March 2019

New Mexico Board of Pharmacy News

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*

Significant Adverse Drug Events

1. A 46-year-old male patient was prescribed lisinopril but was given metoprolol at the point of sale. The patient was sold another patient's medication and took approximately one dose before complaining of light-headedness and dizziness. The error was discovered when the clinic was unable to locate the metoprolol prescription intended for the second patient. The staff recommends verifying the physical ID of a patient prior to sale if a language barrier occurs in the future.
2. An 11-year-old female was prescribed azithromycin 100 mg/5 mL, but she was instead given the 200 mg/5 mL strength. After taking the medication for approximately three days, the patient's mother called the pharmacy to inform them that the patient was experiencing nausea, diarrhea, vomiting, and an upset stomach. The pharmacist stated that this error is a result of the computer system automatically choosing a drug when the prescription is sent electronically, and the staff not following correct data entry procedures when reviewing the medication. The pharmacist recommends manual entry/review of all electronic prescriptions, even when the computer system attempts to choose the drug and strength based on information transmitted from the prescriber's office.
3. A 58-year-old male patient with a history of heart disease was admitted to the Heart Hospital of New Mexico due to shortness of breath. This was attributed to taking 13-16 days' worth of morphine 30 mg extended release tablets instead of the morphine 15 mg extended release tablets that were prescribed. The pharmacist attributes the error to staffing issues and not following proper procedures for filling/verification due to short staffing. The pharmacist recommends following the written procedures for filling and verification as outlined in the pharmacy policy and procedure manual.
4. An adult male patient with hypothyroidism was dispensed liothyronine 50 mcg tablets in place of liothyronine 5 mcg tablets. The incorrect strength was dispensed a total of four times before the pharmacy was notified of the error by the patient's legal representation. The patient reported tiredness, anxiety, and weakness as a result of taking the incorrect dose. The pharmacist attributed the error to an incorrect conversion from mg to mcg. The pharmacist did not offer a recommendation addressing the confusion around multiple strengths.
5. A five-year-old female patient was prescribed 0.5 mL of risperidone 1 mg/mL daily. When the directions were transcribed to the prescription, they were interpreted to be a half teaspoonful instead of a half mL, and thus a label that read 2.5 mL/day was dispensed. After reporting increased somnolence to a physician after three days of taking the medication, the dose was adjusted. The pharmacist attributes the error to poor conversion and suggests entering prescriptions exactly as received unless a conversion is absolutely necessary.
6. A 35-year-old female patient transferred a prescription for hydrochlorothiazide from one pharmacy to another. During the transfer, the strength of the medication was incorrectly transcribed as 25 mg tablets instead of 12.5 mg tablets. After taking the medication for approximately 10 days, the patient was hospitalized for hypokalemia. The pharmacist attributes the error to poor communication during the prescription transfer. The pharmacist recommends counseling on all transferred prescriptions and showing the patient the medication at pickup.
7. A 46-year-old female patient with cirrhosis and hepatic encephalopathy was prescribed lactulose oral solution but was given levetiracetam oral solution in its place. After taking the incorrect medication for approximately three weeks, the patient experienced increased ammonia

continued on page 4

National Pharmacy Compliance News

March 2019

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

Final Guidance Documents Address FDA Policies Related to DSCSA

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm.*

First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Controlled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at *www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act.*

ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The "ASHP Guidelines on Preventing Medication Errors in Hospitals" are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy,* the guidelines are available at *www.ajhp.org/content/75/19/1493.* ASHP's October 2, 2018 press release can be found in the News section at *www.ashp.org.*

FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.* In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf.*

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.* This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals. More details are available in the *Federal Register* notice at *www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf.*

Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at *https://againstopioidabuse.org.*

Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- generic substitution is recommended as part of the pharmacist's dispensing role;
- pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at *www.fip.org* in their respective sections.

FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes,* will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit *http://fdapasediabetes.e-paga.com.*

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at *www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm.*

continued from page 1

levels. The pharmacist attributes the error to storing look-alike, sound-alike medications together. The pharmacist recommends utilizing a tall man lettering system to help differentiate between look-alike, sound-alike medications. The pharmacist also recommends counseling patients on their medications, having the patient read the label on the bottle, or having the pharmacist or technician read the name of the medication on the label as well as the bottle itself, when applicable.

8. A 67-year-old male patient was given furosemide by mistake when his wife picked up his prescription from the pharmacy. The patient received the medication of another patient with the same first and last name. After taking the medication for an undisclosed amount of time, the patient reported increased urination. The pharmacist attributes the error to only verifying the patient's first and last name at pickup. The pharmacist recommends checking an ID and using at least two points of ID verification for all medications picked up at the pharmacy.

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.

Enforcement of Regulations Against Insanitary Conditions

A drug is considered adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health," per section 501(a)(2)(A) of the Food Drug and Cosmetic Act, located in section 21 of United States Code, 351(a)(2)(A). This applies to both 503A and 503B facilities and nonsterile compounding operations. An industry guidance document is available on the Food and Drug Administration (FDA) website at *https://www.fda.gov/drugs/drugsafety/ucm514486.htm.*

This document is titled "Insanitary Conditions at Compounding Facilities," and describes what insanitary conditions are, how they should be addressed, and possible consequences of noncompliance. Within the document, particularly serious examples of insanitary conditions are described for sterile compounding, nonsterile compounding, or both. These include, **but are not limited to:**

- Vermin (eg, insects, rodents) or other animals (eg, dogs) in the production area or adjacent areas
- Visible microbial growth (eg, bacteria, mold) in the production area or adjacent areas
- Sources of non-microbial contamination in the production area or adjacent areas (eg, rust, glass shavings, hairs, paint chips)
- Performing aseptic manipulations outside of a certified International Organization for Standardization (ISO) Class 5 area or area of higher quality air
- Exposing sterile drugs and materials to lower than ISO Class 5 quality air for any length of time. This would include, for example, exposing partially stoppered drug products or stock solutions in a container/closure system that is not fully closed (airtight), and open packages of sterile wipes.
- Cleanroom areas with unsealed or loose ceiling tiles
- Production of drugs while construction is underway in an adjacent area without adequate controls to prevent contamination of the production area and product
- Consistent and frequent pressure reversals from areas of less clean air to areas of higher cleanliness
- Using a filter for product sterilization that is not certified as pharmaceutical-grade and sterilizing-grade
- Using a certified pharmaceutical-grade and sterilizing-grade filter in a manner that is not adequate to accomplish sterilization (eg, using it in excess of its capacity, when it is clogged)
- Using parameters for sterilization (eg, temperature, pressure, time) that are not lethal to resistant microorganisms

Please be aware of potential insanitary conditions, including the ones listed here. Prevention is the best policy if you engage in compounding. These are just a few examples of many considerations that are enforceable by both the Board and FDA. Upon notice of insanitary conditions, a facility must immediately determine the impact such conditions may have had on any drugs produced, and determine if ceasing production and/or recalling drugs may be in order. A facility must also work to correct such conditions **immediately.**

Copying Commercially Available Drug Products

Drugs that are essentially considered copies of a commercially available drug product are not allowed to be compounded under 503A exemptions. A drug will be considered essentially a copy if:

- It has the same active pharmaceutical ingredient(s) (API) as a commercially available product;
- The APIs have the same (within 10%) or easily substitutable strengths; and
- The compounded product and the commercially available product can be administered via the same route of administration.

continued on page 5

continued from page 4

- Two or more commercially available products are combined and meet the previously listed criteria, whether or not the combination is commercially available.

In order to qualify as an exemption, and thus be eligible for compounding, the following criteria must be met:

- There must be a **documented** prescriber-determined change
- The change must be made for an individual patient
- The change must produce a significant difference from the commercially available product

This does not apply to discontinued medications or medications that are on the FDA shortage list. For more information, please visit the FDA website.

Disciplinary Actions

Ronald Scott, RPh – License RP00005294, PC00000159. Settlement agreement. Respondent entered into a settlement agreement with the Board, agreeing to the following stipulations: Must enroll in a monitored treatment program and complete a five-year contract, and must notify potential employers of agreement terms. Respondent must also pay the investigative cost of $225.

Michelle Starr, CPhT – License PT00012564. Summary suspension. Respondent failed to comply with a Board order to appear before the examining committee, and as a result has had her technician registration suspended.

NMAC Update: 16.19.4.9 and 16.19.27.7

Language was added to New Mexico Administrative Code (NMAC) prohibiting the solicitation of prescription business via preselected medications on prescription blanks and/or prescription requests that are not initiated by either the prescriber or the patient. This means that a pharmacy, or other entity providing prescription medications, cannot make a specific request for a new medication by preselecting a drug. Such requests must come from the patient or the provider. This falls under the regulations for both unprofessional conduct and dishonorable conduct. Licensed individuals and/or facilities not in compliance with the new regulations may be subject to disciplinary actions.

Reminders

- FDA will host a Risk Evaluation and Mitigation Strategy-compliant accredited continuing education (CE) course, available starting March 2019, to address the risks of misuse, abuse, addiction, and overdose that are associated with opioid analgesics. This should meet the requirements for CE in the area of safe and appropriate use of opioids. For information, visit the FDA website at *https://www.fda.gov/drugs/drugsafety/informationbydrugclass/ucm163647.htm#blueprint.*
- Per 16.19.37.10.L NMAC: Dispensing, Compounding, and Sale of Drugs; Limitations:

  A resident pharmacy shall limit the interstate dispensing of compounded sterile human drug preparation to five percent of the total prescriptions dispensed by that pharmacy, unless registered with the FDA and the board as an outsourcing facility. This requirement will be effective at the time it becomes enforced by the FDA in states that have not entered into a memorandum of understanding with the FDA.

  FDA will strictly enforce this rule.

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.

Alejandro Amparan - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Suhajda - Communications Manager