August 2015

Oregon State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 NE Oregon St, Suite 150 • Portland, OR 97232

No. 551: REMS Programs

By Katelyn Wright, 2016 PharmD Candidate

Risk Evaluation and Mitigation Strategies (REMS) programs are created by drug sponsors and approved by Food and Drug Administration (FDA) as a way to ensure that the benefits of certain drugs are not outweighed by their risks. FDA will require a REMS program to be in place if it deems that additional measures beyond labeling are necessary to ensure that risks to the patient are minimized. Health care professionals who are a part of the prescribing, dispensing, or shipping processes for these drugs need to be aware of the specific safety measures associated with the relevent REMS programs so that they can comply fully and, thus, ensure that the patient is not only safe, but also that there is no lapse in therapy.

An example of a drug for which a REMS program requires specific action from both the prescriber as well as the agent dispensing the drug is TIKOSYN®. TIKOSYN is an antiarrhythmic agent that must be started in the hospital over the course of several days while the patient is closely monitored until he or she is stable. Both the prescriber and the agent dispensing the medication need to be certified by Pfizer, Inc, as a condition of the REMS program. Upon discharge, it is the health care facility's responsibility to educate the patient and to either provide a free seven-day TIKOSYN supply to the patient or to ensure that the patient's take-home prescription is filled. This portion of the REMS program is vital to minimize the risk that the patient will need to restart the medication in the hospital by ensuring that care is continuous. TIKOSYN-induced arrhythmia is a major life-threatening concern, which is why these precautions must be taken.

The dispensing pharmacy also has several REMS requirements to meet if it is to dispense TIKOSYN once the patient is out of the hospital. First, each pharmacy must designate a representative who will register with Pfizer's TIKOSYN In Pharmacy System (T.I.P.S.) program. Second, the pharmacist dispensing the medication must verify that the prescriber is currently certified by checking the program before dispensing. Each TIKOSYN prescription must be marked with the T.I.P.S. stamp that the pharmacy will receive upon completion of its certification. This stamp indicates that the prescriber's current certification to prescribe TIKOSYN has been verified by the pharmacy. Additional information is available at *www.tikosynrems.com.*

Although the number of REMS programs on newly approved drugs is ever increasing, it is important that health care professionals do not get fatigued, but rather remain vigilant about the REMS program requirements for each drug in order to optimize patient safety and therapy. A list of all current REMS programs and their details can be found at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm.*

No. 552 Physical Therapist Acquisition of Topical Medications

Pursuant to ORS 688.135, a licensed physical therapist (PT) may purchase, store (possess), and administer topical and aerosol medications as part of the practice of physical therapy. For example, procedures like iontophoresis and phonophoresis performed in his or her clinic may require the use of a topical medication. Pursuant to OAR 855-050-0070, an individual may possess a prescription drug without a prescription for the purpose of administration or delivery to a patient.

A question that commonly comes up is how exactly are PTs supposed to acquire a prescription medication, such as dexamethasone, to be used on a patient during a clinic visit. A direct sale can be made from the pharmacy to a health care professional via invoice. An Oregon pharmacy may provide clinicians with medications as long as the total amount distributed does not exceed five percent of the pharmacy's total number of dosages dispensed. It is recommended for pharmacies to have a procedure in place so that employees know what to do with this type of inquiry. Just as a pharmacist must use "professional due diligence" to determine that a clinician has **prescriptive** authority to

continued on page 4

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*.

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

OREGON STATE BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

continued from page 1

prescribe a medication, the professional determination in this situation is that the provider has the authority to **possess and use** a drug. This may include validation of active licensure for the PT via the Oregon Physical Therapist Licensing Board's licensee lookup tool found at *https://hrlb.oregon.gov/ptlb/licenseelookup*. Furthermore, consider that this is not a **prescription,** and therefore the sale cannot be adjudicated to a third-party payer.

Note: This procedure is for medications to be used on patients **during clinic visits** only; PTs do not have the authority to dispense these medications to their patients for "at home" use. Furthermore, PTs do not have prescriptive authority, so the pharmacist should not ask for a prescription when a PT wants to purchase dexamethasone.

No. 553: Automated Fill Rule Promulgated, Effective January 1, 2016

In December 2014, the Oregon State Board of Pharmacy passed new rules regulating the use of automated refill systems to fill prescriptions without the active participation of the patient prior to the initiation of the filling process.

OAR 855-041-1120 takes effect on January 1, 2016, and requires that a patient authorize each individual filling and delivery of a prescription prior to the pharmacy processing the prescription. This new rule also places restrictions on automated prescription reminder programs by requiring that they notify the patient of the drug name and strength along with the date of last fill. The rules impact all pharmacies that dispense directly to patients, including mail-order pharmacies.

These rules were created in response to prescriptions being filled and sometimes shipped without the patient's or his or her agent's knowledge or participation, resulting in duplication of therapy, unintended stockpiling, overdosage, medication waste, and disregard of the prescriber's therapy intent, all of which may potentially endanger patients.

If you use an automated refill procedure or reminder program in your pharmacy, please review OAR 855-041-1120 now and make any necessary changes to your processes prior to January 1. Additionally, it is recommended that pharmacies and pharmacists provide direct communication to patients about anticipated changes.

No. 554: Compliance Staff Hires New Inspector/Investigator

The Board welcomes its newest pharmacy inspector, Cheryl Fox, RPh. Cheryl joined the compliance staff in February 2015. She is a 2000 graduate of Oregon State University College of Pharmacy, and hails from an extensive background in community pharmacy. When she is not working, Cheryl enjoys wakeboarding and spending leisure time with her family on the water.

Due to the changes in the Board's compliance staff over the past few years, the Board thought it would be helpful to share a photo of the current pharmacist inspector/investigator team.

Pictured from left to right: Katie Baldwin, Brianne Cooper Efremoff, Cheryl Fox, Laura Elvers, Michele Cale, Joe Ball, and Gary Miner.

The *Oregon State Board of Pharmacy News* is published by the Oregon State 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.

Marc Watt, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager