March 2018

New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Significant Adverse Drug Events

1. A 76-year-old male patient was electronically prescribed clopidogrel 75 mg tablets to be taken three times daily. The pharmacist filled the prescription as written and did not question the directions. When a refill request was sent to the prescriber approximately three months later, a new prescription was taken via telephone with directions to be taken once daily. Upon comparing the new directions to the old directions during the prescription review process, the prescriber was contacted to verify the frequency/dose. The prescriber verified that the frequency should always have been once daily. The patient did not report any symptoms as a result of the increased frequency. The pharmacist attributed the error to an oversight during the verification process and has since implemented a basket system to focus on verification for one patient at a time.
2. A 61-year-old male patient was prescribed a 90-day supply of levetiracetam 500 mg tablets. While labeling seven stock bottles, a bottle of lithium 300 mg capsules was mislabeled and sold to the patient as part of the prescription. The pharmacist on duty attributes the error to look-alike, soundalike medications and not following pharmacy policies and procedures on correctly utilizing scanning technology. As a result of the error, the patient required hospitalization due to loss of seizure control. The pharmacist recommends scanning each individual stock bottle as part of the verification process prior to dispensing.
3. A 21-year-old male patient was prescribed Suboxone® 2 mg/0.5 mg but was dispensed Suboxone 8 mg/2 mg. The pharmacist attributes the error to workflow mismanagement and to bypassing the technician filling process by the pharmacist filling the prescription instead. The dispensing error was discovered during a follow-up visit, at which time the patient reported gastrointestinal upset and increased drowsiness. The pharmacist recommends utilizing a technician to fill medications so that filling and verification are not done by the same person.
4. A 58-year-old female patient presented a written prescription for trazodone 50 mg tablets to a retail pharmacy. Instead of trazodone, tramadol 50 mg was dispensed to the patient. The patient complained to the prescriber the next day about feeling unwell. The prescriber then contacted the pharmacy and notified them of the dispensing error. The pharmacist attributes this error to look-alike, soundalike medications. The pharmacist recommends utilizing technology alerts more effectively, retraining the technician staff, and reviewing the physical hard copy during the verification process.

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.

Board Member and Staff Changes

The Board would like to congratulate Ben Kesner on his recent retirement in December 2017. Ben worked for the Board for more than 30 years as an inspector and served as executive director/chief inspector for the last three years of his career. The Board appreciates Ben's hard work, dedication, and contribution to the profession and wishes him the best in his future endeavors.

With the retirement of Ben Kesner, Inspector Cheranne McCracken has stepped into the role of executive director/chief inspector. Cheranne brings a wealth of experience and knowledge with her, and the Board looks forward to her leadership as she assumes her new role.

The Board currently has one vacancy for an inspector. For more information, please visit *https://www.governmentjobs.com/careers/newmexico.*

Regulation Changes

Section 16.19.8 of the New Mexico Administrative Code (NMAC) has received a complete overhaul. This regulation now addresses wholesale drug distributors, third-party logistics providers, repackagers, and drug supply chain security. The updated regulation includes definitions, minimum standards, and licensing requirements (among many other rules) for the above-stated license types. This was done in order to align with the Food and Drug Administration's

continued on page 4

National Pharmacy Compliance News

March 2018

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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.

FDA Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for

minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

continued from page 1

Drug Supply Chain Security Act. The updated regulation is available on the Board's website.

Also, 16.19.17 NMAC was amended to require reporting of the sale for any and all over-the-counter products containing ephedrine hydrochloride or ephedrine sulfate.

A detailed list of regulation changes can be found under the Hearing Notices tab on the Board's website.

Reminders

- The next Board meeting is scheduled for Thursday and Friday, April 19-20, 2018. The agenda is posted on the Board's website at least 72 hours prior to the beginning of the meeting. Meetings are open to the public. If a regulation hearing is on the agenda, the notice to the public must be posted on the agenda at least 30 days prior to the hearing. The notice to the public will provide the proposed changes.
- The effective date for United States Pharmacopeia (USP) Chapter <800> is December 1, 2019. At this time, USP also hopes to release the official revised edition of USP Chapter <797>. If you compound sterile and nonsterile products using hazardous drugs, you must be in compliance. To determine if you are in compliance, visit *http://800gaptool.com*.
- Information regarding naloxone is available on the Board's website under the Forms and Applications tab. This will provide you with the standing order prescription you need to dispense naloxone to any New Mexico citizen.
- An impaired licensee must be reported to the Impaired Pharmacist Program or referred to the Board. The Board-approved program is the Monitored Treatment Program (MTP). Failure to report an impaired pharmacist or refer to MTP is considered unprofessional or dishonorable conduct.
- Remember to carefully read all statements prior to signing during the application or reapplication process. Falsifying an application is an offense that the Board takes very seriously and may result in severe penalties against a license or licensee. If you have any questions regarding application or reapplication, please contact the Board office.

Disciplinary Actions

Buy-Rite Drugs, Inc – License PH-4307. Settlement agreement. During the January 2018 Board meeting, the Board and licensee came to terms on a settlement agreement. The licensee agrees to pay fines totaling $1,175.

Bob McClelland III, RPh – License RP-4533. Summary suspension. The Board ordered a summary suspension of this license due to noncompliance with a settlement agreement. The suspension was upheld during the January 2018 Board meeting.

Rudy Nolasco, RPh – License RP-4260. Summary suspension. The Board ordered a summary suspension of this license due to noncompliance with a previous settlement agreement. The suspension was subsequently lifted during the January 2018 Board meeting.

Bishnu J. Rauth – License CS-11686. Voluntary surrender. The Board accepted voluntary surrender of this license during the January 2018 Board meeting. The licensee must pay a fine of $100.

Frequently Asked Questions

This is a new section of the *Newsletter* that illustrates some of the most frequently recurring questions the Board receives throughout the quarter.

1. **Do live continuing pharmacy education (CPE) hours required for my prescriptive authority count toward my 10 hours of live CPE pharmacist renewal requirement?**

   No. According to 16.19.26 NMAC, which outlines the requirements for education and training with regard to prescriptive authority, the following statement can be found: "Such continuing education shall be in addition to requirements in 16.19.4.10 NMAC." This is in the Education and Training sections of each individual prescriptive authority within the regulation cited. The CPE required to maintain prescriptive authority is separate from the CPE required to maintain licensure as a pharmacist.

2. **Can I transfer a controlled substance (CS) prescription before it has been filled?**

   Drug Enforcement Administration (DEA) **does not** allow for the transfer of an unfilled prescription from one DEA registrant to another for the purposes of filling. There is one exception to this. DEA does allow for the forwarding of original prescription information for an electronically prescribed CS from one DEA registrant to another for the purposes of filling. This also includes Schedule II prescriptions.

3. **How long do I have to report the loss or theft of CS?**

   Theft and/or loss of CS **must** be reported to DEA within 24 hours of discovery and to the Board within five days of discovery (16.19.20.36.B NMAC).

4. **How long do I have to report a significant adverse drug event to the Board? Am I required to report all significant adverse drug events?**

   Significant adverse drug events **must** be reported to the Board within 15 days of discovery (16.19.25.8.B NMAC). Reporting of all such events is a requirement, not an option, within the above-cited regulation.

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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