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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 54-year-old male patient was stable on a warfarin regimen consisting of 1 mg tablets. On a refill prescription, the patient was given 5 mg tablets instead of 1 mg tablets. The error was noted by the prescriber when the patient's international normalized ratio was out of range. The dose was corrected with no lasting effects on the patient. The pharmacist on duty attributes the error to incorrect utilization of National Drug Code (NDC) matching during product review. The pharmacist recommends verifying the NDC during both filling and verification.
2. A 75-year-old female patient was electronically prescribed torsemide 10 mg tablets. The prescription was incorrectly entered into the computer system as torsemide 100 mg tablets and placed in a hold status. When the request for fill was made by the patient, the incorrect dose was filled and verified by the pharmacist. The error was discovered approximately three weeks later when the patient presented to the prescriber's office complaining of erratic blood sugar readings, weight loss, and general weakness. The patient also required treatment for dehydration. The pharmacist attributes the error to not validating the strength from the actual hard copy of the prescription. This is due to the process in place for verification of hold status prescriptions. The pharmacist recommends comparing the filled medication against the hard copy prescription, even for hold status medications. The pharmacist also recommends altering how less common strengths of medications come up in the computer system to more readily differentiate doses.
3. A 65-year-old female patient was electronically prescribed topiramate 25 mg extended-release capsules. The prescription was incorrectly filled for topiramate 25 mg immediate-release tablets and dispensed to the patient. The error was identified when the patient attempted to refill the prescription for the first time. Over the course of approximately one month taking the medication, the patient reported increased drowsiness, dizziness, headache, kidney/flank pain, and mood changes. The pharmacist attributes the error to the medication not being listed in the pharmacy computer system. This has since been addressed and added into the pharmacy database.
4. A 12-year-old male patient was prescribed montelukast 5 mg chewable tablets. When the patient attempted to refill the medication, buprenorphine/naloxone 8/2 mg was dispensed in error. The patient was observed in an emergency room; however, no injury or detrimental effect was noted. The pharmacist attributes the error to similarly labeled stock bottles. The pharmacist recommends "red flagging" bottles that are similarly labeled and placed close to each other on the shelf so as to avoid confusion when choosing a product.
5. A 59-year-old female patient attempted to refill a prescription for chlorthalidone 25 mg tablets. The prescription was incorrectly filled with chlorthalidone 50 mg tablets and dispensed to the patient. The patient contacted the pharmacy after approximately one week due to the tablets being a different color than expected. The only adverse effect reported was an increase in the frequency of urination. The pharmacist attributes the error to non-use of the barcode technology as outlined in the policies and procedures. The pharmacist's recommendation is to retrain staff on the importance of using barcode technology, when available, to assist with verification.
6. A 49-year-old male patient was prescribed amitriptyline 100 mg tablets in November 2017. On the first refill request in January 2018, the patient questioned the strength previously dispensed. It was discovered that amitriptyline 10 mg had been dispensed in place of the 100 mg tablets. The patient reported having fallen twice since taking the incorrect dose. The pharmacist attributes the error to high pharmacy volume and 12-hour shifts. The pharmacist recommends placing a hold on all prescriptions with a dose decrease. The hold cannot be removed until the decrease has been verified with the patient.
7. A 43-year-old male patient was prescribed Qsymia® 3.75-23 mg capsules. Because this was unavailable, the pharmacist attempted to fill for a generic alternative, but misread the prescription strength. The prescription was filled for phentermine 37.5 mg capsules. The patient used this medication for three months and was hospitalized for a blood clot and diagnosed with congestive heart failure. The pharmacist attributes the error to having the same staff member enter and verify the prescription. The pharmacist recommends separation of duties by not allowing the same staff member to both enter and verify the same prescription.

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NABPF
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FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

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 at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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8. A 76-year-old male patient was prescribed testosterone cypionate 100 mg intramuscular injection. On the original fill, the prescription was filled for a 200 mg strength of the same drug and filled two subsequent times before the error was caught. The pharmacist attributes the error to the faint print on the original prescription when received via fax. The pharmacist recommends adapting a large-print lettering system to bring attention to and assist with verification on faxes that are difficult to read.

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.

Updates to the Prescription Monitoring Program

The Board reviewed a proposed rule change regarding the New Mexico Prescription Monitoring Program (PMP) at the April 2018 Board meeting. The proposed changes include audit trail information disclosure, mandatory reporting of zero reports, mandatory corrections to a patient record once incorrect data has been identified, and consultant pharmacists' ability to review PMP patient reports. To see the detailed proposed rule changes, visit the Board's website.

In addition, the New Mexico PMP resource page *(www.nmpmp.org)* is undergoing significant changes. Updates include current information, resources, and training slides. Stay tuned!

Disciplinary Actions

Kelsie Current, CPhT – License PT-8609. Voluntary surrender. During the April 2018 Board meeting, the Board accepted a voluntary surrender of this technician's license. The former licensee may not reapply for licensure for five years and must pay a fine of $100.

James Gonzales, RPh – License RP-7378. Summary revocation. During the April 2018 Board meeting, this license was revoked due to noncompliance with a stipulated agreement in place from January 2016.

Richard Marano – License PT-6492. Settlement agreement. During the April 2018 Board meeting, the former licensee entered into the following agreement with the Board: 1) The licensee must pay a fine of $200 plus hearing costs of $145; 2) the licensee must not enter the restricted area or handle any prescriptions for a pharmacy; and 3) should he relicense in the future, the licensee will immediately be placed on probation for three years.

Steven Shaver, RPh – License RP-6830. Settlement agreement. During the April 2018 Board meeting, the former licensee entered into the following agreement with the Board: 1) The licensee must pay a fine of $500 plus investigative costs; 2) the licensee must complete a continuing education (CE) course in error prevention; and 3) the licensee will be on probation for a period of one year.

Regulation Changes

- Language was added to 16.19.20.46 New Mexico Administrative Code (NMAC) regarding partially filled Schedule II prescriptions. Changes include documentation requirements and timetables for completing the partial fills.
- 16.19.20.10 NMAC has been updated requiring triennial renewal of controlled substance registration instead of annual renewal. The fee is now $180 for three years instead of $60 annually. A locum tenens practitioner may still apply for licensure for up to one year for a fee of $60.
- 16.19.20.65 through 68 NMAC was updated, and several medications were added to controlled substance schedules. This includes a number of fentanyl derivatives, which were added to Schedule I.

Reminders

- The August Board meeting has been **rescheduled** for Thursday, August 30-Friday, August 31, 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 at least 30 days prior to the hearing. The notice to the public will provide the proposed changes.
- CPE Monitor® has recently undergone some changes. If you were previously registered, you will have to reregister your account. This is a quick process; however, the Board encourages you to familiarize yourself with the new interface. The National Association of Boards of Pharmacy's® e-Profile FAQs 2 and 4 provide more information on the process. These and other helpful tips may be found at *https://nabp.pharmacy/e-profile/faqs.*
- 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 you are not compliant. This report **must** include an appropriate root cause analysis with recommendation(s) for improvement.
- Pharmacists, be sure that you complete the required CE prior to relicensure. The Board conducts audits on a monthly basis. Some things to keep in mind when completing your CE:
  - ◊ The patient safety requirement and safe/appropriate use of opioids requirement can be combined if a CE course is applicable to cover both topics.
  - ◊ Your New Mexico law CE credits do not count toward your 10-hour live CE requirement.
  - ◊ CE credits required to maintain pharmacist prescriptive authority do not count toward your 30-hour CE requirement.

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

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