September 2015

News

New Mexico Board of Pharmacy

Published to promote compliance of pharmacy and drug law

5500 San Antonio Dr NE, Suite C • Albuquerque, NM 87109 • Tel: 505/222-9830 • Fax: 505/222-9845
In-State Only Toll Free: 1-800/565-9102 • *www.rld.state.nm.us/boards/Pharmacy.aspx*

Automated Drug Distribution Systems in Licensed Health Care Facilities

During the June 24-26, 2015 New Mexico Board of Pharmacy meeting, new section 16.19.6.27 NMAC was added. This section regulates automated drug dispensing systems. An automated drug dispensing system is defined as a mechanical system, used as an extension by a New Mexico pharmacy, that performs actions related to storage, packaging, or dispensing drugs, and collects, controls, and maintains transaction information and records. Please review this regulation if you will be using an automated drug dispensing system to supply medications for patients of a health care facility.

Significant Adverse Drug Events

1. A 68-year-old female was prescribed Lortab® 5/325 mg, but was dispensed Percocet® 5/325 mg. Patient took one dose of the drug and experienced an upset stomach. Pharmacist recommends having enough staff to manage all stations and duties, and to follow normal workflow procedure where a different person inputs the prescription than the one who verifies it.
2. A pharmacy received a prescription for clonazepam 1 mg, but typed and dispensed lorazepam 1 mg. Patient took the medication and reported to the pharmacy that the medication was not working. Pharmacist reports that the prescription was handwritten and very difficult to read. A copy of this prescription was sent to the doctor. No recommendations for improvement were provided.
3. A 25-year-old female was prescribed desipramine 100 mg, but was dispensed disopyramide 100 mg. Patient experienced increased heart rate and pulse, dizziness, headache, nausea, and vomiting. Blood work and EKG tests came back within normal limits. Pharmacist recommends keeping hard copies with prescription label in order to be reviewed at verification.
4. A 72-year-old male was prescribed lorazepam 0.5 mg, but was dispensed another patient's medication of Lomotil® 2.5/0.025 mg. Patient reported experiencing withdrawal symptoms of weakness, dizziness, and shortness of breath. It was determined that the barcode scanner that is normally used to verify the right medication for the right patient was not utilized during checkout. Pharmacist recommends following the correct procedure during dispensing to ensure the right medication gets to the right patient.
5. Pharmacy refilled a prescription for warfarin 1 mg with warfarin 5 mg. Patient's caregiver gave the 80-year-old female patient this medication for one week. As a result, patient experienced excessive bruising and bleeding, which required a week-long hospital stay. Pharmacist recommends filling prescriptions from hard copies, matching National Drug Codes to prescription labels, scanning prescription hard copies into computer allowing easy access, and obtaining handheld scanning devices for barcode verification.
6. A 55-year-old female was prescribed hydroxyzine 50 mg, but was dispensed hydralazine 50 mg. Patient reported experiencing an upset stomach. Pharmacist reports that the prescription was handwritten and hydroxyzine was spelled incorrectly, which led to the error. Pharmacist recommends having pharmacist double-check prescriptions and having more staff on hand to decrease the workload and reduce the chance for errors.
7. A 64-year-old female patient was prescribed tacrolimus 0.5 mg, but was dispensed tacrolimus 5 mg. Patient took a month's worth of medication and reported feeling unwell. She contacted her physician, underwent lab work, and is currently being monitored. Pharmacist recommends limiting multitasking and focusing on one task and prescription at a time.
8. A 33-year-old female patient was prescribed levofloxacin 750 mg, but was dispensed another

continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examini

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*.

continued from page 1

patient's medication of pravastatin 40 mg. Patient took one tablet, but experienced no adverse effects. Pharmacist recommends reviewing all medications with the patient and retraining staff on patient safety.

Disclaimer: The suggestions are made by the pharmacist submitting the Significant Adverse Drug Event Report. The New Mexico Board of Pharmacy may not necessarily agree with these suggestions.

PMP Director

The Board currently has the position posted for New Mexico Prescription Monitoring Program (PMP) director. The position will be posted until September 12, 2015. If you are interested in this position, visit the Board's home page for a link to apply. The link will also provide contact information if you have questions regarding this position. To qualify, you must have at least two years of experience as a registered pharmacist and the ability to register as a pharmacist in New Mexico.

PTCB-Certified Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is celebrating its 20th year. To commemorate, PTCB is sending a gift to all certified pharmacy technicians who have been actively PTCB-certified for 20 years or more. If you became PTCB-certified before January 1, 1996, and have maintained your PTCB certification, you can expect to receive a special commemorative 20-year pin this fall honoring 20 years of commitment to PTCB certification. In order to receive your pin, you will need to complete a brief form for verification and mailing purposes. To access the form, visit the PTCB website located at *www.ptcb.org*.

October Is American Pharmacist Month

According to the American Pharmacists Association (APhA) web page, October is American Pharmacists Month (APhM). The page states: "The goal of [APhM] is to promote your profession and get the attention you deserve among your peers, patients and community. We've filled this site with ideas for activities and events that spotlight pharmacists' contributions toward improving medication use and advancing patient care in all practice settings. Use these ideas throughout October—and all year long—to inspire your celebrations!" To view APhA's APhM web page, visit *www.pharmacist.com/american-pharmacists-month*.

Continuous Professional Development

The Board has authorized a pilot study in continuous professional development (CPD). This program has been offered for several years. Any New Mexico-licensed pharmacist can participate, yet very few have enrolled. Participation in the pilot study exempts you from the current continuing education (CE) requirements. If your practice of pharmacy is specific to a certain area, you could be approved to take different types of CE. For more information, visit the University of New Mexico (UNM) Health Sciences Library & Informatics Center website at *https://hsc-moodle.health.unm.edu/moodle/login/index.php*. Once there, you can create your login and get additional information about the CPD program and its requirements. If you have additional questions or would like more information, visit the Board's home page for a link, or contact Joe Anderson at 505/272-3664 or Kristina Wittstrom at 505/272-3661. In this way, your CE can be in a practice-specific area.

Visit NMboard.pharmacy

The National Association of Boards of Pharmacy® (NABP®) has launched the .Pharmacy Top Level Domain Program. Any website that ends with the .pharmacy domain has been approved as a secure and trustworthy pharmacy or pharmacy-related entity. The .pharmacy program provides consumers around the globe with a means to determine that they are buying medications from legitimately operating online pharmacies. As part of the initiative, the Board has been issued a .pharmacy domain. Enter *NMboard.pharmacy* into your web browser and you will be forwarded to the Board web page. To learn more about the .pharmacy initiative, visit *www.safe.pharmacy.*

NMED Hazardous Waste Requirements

Recently, the New Mexico Environment Department (NMED) has been entering pharmacies and other health facilities to verify if hazardous waste requirements are followed. The NMED is concerned only with medications that are considered hazardous waste. This article is to notify pharmacists of the possibility of a visit from NMED. This is an issue that will be discussed at Board meetings. Hazardous waste is a concern. Hopefully the Board and NMED can reach a solution together. Until then, the only Board-approved way to remove unwanted or expired medications is through a reverse distributor. The following two paragraphs are a synopsis of an article submitted by NMED.

The NMED enforces hazardous waste regulations and may conduct hazardous waste inspections at pharmacies. Waste is considered hazardous if it is ignitable, corrosive, reactive, contains specific concentrations of toxic chemicals, or if it is on a specific "list." Pharmacies are required to conduct hazardous waste determinations on their waste, and NMED provides a guidance document to explain the waste determination process. It can be found at *https://www.env.nm.gov/HWB/documents/HW_Determination_-_Fact_Sheet_6-27-2013.pdf.*

Several regularly prescribed pharmaceuticals meet the definition of hazardous waste, such as insulin, aerosol inhalers, and Coumadin®. NMED provides a pharmaceutical guidance document that can be found at *https://www.env.nm.gov/HWB/documents/FACT_SHEET_Pharm_Waste_5-14-2014.pdf.* Expired pharmaceuticals are not exempt from these requirements. They are considered

continued on page 5

continued from page 4

waste, and waste pharmaceuticals must be managed by the generator, ie, the pharmacy. NMED does not recognize the reverse distribution of expired hazardous waste pharmaceuticals as lawful. If you have questions related to hazardous waste pharmaceuticals or hazardous wastes in general, please call NMED's Hazardous Waste Bureau at 505/476-6000 or toll free at 866/428-6535.

New Board Office Location

The new address for the Board is:

5500 San Antonio Drive NE, Suite C
Albuquerque, NM 87109

This new location is located near the Cracker Barrel Old Country Store and Restaurant. All other contact information for staff remains the same.

Two State Drug Inspectors Hired

The Board has hired two new state drug inspectors. The first inspector is Lorraine "Lori" Carlisle. Lori is a native New Mexican. She graduated from the UNM College of Pharmacy in 1999. During her career, Lori has worked in research, consulting, and retail.

Shawn Avery, the other new hire, is also a native New Mexican. Shawn graduated from UNM College of Pharmacy in 2008. Shawn has worked as a retail pharmacist.

Please join the Board in welcoming these two new hires.

Disciplinary Actions

Bob's Budget Pharmacy, Inc – License PH00002392. Respondent admitted to being delinquent in reporting controlled substance (CS) prescription information to the PMP. Respondent must report in a timely manner as required. Respondent's pharmacy registration is on probationary status for a period of six months. Respondent shall pay $100 fine.

Colbert Pharmacy – License PH00003523. Respondent admitted to being delinquent in reporting CS prescription information to the PMP. Respondent must report in a timely manner as required. Respondent's New Mexico nonresident pharmacy registration is on probationary status for a period of six months. Respondent shall pay $100 fine.

Coram Specialty Infusion Services – License PH00003015. Respondent admitted to being delinquent in reporting CS prescription information to the PMP. Respondent must report in a timely manner as required. Respondent's New Mexico nonresident pharmacy registration is on probationary status for a period of six months. Respondent shall pay $100 fine.

Corporate Pharmacy Services, Inc – License PH00003059. Respondent admitted to being delinquent in reporting CS prescription information to the PMP. Respondent must report in a timely manner as required. Respondent's New Mexico nonresident pharmacy registration is on probationary status for a period of six months. Respondent shall pay $100 fine.

Clevis Management Corp dba Haoeyou Pharmacy – License PH00003723. Respondent admitted to being delinquent in reporting CS prescription information to the PMP. Respondent must report in a timely manner as required. Respondent's New Mexico nonresident pharmacy registration is on probationary status for a period of six months. Respondent shall pay $100 fine.

Lowell's Pharmacy – License PH00001211. Respondent admitted to being delinquent in reporting CS prescription information to the PMP. Respondent must report in a timely manner as required. Respondent's pharmacy registration is on probationary status for a period of six months. Respondent shall pay $100 fine.

David Nunez, RPh – License RP00004873. Respondent failed to maintain proper pharmacy records. Thirty-day response indicated items corrected. However, subsequent inspection revealed continued violations. A hearing was held before the Board. Respondent found guilty of unprofessional conduct. Registration suspended for three months. Placed on probation for period of five years. Must be evaluated by the New Mexico Monitored Treatment Program. Must pay fine of $10,500 and administrative costs of $1,626.73. Must successfully complete NABP's Pharmacist Assessment for Remediation Evaluation®. Must take and pass Multistate Pharmacy Jurisprudence Evaluation®.

Alex White – Pharmacy Technician Applicant. Respondent had pled no contest to felony charge of possession of a CS and was placed on probation. While on probation, respondent applied with Board to be a pharmacy technician. Notice of contemplated action (NCA) was issued. Respondent did not respond to NCA. Application was denied by default. Must pay costs of investigation of $200.

50-Year Pharmacists

The Board has honored Nick Brown and M.R. Delhotal. Both of these pharmacists have joined the 50-year pharmacist club. They each have been registered as an active pharmacist in New Mexico for 50 years. Please join the Board in thanking them for all of their service to the citizens of New Mexico.

Page 5 – September 2015

The *New Mexico Board of Pharmacy News* is published by the New Mexico 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.

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