August 2015

Illinois Department of Financial and Professional Regulation Pharmacy Newsletter

Published to promote compliance of pharmacy and drug law

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A Welcome Message From IDFPR Secretary Schneider

Greetings,

Welcome to the *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter.*

This *Newsletter* is intended to improve the practice of pharmacy in Illinois and enhance communication with licensees.

I want to thank the Illinois State Board of Pharmacy, the National Association of Boards of Pharmacy® (NABP®), and the staff at the Illinois Department of Financial and Professional Regulation (IDFPR) for all their efforts with this *Newsletter.*

I hope that you find this *Newsletter* beneficial to your practice. Please feel free to reach out to me if you have thoughts concerning how the IDFPR can better carry out its mission.

Very truly yours,

Bryan A. Schneider
Secretary, IDFPR
bryan.schneider@illinois.gov
312/793-3676

A Welcome Message From Illinois State Board of Pharmacy Chairperson Patel

Hello,

I am thrilled to introduce the *Newsletter* for the Illinois State Board of Pharmacy under the auspices of the IDFPR, Division of Professional Regulation. I am grateful to Secretary Bryan Schneider, Director Jay Stewart, IDFPR staff, and NABP for their support to launch this important *Newsletter* that will enable the reader to keep up with the ever changing landscape of pharmacy practice and its regulation.

Wishing you all a healthy and safe summer,

Yagnesh V. "Yash" Patel, RPh
Chairperson, Illinois State Board of Pharmacy

Board Update

The Board has new members recently appointed by the Governor. Please join the Board in welcoming them to the team:

- Lemrey "Al" Carter, PharmD, RPh, Chicago, IL
- Despina Kotis, PharmD, RPh, Chicago
- Richard Mazzotti, RPh, Taylorville, IL

Board Meetings

These meetings are held every two months (upcoming meeting dates and locations below) and play an important role in overall governance of pharmacy practice in our State. The Board extends an open invitation to you to attend and participate at these meetings.

Fiscal Year 2015-2016

- September 15, 2015 – Chicago
- November 10, 2015 – Chicago
- January 12, 2016 – Chicago
- March 8, 2016 – Springfield, IL
- May 10, 2016 – Chicago

Chicago location: 100 W Randolph St, 9th Floor
Springfield location: 320 W Washington St

Section 1330.800 Pharmacy Self-Inspection

On April 23, 2015, the IDFPR achieved a major milestone: passing of the new pharmacy practice rules. There are several changes, and the Board encourages you to visit *www.ilga.gov/commission/jcar/admincode/068/06801330sections.html* for details.

One of the new additions to the rules is Section 1330.800 Pharmacy Self-Inspection.

> Every licensed pharmacy shall conduct an annual self-inspection using forms provided by the Division. The annual self-inspection shall be conducted during the same month, annually, as determined by the pharmacy. Documentation of the self-inspection shall be maintained at the pharmacy for 5 years. The primary objective of the self-inspection is to create an opportunity for a pharmacy to identify and correct areas of noncompliance with State and Federal law. This includes, but is not limited to, recordkeeping, inventory, labeling and sanitation requirements.
>
> (Source: Added at 39 Ill. Reg. 6267, effective April 23, 2015)

The self-inspection form may be found at *www.idfpr.com/Forms/PDFs/PharmacySelfInspectionReport.pdf.*

Controlled Substances/Pharmacy Rules Update

Below are brief summaries of amendments to the Illinois Controlled Substances Act and Pharmacy Practice Act Rules. It is the responsibility of all licensed pharmacists to be familiar with and adhere to all regulations related to the practice of pharmacy in Illinois. As such, you are strongly encouraged to visit the websites mentioned below and carefully review the specific changes found therein.

Effective February 27, 2015, the IDFPR's Rules for the Administration of the Controlled Substances Act were amended.

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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!

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*.

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These rules had not been substantially revised in more than 25 years. In that time, there had been numerous amendments to the Controlled Substances Act that were never addressed. Public Act (PA) 97-334 contained the most recent statutory changes to the act, which these adopted amendments implement. The adopted rules' intent is conformance of the rules to the act and federal law. Included in the revisions is the repeal of numerous provisions relating to administrative and disciplinary functions that are provided for by other IDFPR rules or policies and are no longer pertinent. It adds definitions and the enhancement of IDFPR regulatory oversight of the purchase, sale, and storage of controlled substances. It also includes a prohibition on practitioner self-prescribing of controlled substances, as well as a general cleanup of the rules. You may review the specific changes made in the March 13, 2015 Illinois Register, 39 Ill. Reg. 3656 at *www.cyberdriveillinois.com/departments/index/register/register_volume39_issue11.pdf.* The changes to the controlled substances rules begin on page 3,656.

As mentioned previously, the IDFPR's Rules for the Administration of the Pharmacy Practice Act were amended effective April 23, 2015. In 2007, the Pharmacy Practice Act was completely overhauled (PA 95-689, effective October 29, 2007). It put into place, among its many changes, a framework for remote pharmacy and telepharmacy, and resulted in a complete rewrite of the rules in 2010. Those changes were a best guess at how new technology would be used in the practice of pharmacy and how best to regulate it to protect the public. Now, with five years of experience, the amendments contained in the newly adopted rules are meant to adjust the regulations to the reality of what technology is being implemented and how it is being utilized. A new provision was also added to implement PA 97-1043, which lowered the age group that pharmacists are permitted to administer influenza and tetanus, diphtheria, and pertussis immunizations to children 10 years and older. You may review the specific changes made in the May 8, 2015 Illinois Register, 39 Ill. Reg. 6073 at *www.cyberdriveillinois.com/departments/index/register/register_volume39_issue19.pdf.* The changes to the pharmacy rules begin on page 6,276.

A link to the current version of these rules may be found, as always, on the Pharmacy page of the IDFPR's website, *www.idfpr.com/PROFS/Info/pharm.asp,* under the heading "Laws and Rules."

Board Background

The pharmacy profession was placed under the jurisdiction of the IDFPR upon its creation in 1917. The regulatory statute covers the activities of pharmacists and pharmacy technicians and the various categories of pharmacy in which they may work. The Board is composed of nine members, consisting of seven currently licensed pharmacists and two public members. All members are appointed by the Governor. The Board advises the Director on matters involving standards of professional conduct, discipline, and qualifications of candidates and licensees under the Pharmacy Practice Act.

Current Board Members

Philip P. Burgess, MBA, DPh, RPh.....Chicago
Lemrey "Al" Carter, PharmD, RPh.....Chicago
Despina Kotis, PharmD, RPh.....Chicago
Richard Mazzotti, RPh.....Taylorville
Ned Milenkovich, PharmD, JD, RPh.....Chicago
*Yagnesh V. "Yash" Patel, RPh.....St Charles, IL
Prem Rupani, MD, Public Member.....Burr Ridge, IL
Yatin M. Shah, MD, Public Member.....Willowbrook, IL
Ronald A. Weinert, RPh.....Mundelein, IL
*Denotes chairperson

Recent Board meeting agendas and meeting minutes can be found at *www.idfpr.com/Profs/Meetings/PharmMeetings.html.*

'Red Flags' Video Resource

The IDFPR recently posted a link on its website to a video entitled "Red Flags" developed by NABP. The video is focused on red flags that should alert pharmacists to potentially fraudulent prescriptions, and to help them better control the dispensing of controlled substances. A link to the video can be found at *https://www.youtube.com/watch?v=XRbnnbqdKz4&feature=youtu.be.*

Assistance for Illinois Pharmacy Professionals

Illinois Professionals Health Program

The Illinois Professionals Health Program (IPHP) is a statewide program providing support and earned advocacy for health care professionals throughout Illinois. The IPHP is recognized by the Federation of State Physician Health Programs as the approved physician health program for Illinois, and by the National Organization of Alternative Programs as the alternative to discipline program for Illinois. The IPHP assists health care professionals who have difficulties with stress management, substance abuse, medical or psychiatric illness, or other issues that may affect professionals' health, well-being, or ability to practice.

Pharmacists and pharmacy technicians in Illinois currently have a portion of their licensing fees dedicated to certain services provided through the IPHP. This allows these professionals to have the initial screening, enrollment, and monthly case management fees covered by the IDFPR.

The IPHP strives to facilitate and promote the health and well-being of Illinois health care professionals of all disciplines by effectively addressing any and all physical, mental, emotional, and/or behavioral problems that may adversely affect their private or professional lives. This is accomplished in several ways.

- **Screening and referral** to resources who have expertise in the area being addressed and who are familiar with the specialized needs of licensed health care professionals is provided.
- **Consultation and guidance** is offered to people concerned about the health and functioning of a health care professional residing or practicing in Illinois.
- **Support and monitoring** of professionals is offered so that they may be able to sustain meaningful life changes for the sake of their health, and to maintain the trust and confidence of those whom they serve.
- **Accountability** is implemented through documentation of compliance with recommended treatment and/or behavioral plans for professionals who need advocacy with various regulatory or administrative agencies.

IPHP offers an effective way to ensure that the impaired pharmacy professional receives the help he or she needs as quickly as possible. This includes a confidential initial screening, referral to an appropriate network of treatment providers and support systems, education regarding licensure concerns, and help to ensure quality of care, monitoring, and advocacy.

IPHP's ultimate goal is to help the pharmacy professional return to safe practice by giving him or her the best opportunities for career success through an accepted treatment protocol and appropriate aftercare designed for health care professionals.

Confidentiality

The IPHP complies with federal law 42 U.S.C., 290dd-2; 42 C.F.R. Part 2, which protects confidentiality. Participation in the IPHP is voluntary and confidential. **Communication with the IPHP is kept strictly confidential.** Information may only be released with the written consent of the participant. The IPHP has no disciplinary authority. **The IPHP's activities are strictly limited to providing assistance and advocacy.**

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Access

A 24-hour help-line is available to address urgent concerns from anyone regarding a health care professional, including hospital administrators, employers, colleagues, family, or friends.

24-Hour Help-Line: 1-800-215-HELP (4357)

For more information about the IPHP, please contact:
Terry Lavery
701 Lee Street, Suite 100
Des Plaines, IL 60016-4545
847/795-2810, 800/215-4357
www.advocatehealth.com/IPHP
www.fsphp.org

The *Illinois Department of Financial and Professional Regulation Pharmacy Newsletter* is published by the Illinois Department of Professional Regulation (IDFPR) 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 IDFPR unless expressly so stated.

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