



# New Mexico Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Significant Adverse Drug Events

1. A 10-year-old patient was prescribed intravenous ceftriaxone 1,450 mg/50 ml. Patient was dispensed the correct medication with incorrect diluent information on the label and the wrong infusion container. As a result, the medication was infused over 30 minutes instead of the required 60 minutes. Patient experienced an infusion-related flushing reaction. Failure to check the compounding record prior to compounding and preparing the medication during the end-of-day surge of prescriptions were identified as contributing factors to the error. Pharmacist recommends clarifying infusion times with the provider and implementing a minimum infusion time on all patients from the prescriber's clinic.
  2. A 51-year-old patient incorrectly received simvastatin 40 mg, mirtazapine 30 mg, lisinopril 5 mg, trazodone 50 mg, and omeprazole 40 mg. These medications were sold to the wrong patient with the same name. Patient did not report any adverse drug events. Pharmacist recommends verifying other identifiers before selling prescriptions to patients.
  3. A 20-year-old patient was prescribed clindamycin 300 mg but was dispensed hydrochlorothiazide 12.5 mg. Pharmacist on duty placed an incorrect patient's prescription into another patient's prescription bag. Patient reported nausea, vomiting, and dizziness. Pharmacist recommends slowing down, double-checking prescription labels, and only handling one prescription at a time.
  4. A 63-year-old patient was prescribed Percocet® 7.5/325 mg but was dispensed and mailed hydrocodone/acetaminophen 7.5/325 mg. The prescription was entered and filled by the same technician. Patient noticed the error and did not take the incorrect medication. Pharmacist recommends contacting the software company to propose new verification features and for Schedule II prescriptions to be processed only by pharmacists.
- However, if technicians are allowed to process Schedule II prescriptions in the future, pharmacist recommends technicians only be allowed to perform one task, either data entry or filling, but not both.
5. A middle-aged patient was prescribed omeprazole 20 mg but was dispensed topiramate 100 mg. Pharmacist who filled the prescription grabbed the wrong prescription vial from the robot/automated dispensing machine. Patient took four doses of the incorrect medication and reported dizziness and fatigue. Pharmacist recommends pharmacy staff use the robot scanner to scan prescription vial labels to ensure the correct prescriptions are selected.
  6. A 74-year-old patient was prescribed levofloxacin 750 mg with directions "1 tablet(s) by mouth 5 times a day." The pharmacist on duty overrode the drug utilization review (DUR) alert and dispensed the prescription to the patient as written. Patient experienced nausea and vomiting. Pharmacist stated that the DUR alert should have prevented the medication from being dispensed and sold to the patient.
  7. A 61-year-old patient experienced nausea, dizziness, increased heart rate, and hallucinations after taking a 1 mg Chantix® tablet. Patient was not prescribed Chantix. Patient picked up a refill for amlodipine 10 mg and the prescription vial contained two 1 mg Chantix tablets mixed in with amlodipine 10 mg tablets. Pharmacists open and pour out the contents of vials to visually inspect color, shape, and markings during final product verification. Pharmacist stated the error could have been overlooked if the vial was not opened at product verification.
- 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.

## **WHO Launches Global Patient Safety Challenge on Medication Safety**

To reduce severe, avoidable medication-associated harm in all countries by 50% over the next five years, the World Health Organization (WHO) has launched a worldwide initiative, the Global Patient Safety Challenge on Medication Safety. Medication errors cause at least one death every day and injure approximately 1.3 million people every year in the United States. In addition, low- and middle-income countries are estimated to have similar rates of medication-related adverse events as high-income countries.

The Global Patient Safety Challenge on Medication Safety aims to make improvements in each stage of the medication use process including prescribing, dispensing, administering, monitoring, and use. WHO intends to provide guidance and develop strategies, in addition to plans and tools to ensure that the medication process has the safety of patients at its core in all health care facilities.

Previous WHO Global Safety Challenges have included the Clean Care is Safer Care challenge on hand hygiene in 2005 and the Safe Surgery Saves Lives challenge in 2008. Additional information is available in the WHO press release available at <http://who.int/mediacentre/news/releases/2017/medication-related-errors/en>.

## **Continuous Quality Improvement and Patient Safety Organizations**

 *This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting [www.ismp.org](http://www.ismp.org). ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at [www.ismp.org](http://www.ismp.org). Email: [ismpinfo@ismp.org](mailto:ismpinfo@ismp.org).*

Data from the ISMP Medication Errors Reporting Program reveals that medication-related problems are repetitive in nature. An incident of misuse in one setting is likely to repeat itself in another. Most importantly, the system changes that are necessary to prevent errors are similar, and a growing body of literature is available to guide these efforts. Tragically, too many organizations and individual providers do not believe similar incidents could happen to them. They fail to use information about errors occurring elsewhere as a roadmap for improvement in their own organization or practice. It is not until a serious error hits home that aggressive prevention efforts are implemented. With so much evidence-based information about error prevention at hand, there is little excuse for reacting to errors after they happen instead of preventing them.

The development and implementation of continuous quality improvement (CQI) efforts should be the highest priority in all pharmacies. Such efforts must be aimed specifically at preventing

well-known and repetitive dispensing errors. Pharmacies should seek out medication safety information and use it proactively to prevent medication errors. At the same time, safety issues recognized internally and/or reported by patients should be documented and analyzed, with a process to determine the best strategies to prevent future problems and methods to ensure implementation. An annual survey to assess consumer perceptions of the quality of pharmaceutical products and professional services could supply additional information upon which to base improvement strategies. For more information on CQI programs, visit Section 7 of Model Rules for the Practice of Pharmacy in *The Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*.

Informational tools like the *ISMP Medication Safety Alert!* publication, or ISMP's *Quarterly Action Agenda*, which is a readily available list of medication problems compiled from the nation's reporting programs, can be a backbone of any CQI effort. The very purpose of the ISMP Medication Errors Reporting Program – indeed the purpose of any type of safety reporting program and the expert recommendations that stem from it – is to guide the implementation of quality improvement initiatives by practitioners and organizations.

It is important that certain information from the CQI proceedings and records of review be protected from discovery. Patient safety organizations (PSO) are organizations that share the goal of improving the quality and safety of health care delivery. Patient Safety Work Product (PSWP) is the information protected by the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule. PSOs serve as independent, external experts who can collect, analyze, and aggregate PSWP locally, regionally, and nationally to develop insights into the underlying causes of patient safety events, thus improving quality by identifying and reducing the risks and hazards associated with patient care. Communications with PSOs are protected to allay fears of increased risk of liability because of collection and analysis of patient safety events.

For more information on PSOs, visit <https://www.pso.ahrq.gov/faq>.

## **NCPDP Releases Guide to Ensure Patients Get Their Medications During a Disaster**

The National Council for Prescription Drug Programs (NCPDP) released the *NCPDP Emergency Preparedness Information* guide to assist pharmacists and other health care providers during a declared emergency. Prepared by the NCPDP Emergency Preparedness Committee, the guide provides resource information for eligibility and claims processing affecting displaced individuals. The guide is available at [www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation\\_v1\\_4.pdf](http://www.ncdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf). Additional information for pharmacists about emergency preparedness is available on the NCPDP website at [www.ncdp.org/Resources/Emergency-Preparedness](http://www.ncdp.org/Resources/Emergency-Preparedness).

## **FDA Warns of Illnesses and Deaths in Pets Exposed to Fluorouracil**

Food and Drug Administration (FDA) is alerting pharmacists that patients' pets are at risk of illness and death when exposed to the topical cancer medication fluorouracil cream USP 5% (5-FU) that is intended for use in people. Fluorouracil may also be marketed under the brand names Carac®, Efudex®, and

News to a particular state or jurisdiction can only be ascertained  
such state or jurisdiction.

Fluoroplex®. Very small amounts could be dangerous to household pets; thus, patients should use care when applying and storing the medication. FDA has received reports of five dogs that became ill and died after accidentally ingesting the topical cream, notes a Center for Veterinary Medicine Update available at [www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm](http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm537434.htm).

Although FDA has not received any reports involving cats to date, cats are also expected to be extremely sensitive to fluorouracil cream. For instance, if an owner applies fluorouracil cream to an afflicted area and touches his or her cat, the cat may accidentally ingest the medication when grooming itself and suffer adverse events.

FDA advises that pharmacists who fill these prescriptions should advise patients with pets to prevent exposing their pet to the medication. Adverse events may be reported to FDA using the Form FDA 1932a, which may be obtained at [www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm](http://www.fda.gov/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm).

### **FDA Revises Final Guidance Documents on Bulk Drug Substances Used in Compounding**

In January 2017, FDA issued revised versions of two final guidance documents regarding the use of bulk drug substances in compounding.

- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act
- ◆ Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act

FDA clarified that the policies described in the guidances do not apply to inactive ingredients. Inactive ingredients are not included in the definition of a “bulk drug substance” and can be used in compounding without appearing on the bulk drug substances lists developed under sections 503A or 503B of the Federal Food, Drug, and Cosmetic Act, if all applicable conditions are met.

As indicated on its website at [www.fda.gov/Drugs/DrugSafety/ucm502075.htm](http://www.fda.gov/Drugs/DrugSafety/ucm502075.htm), FDA will also provide regular updates to the categories of bulk drug substances described in the guidances. FDA previously stated that it would not evaluate new nominations for placement in one of the three categories until after it completed its review of substances already nominated with adequate supporting information.

Now, the guidances state that FDA will determine after submissions are received whether new nominations, including renominations of substances with additional supporting information, have sufficient information for FDA to review them. After making that determination, FDA will place nominated substances in the appropriate category on FDA’s website. FDA intends to update the categories with any new nominations the first business day of each month. This revised policy will further minimize unnecessary disruptions to patient treatment while FDA develops the lists of bulk drug substances for use in compounding.

The guidances are available online at [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf) and [www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469122.pdf).

### **APhA Resource Guide Applies JCPP Pharmacists’ Patient Care Process to Immunization Services**

The American Pharmacists Association (APhA) published a resource guide that applies the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists’ Patient Care Process to pharmacy-based immunization services. The components of the Pharmacists’ Patient Care Process to collect, assess, plan, implement, and follow-up should be implemented as routine practice along with the National Vaccine Advisory Committee Standards for Adult Immunization Practice, as noted in the resource guide, *Applying the Pharmacists’ Patient Care Process to Immunization Services*. “[P]armacists and other vaccine providers need to strive to constantly improve collaboration, communication, and documentation,” indicates the APhA guide. For more information, visit the APhA Immunization Center at [www.pharmacist.com/immunization-center](http://www.pharmacist.com/immunization-center).

### **CPE Training on Older Adult Fall Prevention Available Online**

Developed in collaboration with the Centers for Disease Control and Prevention (CDC) and the APhA, the Stopping Elderly Accidents, Deaths, and Injuries (STEADI) initiative is offering continuing pharmacy education (CPE) training for pharmacists to prevent falls in adults 65 and older. The training will provide strategies to help pharmacists screen older adults for fall risk, conduct medication review and management, and offer patient education. To participate in the free online training, “STEADI: The Pharmacist’s Role in Older Adult Fall Prevention,” visit the CDC website at [www.cdc.gov/steadi/training.html](http://www.cdc.gov/steadi/training.html) for more information.

### **New FDA Drug Info Rounds Training Video Addresses the Combat Methamphetamine Epidemic Act**

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, “Combat Methamphetamine Epidemic Act,” pharmacists discuss the legal requirements for the sale of over-the-counter drug products that contain pseudoephedrine. Drug Info Rounds was developed with contributions from pharmacists in FDA’s Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at [www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm](http://www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm).

### **FDA Presents Series of CE Webinars for Students and Clinicians**

FDA’s Division of Drug Information in the CDER presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA’s role in medication error prevention and prescription drug labeling. The webinars and presentation slides can be accessed on FDA’s website at [www.fda.gov/DDIWebinars](http://www.fda.gov/DDIWebinars).

## **To Transfer or Not to Transfer**

The Board has received multiple calls regarding transferring controlled substance (CS) prescription information. The following is reprinted with permission from the National Association of Boards of Pharmacy® (NABP®). Drug Enforcement Administration (DEA) provided the information to NABP as part of a partnership through the Controlled Substances Stakeholder Coalition.

The Controlled Substances Act and its implementing regulations outline what can take place regarding prescriptions for controlled substances. In Title 21, Code of Federal Regulations, Section 1306.25 the DEA made a specific exception so that a DEA registered pharmacy can, once it has filled an original prescription for a controlled substance in Schedules III-V, transfer the original prescription information to another DEA registered pharmacy for the purpose of allowing that second pharmacy to then dispense any remaining valid refills still permitted by law and the prescriber's authorization. With one exception, such an allowance currently does not exist for the forwarding of an unfilled prescription from one DEA registered retail pharmacy so that it may be filled at another DEA registered retail pharmacy.

Prescriptions can take the form of paper (including fax), call-in, or electronic prescription for controlled substances (EPCS). The DEA has addressed the forwarding of an EPCS prescription. The DEA published information in the preamble of the notice of proposed rulemaking (NPRM) on EPCS, 73 FR 36722, and the preamble of the interim final rule (IFR) on EPCS, 75 FR 16235. Note, because this was in the preamble and not in the EPCS regulations, it represents the DEA's policy. As posted in the preambles of the NPRM and the IFR, an unfilled original EPCS prescription can be forwarded from one DEA registered retail pharmacy to another DEA registered retail pharmacy, and this includes Schedule II controlled substances.

## **From DEA**

Albuquerque, NM, has been selected as the seventh pilot city to be part of DEA's comprehensive law enforcement and prevention "360 Strategy" to help cities dealing with the heroin and prescription opioid abuse epidemic and crime associated with drug trafficking and abuse.

DEA's 360 Strategy responds to the heroin and prescription opioid epidemic with an innovative, three-pronged approach to combating heroin and opioid use through: (1) coordinated law enforcement action targeting all levels of drug trafficking organizations; (2) engaging drug manufacturers, practitioners, and pharmacists to increase awareness of the opioid epidemic and encourage responsible prescribing practices throughout the medical community; and (3) community outreach and partnerships to equip and empower communities to fight the opioid epidemic.

The second component of DEA's 360 Strategy involves collaboration with health care providers and health organizations to facilitate discussions and develop solutions to prevent prescription opioid abuse, which continues to drive our nation's devastating heroin epidemic. National studies reveal that 80% of all new heroin users started their addictions with prescription painkillers, and national statistics show that more than 35,000 people die every year as the result of heroin or prescription opioid overdoses. The 360 Strategy focuses on preventing pharmaceutical drug diversion by providing education and training within the medical and pharmaceutical community.

## **Thank You**

The Board wishes to congratulate Cynthia McCormick on her recent retirement. Cynthia worked for the Board for over 30 years as a financial specialist. The Board appreciates Cynthia's hard work and dedication and wishes her the best in all her future endeavors.

The Board would also like to thank Shelley Bagwell. Shelley served as the prescription monitoring program (PMP) director. Under Shelley's watch, the PMP continued to improve. Shelley was instrumental in the Board's transition to the PMP AWA<sub>R</sub>x<sub>E</sub> platform, which is hosted by Appriss, Inc. Moving to Appriss significantly reduced downtimes and increased speed of report generation. The Board would like to thank Shelley for her service and support to our New Mexico PMP constituents. The recently launched Emergency Department Information Exchange (EDIE) is a result of Shelley's work. EDIE will allow providers to quickly assess patients' needs as they arrive in emergency departments.

## **Disciplinary Actions**

**Colin Forde, DDS – License CS-217014.** Board accepted order of respondent's voluntary surrender of his CS license. Must pay investigation costs of \$100.

**Tanya Loretto, PT – License PT-5178.** Board accepted voluntary surrender of pharmacy technician license. Must pay investigative costs of \$100.

**Andrei Marchenko, CNP – License CS-216396.** Board accepted order of respondent's voluntary surrender of his CS license. Must pay investigative costs of \$100.

**Christopher Trujillo, RPh – License RP-7033.** Board reinstated pharmacist license. Respondent must continue with Monitored Treatment Program (MTP) contract. Must provide proof of continuing education. Must take and pass the Multistate Pharmacy Jurisprudence Examination®. Must fully comply with conditions of probation involving a criminal case and immediately notify the Board of any material change in terms and conditions of the case.

## **Regulation Changes**

During the June 2017 Board meeting, Regulation 16.19.8 New Mexico Administrative Code was repealed and replaced. This regulation, titled Wholesale Prescription Drug

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Distribution, was repealed and replaced to allow New Mexico to be compliant with the federal law enacted by United States Congress. The Drug Quality and Security Act (DQSA) was enacted by Congress on November 27, 2013. Title II of DQSA, the Drug Supply Chain Security Act (DSCSA), outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the US. This will enhance Food and Drug Administration's (FDA's) ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful. The system will also improve detection and removal of potentially dangerous drugs from the drug supply chain to protect US consumers. The DSCSA directs FDA to establish national licensure standards for wholesale distributors and third-party logistics providers, and requires these entities to report licensure and other information to FDA annually. In addition, to comply, the Board created third-party logistics providers as a new classification of licensure. To review this completely revised regulation, please visit the Board website.

### **Reminders**

- ◆ By regulation, an impaired licensee must be reported to the Impaired Pharmacist Program or referred to the Board. The Board-approved program is MTP. Failure to report an impaired pharmacist or refer to MTP is considered unprofessional or dishonorable conduct.

- ◆ United States Pharmacopeia General Chapter <800> will become effective and enforceable in July 2018. If you compound sterile and nonsterile products using hazardous drugs, you must be in compliance. To determine if you are in compliance, visit <http://800gaptool.com>.
- ◆ Information regarding naloxone is available on the Board website under the Forms and Applications tab. This will provide you with the standing order prescription you need to dispense naloxone to any New Mexico citizen.
- ◆ The next Board meeting is scheduled for Monday and Tuesday, October 23-24, 2017. The agenda must be posted at least 72 hours prior to the beginning of the meeting. Meetings are open to the public.

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