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News

Iowa Board of Pharmacy

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400 SW 8th St, Suite E • Des Moines, IA 50309-4688 • Tel: 515/281-5944
Fax: 515/281-4609 • Website: *www.state.ia.us/ibpe*

Executive Director Position

Members of the Iowa Board of Pharmacy and Board staff have been diligently searching for a successor for Lloyd K. Jessen, JD, RPh, who retired from the executive director position in March 2015 after nearly 30 years of dedicated service to the Board. By the time this *Newsletter* is distributed, the Board hopes to have named a new executive director for the Board. Please check the Board's website *(www.iowa.gov/ibpe)* for further information.

Pharmacy Compounding for Office Use

Under the federal Drug Quality and Security Act, signed into law in November 2013, only a pharmacy that registered with Food and Drug Administration (FDA) as an outsourcing facility is allowed to provide compounded, non-patient-specific drug products (for human use) to another health care provider to be administered in the prescriber's office. If your pharmacy is not an FDA-registered outsourcing facility, you may not sell compounded non-patient-specific drug products to a prescriber for office administration. Your pharmacy may compound and provide drug products to a prescriber, but only after your pharmacy has received a patient-specific prescription for the product. Your pharmacy may perform bulk compounding in anticipation of the needs of a prescriber based on historical dispensing, but the compounded product may not be delivered to the prescriber's office until a patient-specific prescription for the product is received by the pharmacy. As this is a federal law, the Board may not grant a waiver of compliance with the law. Also, be reminded that pharmacies may only compound drugs that are not copies of commercially available drugs. For a compounded product that is essentially a copy of a commercially available product, the compounded product must have a change that produces, for that specific patient, a **clinically** significant difference to meet a medical need as determined and authorized by the prescriber. The laws regarding compounding and compounding for office use are still evolving, so be sure to check the Board's website for updates.

Drug Wholesalers and Reverse Distributors

Most Iowa pharmacies today have a primary wholesaler and one or more secondary wholesalers that the pharmacy uses to replenish their inventories. All wholesalers who do business in Iowa, whether a supplier or a reverse distributor, must maintain an Iowa wholesale drug license. While most primary wholesalers are known nationwide and their Iowa license status is typically up to date, it is important for an Iowa pharmacy to know for sure that any secondary wholesalers or reverse distributors used are licensed in Iowa. A pharmacy can verify a license on the Board's website at *www.state.ia.us/ibpe/verification.html* or contact the wholesaler or reverse distributor directly and request a copy of its assigned Iowa wholesaler license.

Web-Based Marketplaces

In recent years, the web-based marketplace has been an avenue for independent pharmacies to purchase and sell small quantities of non-controlled, unexpired medications to licensed pharmacies in Iowa or other states. The marketplace has also been an avenue for licensed pharmacies in Iowa to obtain medication for short-term patient needs from other licensed pharmacies in Iowa or other states. These are direct pharmacy-to-pharmacy transactions administered or facilitated by the web-based marketplace. Iowa pharmacy law allows Iowa-licensed pharmacies to sell medications, at wholesale, to other licensed pharmacies within or outside Iowa as long as the total of such sales does not exceed 5% of the pharmacy's gross annual sales of prescription products. An Iowa-licensed pharmacy that sells or acquires medications to or from an out-of-state pharmacy must ensure that the laws of the out-of-state pharmacy's home state allow the transaction.

Ensuring Timely License/Registration Renewals

Although license and registration renewal applications are always mailed at least two months prior to expiration of the license or registration, it seemed that more renewal applications were submitted to the Board office for processing in the last week and even the day before their June expiration than the Board has experienced in past years. Subsequently, more individuals were adversely affected because their renewals could not be processed before expiration, resulting in their inability to practice or work. Board staff prides itself on efficient and timely processing of license and registration renewals, but during certain times of the year and including the last week of each month, processing may be delayed due to increased volume. Processing a new registration application or a license renewal application may take two to three weeks (including mail time) before you receive an updated certificate. So keep in mind that if you submit or deliver your renewal application on the date of expiration, you will avoid paying a penalty fee for late renewal, but you will not have an unexpired certificate of license or registration authorizing continuing practice after expiration. The same is true for pharmacies and drug wholesalers. If you want to ensure authority to continue operating after December 31, please submit completed renewal applications no later than the second week in December. And before submitting any application to the Board, review the application to be sure nothing has been omitted and no question has been left unanswered. Incomplete applications will delay the renewal process at least two weeks.

Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/ Ambulatory Settings That Need to Be Resolved!

ISMP
INSTITUTE FOR SAFE MEDICATION PRACTICES

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.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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Record Maintenance

The Board's compliance officers have recently learned that a wholesale distributor is recommending that pharmacies store records inconsistent with the Board's rules. The Board requires a pharmacy to maintain records in the original format received. If the record is originally received in hard copy format, the hard copy record must be retained for the required length of time. The pharmacy may choose to maintain an alternate format (such as scanning for an electronic record), but that may not replace the original format as required by Board rule. For example, when a pharmacy receives a prescription via electronic prescribing, the pharmacy must maintain the original, electronic record for two years from the last date of dispensing. The pharmacy may choose to also generate a hard copy record, but this is not required and cannot replace the maintenance of the electronic record. Likewise, when a pharmacy receives a hard copy invoice for drugs received, it may choose to scan the document into an electronic record, but the pharmacy must still maintain the original hard copy invoice for the period of time required under pharmacy law and rules.

New Statewide Rules Tracking and Comment Site

A new state website, *https://rules.iowa.gov,* allows Iowans to view administrative rules that are open for comment, comment on rules online, find contact information for each specific rule, learn how much longer the comment period is open, and inquire about the administrative rule process. The new website creates a one-stop shop for viewing rules and commenting on proposed rules of interest. Members of the public have a minimum of 20 days to comment on a rule from the date the proposed rule is published. Comments may be submitted directly to the contact person identified in the proposed rule or comments may be submitted on the website. Comments submitted on the website are routed to the contact person identified in the specific proposed rule. The website was built and is maintained by the Iowa Office of the Chief Information Officer.

Regulatory Plan for Fiscal Year 2016

The Board has identified nine regulatory subjects and issues, including telepharmacy, controlled substances collection and disposal, wholesale drug licenses, nuclear pharmacy practice, nonresident pharmacies, and long-term care pharmacy practice, for discussion, review, and possible rulemaking or rule revision during this fiscal year (July 2015 through June 2016). As always, the Board welcomes comments, suggestions, and objections to any current or proposed rules. The regulatory plan is available on the Board's website under Rules/Laws. Note that the dates under "Schedule for Action" are estimates and will be adjusted as needed. Please watch for information on these subjects in the coming months. The address for the current Board website is *www.iowa.gov/ibpe.*

Coming Soon! Redesigned Board Website

Many of you may have noticed that it has been a few years since any substantive changes or improvements have been made to the Board's website. That will soon change. Debbie Jorgenson, administrative assistant and webmaster for the Board, has been working on a website redesign with new features and a new, fresher look. The Board believes the redesigned website will improve the Board's ability to showcase items of interest and concern to Board licensees, registrants, and the public, and will provide more prominent and timely notification regarding important issues. The new website design is compatible with cell phone and tablet use and display, and will also provide the functional base for the eventual capability for online license renewal. Unveiling of the new website is planned for October 2015. Please check out the new website that will be available at a new address: *www.iowa.gov/pharmacy.*

Email List Service Available

To receive email notifications regarding items of timely importance, including notices of proposed and new laws and rules, please subscribe to the Board's email list service. Subscribing is easy and painless – all that is needed is your email address. Scroll to the bottom of any page on the Board's website, enter your email address, and click "Subscribe." You will receive an email asking you to respond, confirming your subscription. Reply to the email to complete your subscription. The email list is used for official Board communications only, and your email address will not be shared or disclosed to others. You can unsubscribe at any time by following the instructions at the bottom of any email received through the list service.

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