June 2019

New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Significant Adverse Drug Events

1. An 83-year-old female patient was prescribed estradiol 0.025 mg/mL (compounded) as hormone replacement therapy. The patient was sent home with estradiol 0.25 mg/mL due to a miscalculation during compounding. After using the medication for an unspecified amount of time, the patient reported breast tenderness. According to the pharmacist, the error occurred because the pharmacist failed to check the calculations made by the technician. The pharmacist recommends checking calculations on all new formulations and all estrogen formulas.
2. A two-year-old female patient was prescribed baclofen 5 mg/mL (compounded) per gastrostomy tube. After using the medication for an unspecified amount of time, the patient was hospitalized due to withdrawals. The pharmacist believes that an incorrect strength of baclofen tablets was used during the compounding process, resulting in a lower strength compound than what was on the prescription label. The pharmacist recommends comparing all National Drug Codes with formulation records when available and will stress this policy going forward.
3. A 10-year-old canine was prescribed furosemide 10 mg to take twice daily for hypertension but was dispensed furosemide 20 mg to take twice daily. After giving the medication to the canine for an unspecified amount of time, the canine suffered a seizure. The pharmacist attributes the error to furosemide not being commercially available in a 10 mg strength and adjusting the strength of what was dispensed to 20 mg, but not adjusting the directions accordingly. The pharmacist also attributes the error to poor multitasking. The pharmacist did not offer a recommendation aside from checking prescriptions more thoroughly.
4. A 59-year-old male patient was prescribed hydroxyzine pamoate 50 mg, two each night. Another patient's hydroxyzine pamoate 25 mg capsules were bagged together with the 50 mg capsules. The patient took the prescribed dose on both prescription vials, for a total of 150 mg nightly, for two days, and experienced nausea and anxiety. The pharmacist attributes the error to leaving filled, unbagged prescriptions on the counter while bagging another patient's medication in close proximity. The pharmacist recommends taking all prescriptions out of the bag prior to dispensing, during counseling to prevent similar errors.

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.

Conscientious Objection

There have been a number of questions raised about the "conscience clause" or "contentious objection" when it comes to filling a prescription. It is important that there are policies and procedures in place beforehand, and that pharmacists and other pharmacy-related health care workers are familiar with, and adhere to, these policies. As written in 24-7A-7 New Mexico Statutes Annotated (NMSA) 1978, a pharmacist who declines to fill a prescription for reasons of conscience shall **personally (emphasis added):**

(1) **promptly so inform the patient,** if possible, and any person then authorized to make health-care decisions for the patient;

(2) **provide continuing care to the patient until a transfer can be effected;** and

(3) unless the patient or person then authorized to make health-care decisions for the patient refuses assistance, **immediately make all reasonable efforts to assist in the transfer of the patient to another health-care provider**

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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.

FDA Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an FDA press release. Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the *Federal Register.*

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements. These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm.*

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy.* The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the "most important criterion of success" is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at *https://www.whitehouse.gov/opioids.*

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP's PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP $AWAR_XE$® Prescription Drug Safety Program's Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the $AWAR_XE$ program, visit the Initiatives section of the NABP website at *www.nabp.pharmacy.*

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open.* The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as "modest," due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take "a stronger and multipronged approach" to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405.*

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

"Now that these risks are identified, we're applying what we've learned to the evaluation of similar manufacturing processes where we now know these risks could arise," the statement notes. The FDA press release is available at *https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm.*

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency's primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug's benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at *https://www.fda.gov/drugs/drugsafety/rems.*

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or health-care institution that is willing to comply with the instruction or decision.

For more information, refer to 24-7A-7 NMSA 1978.

Regulation Changes

Language was added to New Mexico Administrative Code (NMAC) to allow an inpatient hospital pharmacy, not otherwise licensed as a retail pharmacy, to dispense medication to a patient on hospital discharge, on a limited basis. Dispensing restrictions include, but are not limited to:

- The medication must be prescribed by a licensed practitioner of the hospital
- The medication must be dispensed by a pharmacist
- No controlled substances (CS) may be dispensed
- The prescription or order may not be refilled or transferred

For more information, see 16.19.7.16 NMAC.

Federal Law Update

The SUPPORT for Patients and Communities Act was signed into law in October 2018. This is a national mandate that requires electronic prescribing for all CS under Medicare Part D by January 1, 2021.

Disciplinary Actions

Home Sweet Home – License CU00010779. Revocation. During the January 2019 Board meeting, this license was revoked. The former owner (Michael Sanchez) may not own or operate a facility required to be licensed by the Board for a period of 10 years. The former owner must also pay the cost of investigation and a fine equal to $4,000 and $5,000, respectively.

Home Sweet Home – License CU00010929. Revocation. During the January 2019 Board meeting, this license was revoked. The former owner (Michael Sanchez) may not own or operate a facility required to be licensed by the Board for a period of 10 years. The former owner must also pay the cost of the investigation and a fine equal to $2,500 and $5,000, respectively.

New Life Assisted Living – License CU00011277. Revocation. During the January 2019 Board meeting, this license was revoked. The former owner (Michael Sanchez) may not own or operate a facility required to be licensed by the Board for a period of 10 years. The former owner must also pay the cost of the investigation and a fine equal to $2,000 and $5,000, respectively.

New Life Assisted Living – License CU00011278. Revocation. During the January 2019 Board meeting, this license was revoked. The former owner (Michael Sanchez) may not own or operate a facility required to be licensed by the Board for a period of 10 years. The former owner must also pay the cost of the investigation, equal to $500.

John Bray-Morris – License CS00208894. Revocation. During the October 2018 Board meeting, the Board ordered the revocation of this CS registration. The former licensee must pay the cost of the investigation and disciplinary proceedings in the amount of $249.89.

Antonia Weinstein – RP00007502. Probation. During the January 2019 Board meeting, the Board ordered probation for one year, which began in April 2019. The licensee must pay the cost of the investigation and the cost of disciplinary proceedings in the amount of $2,868.92. The licensee must also complete a communication course approved by the Board's executive director.

Robert J. Walantas – License CS00214012. Voluntary surrender. During the January 2019 Board meeting, the Board accepted the voluntary surrender of this certified nurse practitioner's CS registration. The respondent must pay an investigative cost of $350.

Tracy Overbay – License RP00006051. Reinstatement of license. Respondent had his pharmacist license reinstated by the Board during the January 2019 Board meeting, agreeing to the following stipulations: must complete a five-year contract with the Monitored Treatment Program (MTP); must not serve as a pharmacist-in-charge (PIC), consultant pharmacist, or preceptor for one year after returning to work; and must notify potential employers of the agreement terms.

James Gonzales – License RP00007378. Reinstatement of license. Respondent had his pharmacist license reinstated by the Board during the April 2019 Board meeting, agreeing to the following stipulations: must complete a five-year contract with the MTP; must not serve as a PIC, consultant pharmacist, or preceptor for one year after returning to work; and must notify potential employers of the agreement terms.

Reminders

- Upcoming pharmacy law lecture dates:
  - June 7, 2019 – At the Board office in Albuquerque, NM
  - July 10, 2019 – At the Toney Anaya Building – Rio Grande Room in Santa Fe, NM
  - July 12, 2019 – At the Board office in Albuquerque
  - August 2, 2019 – At the Board office in Albuquerque
  - September 6, 2019 – At the Board office in Albuquerque

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- ◊ September 10, 2019 – At Holy Cross Hospital in Taos, NM

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

- ♦ Be sure to submit Adverse Drug Event Reports to the Board **within 15 days of discovery.** This is required by regulation and could potentially result in disciplinary action if not compliant. This report **must** include an appropriate root cause analysis with recommendation(s) for improvement.
- ♦ Pharmacists, be sure that you are completing the required continuing education (CE) prior to relicensure. The Board conducts audits on a monthly basis. Here are some things to keep in mind when completing your CE.
  - ◊ The patient safety and safe/appropriate use of opioid requirements can be combined if a CE course appropriately covers both topics.
  - ◊ Your New Mexico law CE does not count toward your 10-hour live CE requirement.
  - ◊ CE required to maintain pharmacist prescriptive authority does not count toward your 30-hour CE requirement.

Failure to comply with all requirements may result in up to a $1,000 fine and disciplinary action against your license.

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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