September 2016

New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Impaired Licensees

The New Mexico Board of Pharmacy regulations state that failure to report an impaired licensee is dishonorable conduct for pharmacists and pharmacy technicians. The regulations define an impaired licensee as someone who is unable to practice pharmacy with reasonable skill, competence, or safety to the public. This is because of drug abuse, mental illness, the aging process, loss of motor skills, or vision and hearing problems. The regulations require that any person who knows or suspects that a licensee is impaired shall report any relevant information either to the impaired pharmacist program or to the Board. The impaired pharmacist program contracted with the Board is the Monitored Treatment Program (MTP). Please do not refer an impaired licensee to a different treatment program. The alternate treatment program may be effective, but MTP has a requirement to report failed attempts to the Board, and the impaired licensee you refer to an alternate program may discontinue treatment. Without the requirement to report, the licensee may continue to practice while impaired, possibly causing harm to himself or herself, a patient, or any other member of the public.

Do You Know?

- October 18 is National Pharmacy Technician Day. The Board wishes to recognize the invaluable contributions pharmacy technicians make to the practice of pharmacy.
- The mission statement of the Board is to protect, promote, and preserve the public health, safety, and welfare through effective regulation of the practice of pharmacy in New Mexico.
- United States Pharmacopeia (USP) Chapter <800> was approved and becomes effective on July 1, 2018. State drug inspectors have had training on compliance of USP Chapter <800>. If your pharmacy compounds sterile hazardous products, please review this chapter.
- The recently passed Drug Supply Chain Security Act (DSCSA) does not prohibit a pharmacy from transferring medication to another pharmacy to fill a prescription for a specific patient. However, this does not include the transfer of a medication from one pharmacy to another for the purpose of increasing or replenishing stock in anticipation of a potential need. The Board is working on promulgating regulations that implement the requirements and restrictions contained in the DSCSA.

Prescription Monitoring Program

The New Mexico Prescription Monitoring Program (PMP) began collecting information in August 2005. The data in the program has been maintained by the New Mexico Regulation and Licensing Department's Information Technology (IT) section. IT has done an excellent job, but after 11 years of operation, an immense amount of data has accumulated. Because of this, the PMP data is to be hosted by Appriss, Inc. Appriss is the company that hosts the majority of PMPs across the country. Immediate advantages to using Appriss include 24-hour technical support. If the PMP goes down, even on weekends, there will be support to bring the program back online. In addition, Appriss has the necessary security for reporting data that is required by federal institutions, such as the Department of Veterans Affairs and Indian Health Services.

The proposed date for going live with Appriss hosting is on October 31, 2016. Notifications are scheduled to be sent to keep you aware of any upcoming events, but the Board does not anticipate any issues during this transition. After the switch on October 31, Appriss will have a team available to work out any problems that may appear. Hopefully this transition will go smoothly. Your patience and cooperation during this transition are greatly appreciated.

Significant Adverse Drug Events

1. A patient had a new prescription for hydroxyzine 25 mg and was incorrectly dispensed lorazepam 1 mg. The patient realized the error after she took the

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FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

More Selected Medication Safety Risks to Manage in 2016

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.*

Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

References

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3. Lalonde L, Lampron AM, Vanier MC, Levasseur P, Khaddag R, Chaar N. Effectiveness of a medication discharge plan for transitions of care from hospital to outpatient settings. *Am J Health Syst Pharm.* 2008;65(15):1451-1457.
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USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

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. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. 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. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm.*

FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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lorazepam and reported to her doctor that it was not helping. No harm was done to the patient. The error occurred because the pharmacist put the wrong medication in the patient's bag. The pharmacist recommends to follow the policy and procedures, which state the dispensed prescription should be matched with the hard copy. The store was very busy at the time the error was made.

2. A new prescription for 25 mg pregabalin twice a day (BID) increase to three times a day (TID) was incorrectly dispensed as 225 mg BID increase to TID. The patient experienced severe drowsiness, lethargy, and hallucinations. The patient reported to the emergency department and was advised to rest and start the correct dose at a later time. The pharmacist recommends to review the high drug strength with greater scrutiny.
3. A patient was prescribed Halcion® (take one-half tablet prior to appointment and bring remainder to first appointment) and received haloperidol. Patient experienced agitation and stimulation. The error occurred because upon data entry, only the first three letters of the drug were entered to search for the drug instead of the first five letters. The first result upon entering "hal" was haloperidol. The root cause analysis performed by the pharmacist indicates that best practices for data entry product selection is part of all technician software training.
4. A new prescription for rabeprazole was incorrectly dispensed as omeprazole. The patient experienced increased dyspepsia symptoms after taking the incorrect medication for three weeks. The error occurred because a therapeutic interchange request was sent to the primary care practitioner (PCP), and the response was to contact the patient's gastroenterologist. The response from the PCP was mistaken for an approval to interchange the medication. The pharmacist recommends to read the entire response from the physician before processing an interchange request.
5. A renewal for sertraline 50 mg was dispensed with incorrect directions. The directions read "take one tablet every day (QD)" instead of "one and one-half tablet QD." The patient reported increased feelings of depression and reported the medication was not working well. The patient reported the error to the pharmacy. The error occurred because the same pharmacist entered the prescription and verified it. The pharmacist recommends that different people enter and verify a prescription so that there are two sets of eyes reviewing it for accuracy.
6. A prescription for warfarin 5 mg was incorrectly dispensed as warfarin 1 mg. The error occurred because the National Drug Code (NDC) for 5 mg (0093-1721-01) was incorrectly entered as 0093-1712-01, which is the NDC for the 1 mg. The patient took the incorrect dose and had an international normalized ratio (INR) that was "out of whack." The INR clinic called the pharmacy because it thought the patient was not adherent. The pharmacist recommends to avoid this error by ensuring the final check involves checking the right label, right dose, and right patient and to check the label against the order.
7. A renewal prescription was written for levetiracetam sustained release, and levetiracetam immediate release was incorrectly dispensed. The patient experienced a seizure. Although the patient had compliance issues with the prescription, the error occurred because electronic prescriptions sometimes have the incorrect dosage form. The pharmacist recommends to be more diligent at verification to avoid this error.
8. A pharmacist was entering an order for a patient when a nurse asked the pharmacist to enter a "stat" order for a different patient who was agitated. The pharmacist entered the order for Geodon® into the first patient's profile. The first patient received three doses, and the agitated patient received no doses. An hour later, the nurse requested the order be entered again for the agitated patient. The error might have occurred because of the urgency of the order and because the location of the workstation lends itself to interruptions. The pharmacist recommends always checking the order sheet against the computer to verify the name.
9. A prescription for lisinopril 5 mg was dispensed when it should have been discontinued. The error occurred because the physician's office called to say that an electronic prescription was sent in error; it was not to be filled. The person who received that call immediately went on a patient consult and failed to notify the rest of the pharmacy staff not to fill the prescription. The patient took one dose and felt very dizzy and took one-half tablet the next day and reported "seeing stars." The pharmacist recommends to avoid this error in the future by stopping all activity until the message is delivered to staff.
10. Two weeks after receiving a Boostrix® injection, a patient reported that the injection site was still red, sore, and itchy and there was a rash all over the body. The patient was advised to go to urgent care where they were prescribed prednisone, ranitidine, and hydroxyzine. Before being seen, the patient was taking diphenhydramine and ibuprofen.

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.

State Drug Inspectors

The Board would like to thank State Drug Inspectors Shawn Avery and Lori Carlisle for everything they contributed to the Board. Both Shawn and Lori are quick learners and hardworking. They were an asset to the

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Board. However, both have moved on to other avenues within the practice of pharmacy.

The Board will be hiring for two state drug inspector positions. As of the date of writing this article, the positions have not been posted. However, if you are interested, please contact the Board. The Board will notify you when the positions are posted.

Disciplinary Actions

Marguerite Esquibel, RPh – License RP-7494. Settlement agreement. Misfilled prescription. Must pay fine and cost of investigation totaling $500.

First Pharma Associates, LLC, dba Riverpoint Pharmacy – License PH-3338. Settlement agreement. Respondent admitted to being delinquent in reporting controlled substance (CS) information to the PMP. Must timely report to PMP as required. Must pay $100 fine within 30 days. License on probationary status for six months.

Mike Gallegos, RPh – License RP-6838. Settlement agreement. Record-keeping violation. Must pay fine and costs of investigation totaling $1,200.

Guardian Pharmacy – License PH-3720. Settlement agreement. Respondent admitted to being delinquent in reporting CS information to the PMP. Must timely report to PMP as required. Must pay $100 fine within 30 days. License on probationary status for six months.

Imperial Point Pharmacy Center – License PH-3650. Settlement agreement. Respondent admitted to being delinquent in reporting CS information to the PMP. Must timely report to PMP as required. Must pay $100 fine within 30 days.

Jennifer Kobyljanec-Rodgers, RPh – License RP-6539. During the April 21-22, 2016 Board meeting, the pharmacist license of respondent was revoked by default.

Anthony Marrufo, PT – License PT-9481. During the June 27-28, 2016 Board meeting, the Board accepted his voluntary surrender of his pharmacy technician license. Must pay investigation costs of $150.

Robert McClelland III, RPh – License RP-4533. Settlement agreement presented during June 27-28, 2016 Board meeting. Pharmacist license suspended for 30 consecutive days. Probation for five years. Must pay $2,000 fine. Must successfully complete an ethics course. Must hire another pharmacist to work 20 hours per week. Must have a mentor. Mentor will have weekly contact by telephone and meet once a month. Mentor will submit quarterly reports to the Board.

Nowell Pharmacy – License PH-1233. Settlement agreement. Respondent admitted to being delinquent in reporting CS information to the PMP. Must timely report to PMP as required. Must pay $100 fine within 30 days. License on probationary status for six months.

Valuscript Pharmacy – License PH-3708. Settlement agreement. Respondent admitted to being delinquent in reporting CS information to the PMP. Must timely report to PMP as required. Must pay $100 fine within 30 days.

Comprehensive Medication Review and Drug Utilization Review

Currently, pharmacists who work at a nonresident pharmacy must be licensed in the state in which they reside only. There is not a requirement for these pharmacists to also be licensed in New Mexico. If a patient wishes to fill a prescription at a nonresident pharmacy, he or she has certain advantages and disadvantages. One advantage is that generally the medication will cost less. One disadvantage is not having as easy access to pharmacy personnel.

If a patient brings a prescription to a local in-state pharmacy, it is generally expected that the medication is reviewed and filled by a pharmacist who is licensed in New Mexico. There are exceptions; one exception is centralized prescription dispensing. If centralized prescription dispensing is done, the patient is given notification.

A comprehensive medication review as required by Medicare Part D or a drug utilization review is considered to be the practice of pharmacy. The pharmacist who performs these reviews for a patient who brings his or her prescription to a local retail pharmacy must be licensed as a pharmacist in New Mexico.

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.

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