time, Kathy likes to bowhunt, fish, play any type of ball, watch her kids' sports and dance activities, teach Sunday school, and read. Her favorite music group is Rascal Flatts. Her favorite restaurant in Iowa is Pizza King in Council Bluffs.

FDA Requesting Comments on Potential Opioid Analgesic REMS Modification by June 21, 2022

FDA is asking for comments from interested stakeholders on a potential modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (OA REMS) to require that mail-back envelopes be dispensed and education on safe disposal provided with opioid analgesics dispensed in an outpatient setting. Per FDA, "such a requirement could reduce the amount of unused opioid analgesics in patients'

homes, thereby reducing opportunities for nonmedical use, accidental exposure, and overdose, and possibly reducing the development of new opioid addiction." Comments may be submitted online under Docket No. FDA-2022-N-0165 no later than June 21, 2022.

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Andrew Funk, PharmD - State News Editor

Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor

Deborah Zak - Communications and Services Senior Manager

400 SW 8th St, Suite E | Des Moines, IA 50309-4688 | Tel: 515/281-5944
Fax: 515/281-4609 | pharmacy.iowa.gov