JUNE 2024

# IOWA BOARD OF PHARMACY

*newsletter to promote pharmacy and drug law compliance*

## The Board of Pharmacy Has a New Executive Director

In April 2024, Anne Schlepphorst was selected as the Iowa Board of Pharmacy's new executive director. Anne brings with her a wealth of knowledge and experience. She most recently served the Boards of Pharmacy and Medicine as chief investigator and, prior to that time, she was a health professions investigator for the Iowa Board of Medicine. Currently, in addition to serving as the executive director for the Board, she will serve as bureau chief of the Monitoring Bureau within the Division of Professional Licensure and serve the Iowa Board of Nursing in an executive capacity. Welcome, Anne!

## DIAL Website

As part of the Board of Pharmacy becoming part of the Department of Inspections, Appeals, and Licensing (DIAL), Board information will now be accessible on DIAL's website. To navigate to pharmacy-specific information, please use *https://dial.iowa.gov/about/boards/pharmacy.* Here you can access license services such as applying for or renewing your license, verifying a license, or filing a complaint. The section titled "About the Board of Pharmacy" contains a Board member overview, the Board meeting calendar, and contact information including a main phone number, fax number, and an online Contact Us form. Individual contact information for Board staff will no longer be available to the public. A bit further down on the home page, Pharmacy Programs and Services information is available. Here you will find specific information such as statewide protocols, Iowa Prescription Monitoring Program (PMP) information, Iowa Monitoring

***National Pharmacy Compliance News***

A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

***Read National News***

Program for Pharmacy Professionals information, and electronic prescribing mandate information, just to name a few.

**Note:** Board order and action information is now available from the DIAL website home page. Highlighted below, you will be taken to a directory, which can be filtered for the information you need.


## *Beware of Scam Phone Calls*

Licensees continue to report being victimized by scam callers claiming to represent the Board or another government agency.

Techniques used by fake callers include the following:

- A caller claims a licensee is under investigation by the Board, Drug Enforcement Administration (DEA), Federal Bureau of Investigation (FBI), or another government agency. In some cases, the caller also warns of discipline unless the licensee pays a "fine."
- A caller warns a licensee not to report the call to anyone "or else you will jeopardize the investigation."
- A caller requests a licensee's cell phone number.
- A caller gives a fake call-back number.
- A caller spoofs the Board's phone number. This happens when your caller ID screen falsely shows that an incoming call is from the Board.

These calls are scams! In many cases, callers are attempting to extort money or elicit sensitive information – eg, license numbers or DEA registration numbers – from licensees.

What can you do to protect yourself and your pharmacy?

Licensee security is important to the Board. Be aware of the following tips:

- If you have any doubts or questions about someone claiming by phone or in person to represent the Iowa Board of Pharmacy, call the Board at 515/281-5944.
- If a scam caller claims to represent DEA or FBI, report the call to DEA's Extortion Scam reporting program or FBI's Internet Crime Complaint Center.
- If a scam caller's phone number appears to be a Board telephone number, report the scam using the Federal Communications Commission's consumer complaint form.

As a reminder, Board staff may reach out by phone for an interview if an investigation is being conducted; however, payment will never be requested over the phone.

## *Security Breaches in Relation to CS*

It was recently reported to the Board that a pharmacy in Iowa experienced a security breach from an outside party attempting to open wholesaler accounts using the pharmacy's name and information to obtain controlled substances (CS). The culprit attempted to open accounts as many as 15 times at various wholesale distributors. Please ensure that you are keeping a close eye on your orders and doing all you can to make sure your information is secure. If you notice any fraudulent or suspicious activity, please contact your local law enforcement, DEA, and the Board at 515/281-5944.

## *Flooring Required for Nonsterile Compounding*

A common question that arises in the world of nonsterile compounding is the flooring requirement set forth by United States Pharmacopeia Chapter <795>. This chapter states that floors in the compounding area should be easily cleanable and should not be porous or particle generating. In pharmacies that have carpeted floors, it is acceptable to place a cleanable mat over the carpet in the area where compounding will be performed. This mat should be cleaned daily on days when compounding occurs, after spills, and when surface contamination (eg, from splashes) is known or suspected. Appropriate cleaning agents must be selected and utilized as well.

## *Counterfeit Botox Injection*

Food and Drug Administration (FDA) issued a statement on April 16, 2024, alerting health care professionals and consumers that unsafe versions of Botox® (botulinum toxin) have been found in multiple states and administered to consumers for cosmetic purposes.

FDA is aware of adverse events, including hospitalizations, linked to the counterfeit Botox. Symptoms included blurred or double vision, difficulty swallowing, dry mouth, constipation, incontinence, shortness of breath, weakness, and difficulty lifting one's head following injection of these products. These symptoms are similar to those seen when botulinum toxin spreads to other parts of the body.

FDA takes reports of counterfeit products seriously and is working closely with Centers for Disease Control and Prevention, state health departments, and manufacturers to help protect the nation's drug supply. FDA's investigation is ongoing, and the agency is currently working with AbbVie (the manufacturer of Botox) to identify, investigate, and remove suspected counterfeit Botox products found in the United States.

**Information for Health Care Professionals**

- Purchasing and administering counterfeit products puts your patients at risk.
- Check the product for any signs of adulteration before using it.
- Federal law requires that all health care providers who dispense or administer prescription drugs purchase those products only from authorized trading partners.
- Visit FDA's website for information about how to safely purchase prescription drugs for your patients: "Know Your Source: Protecting Patients from Unsafe Drugs."

## *CMS Issues Final Rule to Adopt NCPDP SCRIPT Standard Version 2023011*

Centers for Medicare & Medicaid Services (CMS) has issued a final rule for health information technology standards to adopt the National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 2023011. The updated SCRIPT Standard Version will allow electronic CS prescription transfers between pharmacies. The transition period from NCPDP SCRIPT Standard Version 2017071 to Standard Version 2023011 will end on January 1, 2028.

## *Partial Filling of Schedule II CS*

Board staff continues to receive questions from licensees about the various legal options for partially filling Schedule II CS prescriptions. As provided in DEA federal regulations, pharmacies may partially fill Schedule II CS as follows:

- Due to insufficient supply, the remaining quantity must be dispensed within 72 hours.
- For a long-term care facility patient, partial fills may be dispensed for a prescription over the course of 60 days from the original date of issue so long as the total quantity dispensed does not exceed the quantity authorized.
- In response to a specific request to partially fill a prescription from a patient or prescriber, any remaining quantity available to the patient may be dispensed within 30 days of the original date of issue so long as the total quantity dispensed does not exceed the quantity authorized.

All partial dispensing must be documented and conducted within the conditions authorized by federal regulations and Board rules.

## *Legislative Recap*

The Iowa Legislature has concluded its second session of the 90th General Assembly. Several bills were enacted that will impact the Board and its licensees.

- House File (HF) 555, introduced by the Iowa Pharmacy Association, was enacted and will be effective July 1, 2024. The bill updates the Pharmacy Practice Act and provides clarity for the practice of pharmacy, authorizes pharmacist-initiated therapeutic substitution, authorizes pharmacist-initiated protocols, authorizes the Board to assess administrative penalties up to $500 for various infractions, removes the requirement that a pharmacy license be issued in the name of a pharmacist-in-charge, removes the 10-mile radius restriction for a telepharmacy location, and provides general code cleanup.
- HF 2538 requires all agencies to develop and annually update a strategic and operational plan.
- HF 2686 is a cleanup bill in follow-up to the state government realignment but includes a provision in Section 13 to allow licensees to carry over continuing education (CE) that was completed but not used to satisfy the CE requirement in the current renewal period for the next renewal period; however, the carryover is limited to no more than 50% of the total CE requirement.
- Senate File (SF) 2370 codifies the intensive review and re-promulgation of rules that were required in the governor's Executive Order 10, which agencies will have to complete every five years.
- SF 2385 reestablishes the Boards and Commissions Review Committee, requires DIAL to conduct a licensure renewal cycles study and a licensure fee study and submit a report by September 1, 2024, and modifies the PMP Advisory Council to be an Advisory Committee.

For any area of practice that a bill requires the Board to adopt for rulemaking, the Board will incorporate such rules as part of its overall re-promulgation as required by Executive Order 10, which the Board must complete in 2024.

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