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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 68-year-old male patient was given three medications that belonged to another patient with the same first and last names. The medications in question are: venlafaxine 75 mg extended release, mirtazapine 30 mg, and clonidine 0.2 mg. The patient took the three medications and reported feeling dizzy and drowsy after one dose. The error was discovered by the pharmacy staff after approximately one week. The pharmacist attributes the error to a break in protocol by not verifying the patient's date of birth and/or home address.
2. A 75-year-old male patient was prescribed warfarin 5 mg tablets as directed but was given warfarin 3 mg as directed instead. The patient took 34 total tablets of the 3 mg strength before the error was discovered and brought to the attention of the pharmacy. The pharmacist cites inattention and distraction as contributing factors to the error.
3. A 79-year-old female patient was prescribed hydralazine 10 mg (three times daily) but was dispensed hydralazine 100 mg (three times daily). Upon dispensing, the patient was counseled regarding the seemingly high dose. After taking the medication for almost two weeks, the patient reported orthostatic hypotension and dizziness, at which time the error was discovered. The patient was later diagnosed with hydralazine toxicity in the emergency department. The pharmacist attributes the error to a busy pharmacy, distractions from staff, and not appropriately contacting the prescriber with concerns surrounding the high dose. The pharmacist recommends amending the policy and procedure for contacting the prescriber in all instances when there is a question about dosage.
4. A 69-year-old male patient was prescribed amiodarone 200 mg daily. Instead of once daily, the pharmacy dispensed the dose as twice daily. As a result of taking the incorrect dose, the patient was admitted to the intensive care unit due to uncontrollable internal and rectal bleeding (the patient was on warfarin concurrently). The pharmacist attributes the error to inattention while verifying the titration dose during the final check and attempting to combine a titration dose with a routine dose on the same prescription. The pharmacist indicated that this would normally be entered as two separate prescriptions because of the titration dose.
5. Within a hospital Pyxis machine, it was identified that a bupropion cell was inappropriately restocked with fluphenazine. The error was not identified until two adverse drug events were reported that were not typical to bupropion. A total of 22 patients were identified who may have received fluphenazine instead of bupropion. Of the 22 charts reviewed, eight patients were identified who had symptoms suggestive of receiving fluphenazine instead of bupropion. The pharmacist attributes the error to 1) a break in protocol because all Pyxis restocks are verified through barcode scanning; and 2) the pharmacist noticed the error and asked the technician to fix it but it was restocked anyway, likely by other staff unaware of the situation. The pharmacist recommends creating a bin for temporary storage of restock products that need to be corrected before being placed within the Pyxis machine.
6. A 50-year-old female patient (patient A) was given metoprolol 100 mg (twice daily) that belonged to another patient (patient B) with a similar name. Patient A had three medications ready to be picked up; when the metoprolol for patient B was verified, it was mistakenly added to patient A's bag of prescriptions that were ready to be picked up. After taking six doses of the medication, the patient returned to the clinic with complaints of nausea, diarrhea, dizziness, headache, body aches, and chest tightness. The pharmacist attributes the error to a break in policy by placing a newly verified medication into a bag of medications that was previously verified.

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National Pharmacy Compliance News

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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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

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

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. 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 legitimate investigation or legal action is 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.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

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7. A 74-year-old female patient was prescribed fluvoxamine 100 mg tablets but was dispensed flecainide 100 mg tablets. After taking the medication for an unspecified amount of time, the patient complained of tachycardia and had to be seen at an emergency room. The pharmacist attributes the error to a break in procedure; the stock bottle was not checked appropriately during verification. The pharmacist recommends checking in all cell phones while on duty to minimize distractions.

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.

New Mexico Senate Bill 221 Summary

There have been an overwhelming number of questions surrounding the new Senate bill that was enacted involving the prescribing of opioids. A brief description of the new law can be found below. (emphasis added)

- A health care provider who prescribes, distributes, or dispenses an opioid analgesic for the first time **must** counsel the patient on overdose risks and the availability of an opioid antagonist.
- If a patient has previously received a prescription for an opioid analgesic, the counseling described above **must** be given again on the first occasion in each calendar year when a prescription, distribution, or dispensation by a health care provider occurs.
- Any health care provider who prescribes an opioid analgesic **must** co-prescribe an opioid antagonist if the opioid analgesic quantity is greater than or equal to a five-day supply.
- A prescription for an opioid analgesic **must** be accompanied by written information related to the temporary effects of an opioid antagonist and techniques for administration.
- The term "health care provider" for this Senate bill is defined as "a person who is licensed or otherwise authorized by law to provide health care in the ordinary course of business or practice of the person's profession **and** who has prescriptive authority within the limits of the person's license."

Disciplinary Actions

A&W Pharmacy – PH00004883. Settlement agreement. During the June 2019 Board meeting, the respondent pharmacy entered into a settlement agreement with the Board, containing the following stipulations: 1) respondent must be licensed with the Board to ship medications into the state; and 2) respondent must pay a fine of $2,800.

Andrew Ngo – IN00003543. Pharmacist licensure denied. During the June 2019 meeting, the Board denied the respondent's application for pharmacist licensure due to a violation of the Pharmacy Act. The respondent must pay the cost of the investigation and hearing in the amount of $739.73.

Catharine Hanson – PT00009294. Voluntary surrender. During the June 2019 meeting, the Board accepted the voluntary surrender of this technician's Board registration.

Complete Pharmacy Medical Solutions – PH00003406. Settlement agreement. During the June 2019 Board meeting, the respondent pharmacy entered into a settlement agreement with the Board, containing the following stipulations: 1) must submit an application in proper form for each license; 2) complete a five-year probationary period, during which time respondent will maintain proper licensure and standards of operation for sterile compounding; and 3) pay a fine of $15,000.

Complete Pharmacy Medical Solutions Outsourcing Facility – license number pending. Settlement agreement. During the June 2019 Board meeting, the respondent pharmacy entered into a settlement agreement with the Board, containing the following stipulations: 1) must submit an application in proper form for each license; 2) complete a five-year probationary period, during which time respondent will maintain proper licensure and standards of operation for sterile compounding; and 3) pay a fine of $10,000.

Jed Lyden – RP00006503. Revocation. During the June 2019 meeting, the Board revoked this pharmacist's registration. The respondent must pay the cost of the investigation and must also pay a fine amounting to a total of $1,062.50.

Joel Villarreal – RP00006498. Settlement agreement. During the June 2019 Board meeting, the respondent entered into a settlement agreement with the Board, containing the following stipulations: 1) must complete a five-year Monitored Treatment Program (MTP) contract; 2) must not work as a pharmacist-in-charge, consultant pharmacist, or worksite monitor; 3) must notify potential employers of the agreement; 4) must notify the Board if residing out-of-state; 5) must retake and pass the Multistate Pharmacy Jurisprudence Examination®; and 6) must pay the cost of the investigation: $875 plus the cost of the hearing, which has yet to be determined.

Samuel Sandoval – PT00012305. Revocation. During the June 2019 meeting, the Board revoked this technician's

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registration until such time that the respondent comes into compliance with Board regulations.

Tawnia Gaylor – RP00004882. Settlement agreement. During the June 2019 Board meeting, the respondent entered into a settlement agreement with the Board, containing the following stipulations: 1) must complete a five-year MTP contract; 2) must not work as a preceptor or worksite monitor for the first year of the agreement; 3) must pay the investigative cost of $400; 4) must notify potential employers of the agreement; and 5) must notify the Board if residing out-of-state.

Shasta Baca – PT00003604. Voluntary surrender. During the June 2019 meeting, the Board accepted the voluntary surrender of this technician's Board registration.

More information on disciplinary actions can be found on the Board website.

Upcoming Pharmacy Law Updates

Upcoming pharmacy law lecture dates are as follows:

- **September 6, 2019**
  Board office
  Albuquerque, NM
- **September 10, 2019**
  Holy Cross Hospital
  Taos, NM
- **October 4, 2019**
  Board office
  Albuquerque
- **October 8, 2019**
  Alta Vista Regional Hospital
  Las Vegas, NM
- **November 1, 2019**
  Board office
  Albuquerque
- **November 5, 2019**
  Lea Regional Medical Center
  Hobbs, NM
- **December 3, 2019**
  Memorial Medical Center
  Las Cruces, NM
- **December 4, 2019**
  MountainView Regional Medical Center
  Las Cruces
- **December 6, 2019**
  Board office
  Albuquerque

The full list of law updates can be found on the Board website.

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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