December 2016

Iowa Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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

Applications – Timeliness and Disclosing Criminal and Disciplinary History

By Jennifer O'Toole, RPh

The Iowa Board of Pharmacy licenses many different license types, including pharmacists, pharmacy technicians, pharmacy support persons, prescribers, pharmacies, wholesalers, manufacturers, and emergency medical services, to name a few. Please allow two weeks for processing, as hundreds of applications are received in the office daily and are processed in the order in which they are received. Waiting until the last minute may result in your license or registration becoming delinquent. Renewal applications are mailed by the Board to the address on file about 60 days prior to expiration. If you did not receive this mailing, check to make sure the Board has your current address on file.

When filling out an application, make sure all requested information is completely filled out and appropriate documentation is provided. If the application is not complete or is missing documentation, the application will at minimum be delayed and possibly returned to you.

Providing criminal and disciplinary history can be confusing. Remember to answer the questions asked and provide all documents. Any felony or misdemeanor charges must be disclosed even if the disposition was a deferred judgment. If the application asks if you have **ever** been charged, etc, then you must provide all documentation for any history regardless if you have already provided this information on previous applications. The documentation required is official court documents and a summary of the events. One sentence on a sticky note is not sufficient.

Contact the Board office at 515/281-5944 if you have any questions while filling out applications.

Notifying the Board of Address or Name Changes – Technicians, Pharmacy Support Persons, Pharmacists, and Prescribers

By Jennifer O'Toole, RPh

If you have changed your name or have moved, you need to notify the Board office within 10 days. Failure to notify can result in disciplinary action. Remember, the Board sends out renewal applications to the address on file. If you have not updated your address, you may not receive this application. Notifications to the Board can be sent via email to Ann Jarnagin at ann.jarnagin@iowa.gov, faxed to 515/281-4609, or sent via regular mail to 400 SW 8th St, Ste E, Des Moines, IA 50309.

Who Do I Call If I Have Questions?

By Jennifer O'Toole, RPh

If you have a question regarding pharmacy law or Board rules, your first call should be to the compliance officer assigned to your location. A complete territory list can be found on the Board website at *https://pharmacy.iowa.gov* under the Contact Us tab. Office staff are also listed with the type of questions that should be directed to each staff member. Click on the staff person's name to email him or her directly.

Law Reference Online

By Jennifer O'Toole, RPh

A direct link to Board rules and the Iowa Code can be found on the Board website by clicking the Rules/Laws tab. This will take you to the Rules/Laws page, where you can select either the 657 Iowa Administrative Code link or one of the three Iowa Code links. The 657 Iowa Administrative Code link will redirect to the Iowa Legislature website, where the Board rules are listed by chapter. You may view a listing of the separate rules within the chapter or each chapter in its entirety in PDF form. To find a PDF of the complete rules of the Board, click on the Agency PDF link

Continued on page 4

FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition *by visiting* www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

Continued from page 1

at the top. If you do not know what chapter you want, click on the Agency PDF link. Then, using a search tool (eg, type "Ctrl+F" (Windows) or "Command+F" (Mac)), type a keyword to locate the desired section. If you need any assistance, please contact your compliance officer or the Board office.

Are Non-Safety Cap Signatures Required for Compliance Packs and Med Paks?

By Jennifer O'Toole, RPh

The answer is **yes.** The only exception would be care facilities where med paks are in the care of a health care professional until utilized. There is no special exemption for patient med paks from the requirements of the Poison Prevention Packaging Act. Thus, if the patient med pak does not meet child-resistant standards, it shall be placed in an outer package that does comply, or the necessary consent of the purchaser or physician to dispense in a container not intended to be child-resistant shall be obtained.

Controlled Substance Drop-Off Locations

By Jennifer O'Toole, RPh

The Governor's Office of Drug Control Policy has created a new map showing all of the permanent controlled substance (CS) drop-off locations at law enforcement offices throughout the state of Iowa. This map can be found by visiting *https://odcp.iowa.gov/rxtakebacks.* Click on the map to find available sites or click the link for the list of Iowa locations by city.

Any manufacturer, distributor, reverse distributor, narcotic treatment program, hospitals/clinics with an on-site pharmacy, and retail pharmacy with the authority to handle Schedule II CS may register with Drug Enforcement Administration (DEA) as an "authorized collector." Registration with DEA is free and can be done online at *www.deadiversion.usdoj.gov.* Once the registration is authorized by DEA, the entity may begin collecting CS in accordance with DEA rules. Currently, no additional registration or notification is required through the Board.

Rules pertaining to the operation and record-keeping requirements for entities registered with DEA as CS take-back sites may be found at *www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf.*

TakeAway and MedDrop Drug Disposal Options

By Jennifer Tiffany, RPh

In an effort to curtail diversion and improper discarding of unwanted and unused patient medications, the Board has initiated contracts with the Iowa Pharmacy Association (IPA) and Assured Waste Solutions, LLC (AWS) to provide non-CS and DEA-compliant CS disposal receptacles to Iowa pharmacies.

TakeAway boxes are available to pharmacies at no cost through IPA. Patients may dispose of nonprescription and prescription medications in these receptacles. No CS are accepted. TakeAway's 20-gallon Environmental Return Systems can be obtained by contacting IPA at ipa@iarx.org or 515/270-0713.

DEA-compliant MedDrop kiosks will be available through AWS to a limited number of pharmacies each fiscal year. The metal take-back receptacles are permanent fixtures that must be bolted to the floor and accessible by customers. Each kiosk has a 40-gallon inner mail-back receptacle with a liner. Both CS and non-CS medications may be placed in the units by end users. This includes over-the-counter items, pet medications, liquids, and EpiPens®. No aerosols, sharps, needles, or illicit drugs are allowed. Please contact Jennifer Tiffany with the Board at jennifer.tiffany@iowa.gov if you are interested in receiving a MedDrop kiosk at no charge.

Both TakeAway boxes and MedDrop kiosks are not intended for disposal of pharmacy stock. Disposition of expired or unusable pharmacy stock must be accomplished through a reverse distributor or, on a small scale, by on-site destruction with a Board compliance officer.

Naloxone Statewide Standing Order

Beginning November 3, 2016, pharmacists in the state of Iowa may dispense naloxone pursuant to a statewide standing order. Steps for a pharmacist or intern to dispense naloxone pursuant to the standing order are as follows:

1. Complete at least one hour of continuing education (CE) relating to opioid overdose and treatment.
2. Download the statewide standing order and have all pharmacists who qualify to dispense naloxone sign the order. Maintain this order in the pharmacy.
3. Research and identify substance abuse or behavioral health treatment programs in the pharmacy's area to provide this information during recipient training and education consultation sessions.
4. Download the eligibility assessment form.
5. Get the word out that your pharmacy is now offering this product and service.

The statewide standing order, the eligibility assessment form, and links to free CE programs are available on the Board website at *https://pharmacy.iowa.gov* under the Misc. tab.

Facebook "Iowa Board of Pharmacy"
www.facebook.com/pages/Iowa-Board-of-Pharmacy/223126781053672

Twitter "IABoardPharmacy"
https://twitter.com/IABoardPharmacy

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
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager