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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 39-year-old female patient was given a new prescription for amoxicillin-clavulanate 875/125 mg to be taken once every 12 hours. The pharmacist verified the prescription to be taken once every two hours. After taking the medication for approximately seven days, the patient developed a severe yeast infection and contacted the pharmacy to verify the prescription directions. The patient was seen at urgent care as a result of the prescription error. The pharmacist attributes the error to staffing issues.
2. A 47-year-old female patient was given a new prescription for hydrocodone/APAP 7.5/325 mg tablets. At the time of dispensing, the patient was given hydrocodone/APAP 10/325 mg tablets. The error was discovered on a post-fill audit log approximately 15 minutes after the prescription was dispensed. The patient took one dose and reported no side effects as a result. The pharmacist attributes the error to being distracted. The pharmacist recommends implementing a pre-verification step as an extra check before prescriptions go through the final check.
3. A 56-year-old female patient was prescribed Neomycin-Polymyxin-Hydrocortisone ophthalmic solution. Instead, the patient was given Neomycin-Polymyxin-Hydrocortisone otic suspension and was instructed to use it in the eye. The patient contacted the pharmacy to verify the dispensing error but did not report any side effects from using the otic suspension in her eyes. The pharmacist attributes the error to inattention. The pharmacist recommends separating ophthalmic products and otic products that have the same or similar names.
4. A 47-year-old male patient with hypertension on valsartan 160 mg was instead dispensed alprazolam 1 mg tablets upon a refill request. After approximately two and a half weeks, the patient had to be treated for highly elevated blood pressure and headache. The pharmacist attributes the error to distraction with a prior patient's questions regarding a prescription monitoring program report. Inadequate counseling may have also been a contributing factor. The pharmacist recommends establishing a new policy to minimize distractions in the workplace.
5. A 12-year-old male patient with asthma was given generic Suboxone® sublingual tablets, in place of his prescribed Singulair® tablets, by a retail pharmacy. It is unknown what symptoms the patient experienced as a result of taking the incorrect medication for approximately one week, but the patient did require an emergency room visit. The error seems to have been caused by a technician who did not give the medication to the pharmacist for the final check. The pharmacist recommends implementing barcode technology so that prescriptions cannot be sold without having first been verified by a pharmacist.
6. A 62-year-old female patient complained to her pharmacy of chest pain and morning drowsiness due to "the new brand" of oxcarbazepine 300 mg dispensed on her most recent refill. On further examination, the pharmacy discovered that the medication was filled with quetiapine 300 mg tablets. The pharmacist attributes the error to verifying multiple prescriptions simultaneously and not comparing the filled medication against the stock bottle. The pharmacist recommends verifying only one prescription at a time and verifying the medication with the stock bottle in hand, no exceptions.
7. A 69-year-old male patient was prescribed Azulfidine® 500 mg but was dispensed sulfadiazine 500 mg on the first fill. The error was caught when the patient attempted to refill the medication. The patient took the medication for a month but reported no side effects or symptoms as a result. The pharmacist attributes the error to unfamiliarity with brand/generic medications that share similar names with other brand/generic medications. The pharmacist recommends tallman lettering to help differentiate names.
8. A 41-year-old female patient was sold quetiapine 50 mg tablets that were intended for a different patient with the same first name and a similar last name. As a result of taking approximately 23 doses, the patient reported feelings of anhedonia and vertigo. The pharmacist attributes the error to inattention on the part of the cashier. The pharmacist recommends that all cashiers use three points of verification going forward, such as name, address, and date of birth.
9. A prescription renewal for clonazepam was called in to a retail pharmacy for a 50-year-old male patient with a history of seizures. Upon data entry, the technician did enter the additional refill that was called in and the pharmacist

continued on page 4

National Pharmacy Compliance News

September 2018

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.

DEA Launches New Tool to Help Distributors Make Informed Decisions About Customers

In February 2018, Drug Enforcement Administration (DEA) launched a new tool to assist drug manufacturers and distributors with their regulatory obligations under the Controlled Substances Act. The agency added a new feature to its Automation of Reports and Consolidated Orders System (ARCOS) Online Reporting System, a comprehensive drug reporting system that monitors the flow of controlled substances (CS) from their point of manufacture through commercial distribution channels to the point of sale at the dispensing/retail level. This newly added function will allow the more than 1,500 DEA-registered manufacturers and distributors to view the number of registrants who have sold a particular CS to a prospective customer in the last six months.

DEA regulations require distributors to both "know their customer" and to develop a system to identify and report suspicious orders. Manufacturers and distributors have asked DEA for assistance in fulfilling these obligations and have requested ARCOS information to help them determine if new customers are purchasing excessive quantities of CS. This new tool will provide valuable information for distributors to consider as part of their assessment. More details are available in a news release at *www.dea.gov/divisions/hq/2018/hq021418.shtml.*

PTCB Launches Certified Compounded Sterile Preparation Technician Program

In January 2018, the Pharmacy Technician Certification Board (PTCB) launched the PTCB Certified Compounded Sterile Preparation Technician (CSPT) Program. To be eligible to apply, a technician must:

- Be a PTCB certified pharmacy technician (CPhT) in good standing; and
- Have completed either a PTCB-recognized sterile compounding education/training program and one year of continuous full-time compounded sterile preparation work experience, or three years of continuous full-time compounded sterile preparation work experience.

To earn CSPT Certification, eligible CPhTs are required to pass the CSPT Exam and submit competency attestation documentation from a qualified supervisor. The two-hour, 75-question CSPT Exam covers hazardous and nonhazardous compounded sterile products in the four domains of:

- Medications and components (17%);
- Facilities and equipment (22%);
- Sterile compounding procedures (53%); and
- Handling, packaging, storage, and disposal (8%).

The purpose of the Attestation Form is to document the candidate's completion of required training and certain skill and competency assessments in such areas as aseptic technique, equipment cleaning, and use of personal protective equipment. More details about the CSPT Program are available on PTCB's website at *www.ptcb.org.*

DEA Enables Mid-level Practitioners to Prescribe and Dispense Buprenorphine

In January 2018, DEA announced a deregulatory measure that will make it easier for residents of underserved areas to receive treatment for opioid addiction. Nurse practitioners and physician assistants can now become Drug Addiction Treatment Act-Waived qualifying practitioners, which gives them authority to prescribe and dispense the opioid maintenance drug buprenorphine from their offices. This final rule took effect January 22, 2018. More details about DEA's amendments are available in a Federal Register notice titled "Implementation of the Provision of the Comprehensive Addiction and Recovery Act of 2016 Relating to the Dispensing of Narcotic Drugs for Opioid Use Disorder" (Document Number: 2018-01173).

New CDC Training Offers CPE on Antibiotic Stewardship

The Centers for Disease Control and Prevention's (CDC's) Office of Antibiotic Stewardship is offering free continuing education opportunities for health care professionals. Focused on judicious antibiotic prescribing and antibiotic resistance, the online training is offered in four sections, each with multiple modules. Section 1 of the "CDC Training on Antibiotic Stewardship" is open now and can be accessed at *www.train.org/cdctrain/course/1075730/compilation.* Additional sections will be released throughout 2018. More information and resources about CDC's national effort to help fight antibiotic resistance and improve antibiotic prescribing and use are available on CDC's website at *www.cdc.gov/antibiotic-use/index.html.* CDC is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for 0.258 CEUs of CPE credit. The ACPE Universal Activity Number is 0387-0000-18-031-H05-P.

Walmart to Provide Free Solution to Dispose of Medications With Schedule II Prescriptions

In partnership with Walmart, DisposeRx will provide a safe and easy way to neutralize unused, unwanted, or expired prescription opioids. DisposeRx developed a powdered product, also called DisposeRx, that permanently dissolves when

mixed with water and sequesters excess opioids and other drugs in a stiff, biodegradable gel that can be safely thrown in the trash. Walmart will provide a free packet of DisposeRx with every new Schedule II prescription filled at its 4,700 pharmacies nationwide. "This partnership with DisposeRx is an exciting opportunity for Walmart to protect the safety of its customers and public health. Unwanted or expired prescription medications left inside consumers' medicine cabinets can be an easy source for those seeking to misuse or abuse a prescription drug," said Pharmacy Clinical Services Manager for WalMart Health and Wellness and NABP Past President Jeanne D. Waggener, RPh, DPh. "We're not just making it easy for patients to safely dispose of their medications, but we're also helping prevent abuse before it starts." Additional information is provided in a January 17, 2018 news release titled "Walmart Launches Groundbreaking Disposal Solution to Aid in Fight Against Opioid Abuse and Misuse."

ASHP Research and Education Foundation Predicts Trends to Affect Pharmacy in 2018

In the 2018 Pharmacy Forecast: Strategic Planning Advice for Pharmacy Departments in Hospitals and Health Systems, the American Society of Health-System Pharmacists (ASHP) Research and Education Foundation provides guidance on eight topics that will challenge pharmacy practice leaders in hospitals and health systems. Published in the January 15, 2018 issue of American Journal of Health-System Pharmacy, the new report focuses on the following areas:

- Therapeutic innovation;
- Data, analytics, and technology;
- Business of pharmacy;
- Pharmacy and health-system leadership;
- Advanced pharmacy technician roles;
- Population health management;
- Public health imperatives; and
- Coping with uncertainty and chaos.

The 2018 report is available at *www.ajhp.org/content/75/2/23.*

USP Encourages Pharmacists to Help Patients Find Quality Dietary Supplements

Recall announcements, enforcement actions, and reports challenging the quality of dietary supplements are problematic issues facing pharmacists who want to ensure that the over-the-counter (OTC) products they are recommending to patients are of good quality. Many consumers purchase OTC dietary supplements and herbal products, often assuming they are regulated like prescription medications. While the law requires pharmaceuticals to meet specific quality standards set by the United States Pharmacopeial Convention (USP), the same requirements do not apply to supplements. For this reason, USP has created quality standards and a verification process specifically for these health products. Brands displaying the USP Verified Mark signal to the public that "what's on their label is what's in the bottle." Health care practitioners can learn more about USP's efforts at *www.usp.org/dietary-supplements-herbal-medicines.*

Further,,USP Dietary Supplement Verification Services are available to manufacturers and brands worldwide. They include Good Manufacturing Practice facility auditing, product quality control and manufacturing product documentation review, and product testing. Manufacturers that are participating in USP's verification program for dietary supplements can be found at *www.usp.org/verification-services/program-participants.*

New CPE Monitor Subscription Service Makes Licensure Compliance Easier

To help pharmacists easily monitor their CPE compliance, NABP partnered with the Accreditation Council for Pharmacy Education (ACPE) to expand CPE Monitor® by offering a new subscription service. Users can keep their free, Standard version of CPE Monitor or upgrade to the Plus subscription plan. Launched in April 2018, the new Plus plan enables pharmacists to perform a variety of advanced functions beyond the Standard plan, including:

- Verifying how much CPE credit must be earned to satisfy renewal requirements;
- Receiving alerts when a license is nearing the end of a CPE cycle;
- Uploading non-ACPE credits to a licensee's e-Profile;
- Viewing consolidated transcripts for each state license;
- Connecting to My CPD, which allows licensees to maintain their continuing professional development (CPD) in one place; and
- Connecting to the Pharmacists' Learning Assistance Network, where licensees can easily search for ACPE-approved courses.

The Plus subscription is available for an annual, renewable fee of $29.95, regardless of how many licenses a pharmacist has or adds at a later date. It is only available via NABP's new mobile app. Search for NABP e-Profile in Google Play Store (Android) or the App Store (iPhone).

The Standard plan is still available for free and can also be accessed via the app or a desktop by signing in with NABP e-Profile login credentials.

For more information, visit *www.nabp.pharmacy/CPE.*

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their CPE credit electronically.

continued from page 1

missed the refill on verification. A month later, the patient was told that they did not have a refill on his medication. While waiting for a renewal, the patient ran out of medication, and as a result, suffered from a seizure that required medical attention. The pharmacist attributes the error to inadequate training of a new technician. The pharmacist recommends fully training pharmacy personnel prior to allowing them to enter prescriptions.

10. A 65-year-old female patient was prescribed ropinirole 1 mg tablets but was dispensed risperidone 1 mg tablets. After taking the medication for three days, the patient reported nausea and not feeling well to a visiting nurse. The prescribing physician was contacted and verified that the incorrect drug was dispensed. The pharmacist attributes the error to look-alike, sound-alike (LASA) medications located near each other. The pharmacist recommends relocating LASA medications so that they are not in close proximity and verifying the bottle that the drug is poured from immediately.

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.

Monitored Treatment Program

The Monitored Treatment Program (MTP) was established to confidentially assist health professionals who have problems that can cause or contribute to impairment; including substance-related disorders, psychiatric problems, behavioral problems, and physical disabilities. Participation in MTP can be mandatory as ordered by the Board. Participation in MTP can also be voluntary. MTP is the only program recognized by the Board to provide assessment, monitoring, reporting, and treatment planning services. Utilization of other treatment facilities or programs is not allowed. This is because those treatment facilities do not provide the monitoring and reporting services to the Board that are provided by MTP. Finally, pursuant to regulation 16.19.4.12, New Mexico Administrative Code (NMAC), any person who knows or suspects that a licensee is impaired, is required to report any relevant information either to the Impaired Pharmacist Program, which is MTP, or to the Board. Failure to report an impaired licensee is considered unprofessional, dishonorable conduct.

Biosimilar vs. Interchangeable

Did you know that biosimilar products are not necessarily interchangeable? Biological drugs are becoming more and more important in the modern health care system, however, the rules around substitution of these sometimes-costly medications can be murky. Food and Drug Administration (FDA) has a reference available on its website known as the "Purple Book." This contains a list of FDA-approved biological products and compares biosimilarity and/or interchangeability. Products that are denoted as interchangeable may be substituted for the reference product, at the pharmacy, without the intervention of the prescriber. Unless they are denoted as interchangeable, biosimilar products may not be substituted at the pharmacy level without prescriber permission. For more information, please refer to the FDA website.

Disciplinary Actions

Sandra Alvarez, CPhT – Licence PT-3069. Default revocation. During the April 2018 Board meeting, this license was revoked.

Richard Heise, DVM – License CS-21064. Voluntary surrender. During the June 2018 Board meeting, the Board accepted a voluntary surrender of this veterinarian's controlled substance (CS) license. The former licensee must pay an investigative cost of $100.

Andrew Ngo, Pharmacy Intern – License PT-9564 and IN-3543. Default revocation. During the April 2018 Board meeting, these licenses were revoked.

Tracy Overbay, RPh – License RP-6051. Voluntary surrender. During the June 2018 Board meeting, the Board accepted a voluntary surrender of this pharmacist's license. The former licensee must pay an investigative cost of $100.

Diego Reyes-Dzul, Pharmacy Intern – License IN-3685. Summary suspension. During the April 2018 Board meeting, this license was suspended due to noncompliance with a Board order.

Sylvia Tellez, CPhT – License PT-2310. Default revocation. During the April 2018 Board meeting, this license was revoked.

Reminders

- On July 27, 2018, the United States Pharmacopeial Convention (USP) released a proposed revision of USP Chapter <797> Pharmaceutical Compounding—Sterile Preparations. This is an update to the revision released in 2015. The latest revision is expected to be very close to what the chapter will look like starting December 1, 2019, when it becomes enforceable.
- A reminder from the National Transportation Safety Board (NTSB): The NTSB would like to remind all health care providers of the importance of routine patient counseling related to the possible effects of CS used to treat pain. It is important to convey how diagnosed medical conditions or recommended drugs may have an effect on a patient's ability to safely operate a vehicle in any mode of transportation. The requirements for pharmacist consultation can be found in regulation 16.19.4.16(F), NMAC.
- Epidiolex®, a cannabidiol oral solution, has recently been approved by FDA for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome. As of the time of writing, Drug Enforcement Administration is currently in the process of scheduling Epidiolex. The scheduling of Epidiolex applies only to the FDA-approved product.

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