SEPTEMBER 2023

IOWA BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Watch Out for Expiration Dates!

An issue of concern that is increasingly observed by the Iowa Board of Pharmacy is the failure of pharmacies to ensure proper monitoring and removal of expired products or products nearing expiration, including over-the-counter (OTC) products, resulting in those expired or nearly expired products being dispensed or sold to patients. Pharmacies have a duty to their patients to dispense or sell products that are not outdated, adulterated, or subject to a manufacturer recall. Pharmacies must establish and implement sufficient policies and procedures that ensure the review of the pharmacy's inventory so that outdated, adulterated, or recalled products are removed and segregated from dispensing shelves until they can be appropriately removed.

Board Has Discontinued Printing License and Registration Certificates

As of January 1, 2023, the Board has discontinued its practice of printing certificates to mail to licensees and registrants (except for new pharmacist wall licenses). Upon issuance of a license or registration, including when renewed, the licensee or registrant will receive an electronic, printable certificate via email. Licensees need to ensure that the Board has the most current email address on file, which the licensee routinely monitors. Alternatively, licensees and registrants may log in to their Board online profile to print a certificate.

Board Member Updates

On May 1, 2023, pharmacist Connie Connolly began her three-year appointment to the Board, filling the seat of outgoing pharmacist

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

Board Member Gayle Mayer. In June, public Board Member Sherill Whisenand resigned from her position. Gayle and Sherill's prior service and Connie's willingness to serve are greatly appreciated.

Recent Board Rulemaking in Response to SF 2383

During the 2022 legislative session, Senate File (SF) 2383 was enacted, which provided several provisions to reduce the barriers to licensure for service veterans and spouses of active-duty military personnel. The bill provides fee waivers for new applicants and for one renewal for licensees who are within five years of discharge from service. This provision has been implemented in the Board's application processes. Additionally, the bill reintroduced the requirement to expedite license and registration applications from spouses of active-duty military personnel. The Board's rules and internal procedures have been amended to implement this provision.

Opioid Antagonists – Updates to the Board's Statewide Protocol

In May 2023, Food and Drug Administration (FDA) approved a new opioid antagonist for reversal of opioid-related overdose – Opvee® nasal spray (nalmefene). In response to the new non-naloxone opioid antagonist, the Board recently approved updates to its statewide protocol for pharmacists. As part of 2023 Iowa Acts, House File (HF) 595, the language relating to Board-approved statewide protocols in Iowa Code Section 155A.46 was amended to provide for more broad distribution of overdose reversal opioid antagonists. Where the law previously authorized a protocol for "naloxone," the bill amended the language to read "opioid antagonists for overdose reversals." The protocol has been updated to provide that a pharmacist may order and dispense any FDA-approved opioid antagonist for the reversal of an opioid overdose to any eligible recipient ages 18 or older.

The recent FDA approvals of Narcan® 4 mg nasal spray or RiVive™ 3 mg nasal spray to OTC status do not impact the Board's statewide protocol. The OTC products would still be eligible for dispensing under the Board's protocol due to their status as being FDA approved for opioid overdose reversal.

Konvomep and Impact on Compounding Omeprazole Suspensions

In August 2022, FDA approved a reconstitutable formulation of omeprazole suspension – Konvomep™. Prior to this approval, some patients required specially compounded formulations due to the inability of existing omeprazole formulations to meet the patient's needs. Prior to the approval of Konvomep, pharmacies had access to FIRST-Omeprazole Compounding Kits. These kits were not FDA approved but simply convenience kits containing the bulk ingredients for pharmacists to compound formulations under section 503A of the Federal Food, Drug,

and Cosmetic Act. With FDA approval and market availability of Konvomep, pharmacies are now prohibited from compounding omeprazole suspensions unless the compound meets the conditions identified in state and federal regulations for compounding essentially copies of commercially available drugs.

Utilization of a QR Code in Lieu of Printed Drug Monographs

A trend increasingly observed in pharmacies has been the utilization of a QR code printed on a patient's prescription receipt in lieu of a printed patient drug monograph. While the Board's rule authorizes alternative forms (and encourages multiple forms) of patient information, pharmacies are reminded that such alternative forms of information are not intended to be in place of verbal counseling from pharmacists for new and changed prescriptions. Further, pharmacies should be cognizant of the patient's ability to access a QR code on a receipt. If the patient does not have access to a readable device, the pharmacy should ensure that the patient drug monograph is provided.

From the Iowa PMP

The Iowa naloxone (Narcan and Kloxxado®) and disposal kit dispensing programs continue to be very successful. Over 7,500 naloxone and 40,000 drug disposal kits have been dispensed to Iowans, with more than 350 Iowa pharmacies participating. A few reminders about the programs are listed below:

1) All adult (18 years of age and older) Iowa patients are eligible to receive a naloxone nasal kit. All Iowa patients (no age restrictions) are eligible to receive an at-home drug disposal kit. Both programs are offered at no cost to patients (no co-pay).

2) Pharmacies are reimbursed the Centers for Medicare & Medicaid Services-listed cost of naloxone plus a $20 dispensing fee for patient education and counseling under the naloxone program and are reimbursed a total of $7.50 for providing a disposal kit along with patient education and counseling under the disposal kit program.

3) Pharmacies are strongly encouraged to utilize a generic formulation of naloxone when available.

4) Pharmacies may utilize a prescriber prescription, the statewide protocol, or the statewide standing order under the naloxone program.

5) It is anticipated that OTC naloxone National Drug Code(s) will be added to a list of covered products once they reach the market.

6) As with any dispensing of naloxone for overdose reversal, the dispensing must be reported to the Iowa Prescription Monitoring Program (PMP).

A few additional disposal program promotional kits, which were mailed to pharmacies at the start of the program, are still available. Pharmacies that would like an additional promo kit or more information about participating in either program may contact the Iowa PMP via email at pmp@iowa.gov. The Iowa PMP thanks the Iowa Department of Health and Human Services for its ongoing support of this project!

Other Legislative Session Action

During the 2023 legislative session, HF 265 was enacted and signed by Governor Kim Reynolds, which establishes licensure requirements for the practice of midwifery in Iowa. The bill requires any individual who is engaged in the practice of midwifery and who is not otherwise licensed as a nurse or advanced practice registered nurse to be licensed with the Iowa Board of Nursing no later than July 1, 2024. The bill authorizes licensed midwives to obtain and administer certain medications associated with the care of their clients, but specifically prohibits the utilization of controlled substances (CS).

The Board of Nursing is currently in the process of promulgating rules related to the licensure and practice standards of licensed midwives in consultation with the Midwifery Advisory Council, which was also established by HF 265.

As with any other distribution of prescription drugs to authorized practitioners (ie, authorized trading partners), pharmacies are required to verify the credentials of the trading partner prior to such distribution.

Compounding Pearl

Hand hygiene is a requirement in the revions of United States Pharmacopeia (USP) Chapter <795> and remains a requirement for USP Chapter <797>. One of the most frequent observations during a compounding inspection is inadequate hand hygiene.

Revised USP Chapter <795> requires that knowledge and competency must be demonstrated initially and at least every 12 months in several core competencies, including hand hygiene. Personnel must perform procedures necessary for appropriate hand hygiene when entering the compounding area. Complete and compliant hand hygiene includes washing hands with soap and water for at least 30 seconds, drying hands completely with disposable towels or wipers, and donning gloves.

Revised USP Chapter <797> requires that personnel must complete training and be able to demonstrate knowledge of principles and competency of skills, including hand hygiene, every 12 months. Completion of adequate handwashing procedures is required every time prior to initiating sterile compounding. The use of a disposable nail cleaner is not optional. Complete and compliant hand hygiene includes cleaning underneath the fingernails under warm running water using a disposable nail cleaner, washing hands and forearms up to the elbows with soap and

water for at least 30 seconds, and drying hands and forearms up to the elbows completely with low-lint disposable towels or wipers.

Schedule III-V CS Accountability

The amendments to Board rules relating to CS accountability of Schedules III-V became effective last year on July 6, 2022. To provide flexibility for each pharmacy to be compliant with these new rules, the following options were provided, which a pharmacy may utilize in **any combination** to ensure that all substances are accounted for:

1. Perpetual inventory log, which may be maintained by electronic means, so long as the system complies with the perpetual inventory requirements in rule 657—10.18(124).
2. Documented audit and reconciliation of all CS every six months.
3. Routine documented cycle counts of substances, so long as all CS are counted every 90 days and identified discrepancies are investigated and documented.
4. Other measures preapproved by the Board.

USP Webinar Available Now for Iowa Pharmacists and Technicians

The *Updates to USP General Chapters <795> and <797>* webinar course is now available on demand. The Board, in cooperation with CEimpact, presents updates to the revised USP Chapters <795> and <797> on the compounding of nonsterile and sterile preparations, for which revisions become effective November 1, 2023. The revisions are in comparison to the currently official USP compounding chapters. This course is for supplemental education purposes only and does not contain all content or requirements from the revised USP Chapters <795> and <797>. The course is a recording of the live webinar with a question-and-answer session that took place on July 11, 2023. Links to the course may be found at *https://pharmacy.iowa.gov/quick-links.*

Continuing Education: 1.5 contact hours available at no cost.

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