March 2020

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 51-year-old female patient was prescribed Lyrica® 50 mg, but was given pregabalin (generic Lyrica) 150 mg by the dispensing pharmacy. The patient reported feeling dizzy and nauseous as a result of taking the incorrect strength for three days. The pharmacist attributes the error to workload and working at a fast pace. The pharmacist recommends verifying all medications prescribed with higher than normal start doses.
2. A 57-year-old female patient was prescribed duloxetine 30 mg capsules electronically, but was given primidone 50 mg by the dispensing pharmacy. The primidone was intended for a different patient, but was bagged incorrectly while two pharmacists were performing the same task. After taking one dose of the incorrect medication, the patient reported feeling nauseous and drowsy. The pharmacist attributes the error to multiple people performing the same task simultaneously in close proximity. The pharmacist recommends having only one pharmacist bagging medication at a time to prevent similar errors.
3. A 57-year-old male patient attempted to pick up a refill for paroxetine 20 mg, but was given quetiapine 200 mg by the dispensing pharmacy. As a result of taking the medication for an unspecified amount of time, the patient reported feeling "out of it" and was eventually admitted to the emergency room due to disorientation and slurred speech. The pharmacist stated that the correct medication was scanned during the filling process, but a different bottle of medication was used to fill the prescription. The pharmacist recommends:
   - ♦ returning stock bottles to the shelf immediately after filling;
   - ♦ immediately pouring and filling a medication after scanning;
   - ♦ allowing no more than one person to use a filling station at a time; and
   - ♦ canceling out of verification screen if interrupted and starting over.
4. A 24-year-old female patient was prescribed Macrobid®/nitrofurantoin, but was given Prometrium®/progesterone by the dispensing pharmacy. After taking the incorrect medication for an unspecified amount of time, the patient reported cramps to the pharmacy. The pharmacist stated that the error occurred because the technician made a third-party payer update at the point of sale, and relabeled the incorrect bag of medication. The pharmacist recommends that all reprinted prescription labels must go through the pharmacist for reverification prior to bagging.
5. A 38-year-old female patient attempted to pick up a renewal of hydroxyzine 10 mg but was given levothyroxine 50 mcg, intended for a different patient, by the dispensing pharmacy. The two patients have the same first name and similar last names. Seeing a white-round tablet as expected, the patient took the incorrect medication for an unspecified amount of time and she reported that she experienced a relapse in bipolar manic symptoms, including increased agitation and anxiety. The pharmacist attributes the error to not following policy in verifying patient information before selling the prescription. The pharmacist recommends verifying the date of birth for all patients picking up prescriptions.
6. A 39-year-old female patient attempted to pick up her prescription for Synthroid® 100 mcg, but was given Synthroid 88 mcg by the dispensing pharmacy. After taking the incorrect strength for approximately one month, the patient reported that she had not been feeling good. The pharmacist attributes the error to

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National Pharmacy Compliance News

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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.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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inattention by the pharmacist during the double-check phase of drug labeling/filling. The pharmacist recommends marking all prescriptions with a dose change on the bag so it can be addressed during counseling.

7. A 46-year-old female patient attempted to pick up her refill for lisinopril 20 mg tablets, but was given lisinopril/hydrochlorothiazide 20/25 by the dispensing pharmacy. The pharmacist attached the incorrect label to a finished prescription intended for a different patient. The patient reported dizziness as a result of taking the incorrect medication for approximately one month. The pharmacist recommends verifying the patient's date of birth at the register when selling prescriptions.
8. A 38-year-old male patient was prescribed ibuprofen 600 mg for a dental procedure, but was given bupropion 300 mg in addition to ibuprofen at the point of sale. The patient took the bupropion for approximately 18 days and did not report experiencing any adverse effects; however, the prescriber determined that a 14-day taper dose of bupropion would be the best course of action. The pharmacist attributes the error to multitasking and recommends that only one patient basket should be in front of the pharmacist at a time while performing the final check.
9. A 61-year-old female patient received trazodone 100 mg intended for a different patient. According to the pharmacist, the prescription was scanned into the incorrect patient profile. After taking three doses, the patient reported worsening of her (untreated) seizure/neuromuscular disorder, muscle spasms, and insomnia. The pharmacist attributes the error to improper workflow training. The pharmacist recommends only entering information for one patient at a time.
10. A 34-year-old male patient was prescribed aripiprazole 30 mg, but was given aripiprazole 5 mg by the dispensing pharmacy. As a result of taking two doses of the lower strength, the patient reported experiencing increased anger and anxiety. The pharmacist attributes the error to a break in process by not matching the National Drug Code (NDC) with the product filled. The pharmacist recommends initialing the NDC on the label when the product is verified.

Disclaimer: These 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.

Regulation Updates

- **16.19.18 New Mexico Administrative Code (NMAC) – Nuclear Pharmacy:** Training requirements have been updated to reflect current standards. The utilization of paper or electronic access to regulations has been added. The minimum equipment requirements as appropriate for the scope of services provided have been added and are in addition to those found in 16.19.6.11 NMAC. All nuclear pharmacies must operate in conformance with United States Pharmacopeia Chapter <825> (once the chapter becomes official) and all applicable chapters below <1000>.
- **16.19.20 NMAC – Controlled Substances (CS):** The following was updated in the CS regulation:
  - Renewal applications may be mailed to physical, mailing, or electronic addresses located on the application (section 9)
  - Update/clarification on inventory requirements (section 20)
  - Update/clarification of CS waste process/disposal (section 37)
  - Update on disposition of unusable, outdated, or unwanted CS (section 38)
  - Update allowing for prescribing of narcotic CS approved by Food and Drug Administration (FDA) for maintenance/detoxification treatment (section 41)
  - Phenazepam added to Schedule I (section 65)
  - Dronabinol in an oral solution in a drug product approved for marketing by the US Food and Drug Administration
  - Brivaracetam and drug product approved for marketing by FDA and that contains cannabidiol derived from cannabis and no more than 0.1% tetrahydrocannabinols added to Schedule V (section 69)

For more details, please reference the cited regulation(s) available on the Board's website under "Rules and Laws."

Disciplinary Actions

William Bernstein – License CS213198. Voluntary surrender of license. Former licensee must pay an investigative cost of $100.

Kenneth Cooper, Jr, Las Cruces Apothecary – RP6912, PH3866. Two-year probation. Licensee must pay the following within 90 days: a fine in the amount of $1,500; the cost of investigation in the amount of $137.50; the cost of hearing in the amount of $690.43.

Daniel Hall – RP6813. Settlement agreement. License suspended for 90 days or until cleared to work by the Health

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Professional Wellness Program (whichever comes later). Licensee must complete a five-year Monitored Treatment Program (MTP) contract. Ten-year probationary period. Licensee may not serve as pharmacist-in-charge, work site monitor, or consultant pharmacist for one year after returning to work or completion of first year of MTP contract (whichever comes later).

Josip Gazic – CS213095. Revocation of license. During the October 2019 Board meeting, the Board revoked the above CS registration.

Pacifico National Inc – PH3202. Settlement agreement. Licensee agrees to surrender license and reapply within six months. Five-year probationary period; may not ship sterile compounds into New Mexico during this time. Must pay a fine in the amount of $8,000 and the cost of investigation in the amount of $1,500.

Christopher Staley – CS20763. Voluntary surrender of license. Former licensee must pay an investigative cost of $100.

Reminders

Upcoming Albuquerque, NM, pharmacy law lecture dates are as follows:

- Friday, March 6, 2020
- Thursday, April 2, 2020
- Friday, May 1, 2020
- Friday, June 12, 2020
- Friday July 10, 2020
- Friday, August 7, 2020
- Friday, September 4, 2020
- Friday, October 2, 2020
- Friday, November 6, 2020
- Friday, December 4, 2020

All law lecture updates will be at the Board offices unless otherwise noted.

Upcoming pharmacy law lecture dates outside of Albuquerque are as follows:

- **Tuesday, March 10, 2020**
  Presbyterian Española Hospital
  Española, NM
- **Tuesday, March 17, 2020**
  Gila Regional Medical Center
  Silver City, NM
- **Tuesday, April 21, 2020**
  Rehoboth McKinley Hospital
  Gallup, NM
- **Tuesday, May 5, 2020**
  Long Term Miners' Colfax Medical Center
  Raton, NM
- **Tuesday, May 19, 2020**
  Rehoboth McKinley Hospital
  Gallup
- **Tuesday, June 16, 2020**
  Gerald Champion Regional Medical Center
  Alamogordo, NM
- **Tuesday, November 17, 2020**
  Carlsbad Medical Center
  Carlsbad, NM
- **Tuesday, December 1, 2020**
  MountainView Regional Medical Center
  Las Cruces, NM
- **Wednesday, December 2, 2020**
  Memorial Medical Center

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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