JUNE 2023

IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Hazardous Drug Labeling Regarding Administration by Nonpatient

When a pharmacy dispenses a hazardous drug to a patient or caregiver, consideration must be given regarding who will be handling the medication. Between nursing homes, assisted living, in-home care, and family caretakers, a diverse population of people may come into contact with these medications during administration. Due to the diversity in medication administration, labeling of hazardous substances dispensed by a pharmacy is necessary for overall safety. Per regulations on prescription labeling requirements (Iowa Administrative Code (IAC) 657 – 6.10(1)f), any precautions to be observed must accompany directions or instructions for use. This is typically accomplished with the use of auxiliary labels that indicate the hazardous nature of a medication. The risks associated with exposure to hazardous drugs should be included on prescription labeling to notify the medication handler.

For information regarding the best practices for handling hazardous drugs, please refer to United States Pharmacopeia Chapter <800>.

657—6.10 (126,155A) Prescription label requirements.

6.10(1) *Required information.* The label affixed to or on the dispensing container of any prescription drug or device dispensed by a pharmacy pursuant to a prescription drug order shall bear the following:

a. Serial number (a unique identification number of the prescription);

b. The name, telephone number, and address of the pharmacy;

c. The name of the patient or, if such drug is prescribed for an animal, the species of the animal and the name of its owner (. . .);

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

d. The name of the prescribing practitioner;

e. The date the prescription is dispensed;

f. The directions or instructions for use, including precautions to be observed;

Rules Adopted Relating to Bronchodilators and Opioid Antagonists for Schools; Practice of Nursing Under Pharmacist Orders

The Iowa Board of Pharmacy recently amended rules in multiple chapters to implement changes to the Iowa Code during the 2022 legislative session – House File (HF) 771, HF 2573, and HF 2169.

HF 771 amended Iowa Code Section 280.16A (Uniform school requirements), which previously authorized a licensed health care professional to prescribe epinephrine autoinjectors in the name of a school district or accredited nonpublic school. The bill, enacted and now codified, added bronchodilator canisters, with or without a spacer, as prescription items, which may be prescribed in the name of a school district or accredited nonpublic school.

HF 2573 amended Iowa Code Section 135.190 (Department of public health), which provides broad access to opioid antagonists for persons in a position to assist an individual experiencing an opioid overdose. The bill, enacted and now codified, adds language authorizing a school district to obtain a valid prescription for an opioid antagonist.

HF 2169, introduced by the Board, amended Iowa Code Section 152.1 (Nursing), and created new Iowa Code Section 155A.33B (Pharmacy). The bill, enacted and now codified, provides that registered nurses are authorized to assist in the administration of immunizations and vaccinations and the utilization of statewide protocols, pursuant to a pharmacist's order and consistent with the practice of the registered nurse's profession, without obtaining Board registration.

The rulemaking provides an exemption from registration for licensed registered nurses engaged in the practice of nursing under a pharmacist's order and amends the various exemptions in the Board's rules that otherwise require a patient name as a required element on a prescription or prescription label. The amendments were effective April 26, 2023.

Approval of OTC Naloxone and the Impact on the Board's Protocol and Statewide Standing Order

On March 29, 2023, Food and Drug Administration (FDA) approved Narcan® 4 mg nasal spray for over-the-counter (OTC) use, the first naloxone product approved for use without a prescription. Narcan's OTC product may not be introduced into the market for several months. In the meantime, supplies of Narcan that are currently labeled as "Rx only" will remain as such and will continue to require a prescription for dispensing. Pharmacies are encouraged to continue to identify individuals who would benefit from having naloxone available and utilize either the Board's statewide protocol or Dr Robert Kruse's statewide standing order to dispense it. Since there will continue to be prescription-only naloxone products in the marketplace, until those products seek and obtain FDA approval for

OTC labeling, the Board's protocol and Dr Kruse's statewide standing order will continue to be available for dispensing naloxone products to eligible recipients. Additionally, the Board's Narcan Dispensing Program will continue to be available for pharmacies to submit for reimbursement of the naloxone product and dispensing fee. Once the National Drug Code of the OTC Narcan is known, the Board anticipates the product will be added to the Narcan Dispensing Program list of covered products and, depending on cost, may be the preferred agent.

Opioid Manufacturer Provision of Mail-Back Envelopes

On April 3, 2023, FDA announced it is requiring manufacturers of opioid analgesics dispensed in outpatient settings to make prepaid mail-back envelopes available to outpatient pharmacies and other dispensers as an additional opioid analgesic disposal option for patients. All manufacturers of opioids used in outpatient settings are required to submit proposed modifications to the Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) within 180 days. FDA anticipates approval of the modified REMS in 2024. Once implemented, outpatient pharmacies will have the option of ordering prepaid mail-back envelopes from opioid manufacturers to provide to their patients who are prescribed opioids. The REMS modification will also require manufacturers to develop educational materials for patients on safe disposal of opioids. FDA Commissioner Robert M. Califf, MD, noted that he believes "these efforts will not only increase convenient disposal options for many Americans, but also reduce … nonmedical use, accidental exposure, overdose and potential new cases of opioid use disorder."

Importance of Ensuring That Applications Are Complete

The Board encourages the use of online applications to ensure that licenses and registrations are issued as quickly as possible. Filing incomplete applications delays the time to license issuance. The most common reason individual registration issuance is delayed is because the application does not include employer information or start date. The second most common reason for an issuance delay is not providing complete information about criminal history. If there is **any** criminal history to document, it is recommended to obtain court documents from the clerk of courts and put all the documentation into a pdf and upload it with your application. Please remember, a printout of Iowa Courts Online is not acceptable.

Reminder of the Security Requirements Effective July 6, 2023

Last summer, the Board amended its rule (657 IAC 6.7) relating to the security requirements for general pharmacy licensees. New subrule (5) provides that each Iowa pharmacy is required to develop and implement policies and procedures to ensure appropriate physical security and monitoring of the pharmacy to prevent unauthorized access to prescription drugs, including controlled substances (CS), and pharmacy records. The policies and procedures require the implementation of security and monitoring methods, in addition to those identified in the subrule, commensurate with the pharmacy's unique operation. The policies and procedures must also be able to identify the retention

of documentation of activities or recordings retained from the alarm and video surveillance systems, as well as contingencies for when the systems are temporarily unavailable. While the new subrule was effective July 6, 2022, the language provided for delayed implementation of the requirements for basic alarm and video surveillance systems. Those components will be effective and must be operational no later than July 6, 2023. Questions have been posed regarding situations where the general (outpatient) pharmacy is co-located within another business (retail store, clinic, or hospital) and that business has a basic alarm system. The business' alarm system is sufficient to cover the pharmacy only when the business and the pharmacy maintain the same operating hours. If a pharmacy closes and the business in which the pharmacy is co-located remains open and operational, the pharmacy must have a separate alarm system that will be triggered upon a breach to the pharmacy. Additional questions may be directed to the pharmacy's designated compliance officer.

Governor Reynolds' Executive Order Number 10

In January 2023, Governor Kim Reynolds signed Executive Order 10, which requires all state agencies to conduct a retroactive analysis on its administrative rules and repromulgate rules that the agency determines are necessary and statutorily authorized. Each agency is assigned a year for this review. The Board has been assigned to review its rules (657 IAC) in 2024. The Board's Rules Committee has developed a schedule to review the Board's rules in relation to rulemaking authority or directives found in the Iowa Code and appropriate standards for licensure and practice to protect the public. The Board's intention is to repeal and replace 657 IAC in one action, which will result in a complete restructuring of the Board's rules for efficiency. The Rules Committee plans to review the different topics relating to licensing/registration, practice standards, distribution standards, CS, etc, no later than June 2024. Upon the completion of its work to develop a proposed replacement 657 IAC, the proposed language will be reviewed by the Board, and two public hearings will be scheduled to solicit public comment prior to the rulemaking being submitted for Notice of Intended Action. More information about the schedule of the Board's review can be found on the Board's website at *https://pharmacy.iowa.gov/rules-laws/executive-order-10-rule-making-information*.

The Iowa Board of Pharmacy News is published by the Iowa Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

Andrew Funk, PharmD - State News Editor

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

Megan Pellegrini - Publications and Editorial Manager

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