September 2020

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 38-year-old female patient requested that a pharmacy provide her with four vaccines: Tdap, HEP-B, MMR, varicella, and a TB test. The pharmacy recommended that all live vaccines and TB test be given the same day, so the patient returned two days later due to lack of funds. In the meantime, the pharmacy determined that Tdap was not necessary since the patient had received it approximately four years prior; however, Tdap was administered to the patient with all other requested vaccines. The patient reported arm pain, general malaise, and an urgent care visit after the immunization. The pharmacist attributes the error to inadequate diligence in double-checking vaccine necessity according to the available patient record. The pharmacist recommends adding a double check with the patient of the requested vaccination immediately prior to administration.
2. A 31-year-old female patient received gabapentin 800 mg in place of ibuprofen 800 mg. After taking the wrong medication for an unspecified amount of time, the patient reported that she had a seizure and was seen in the emergency room. The pharmacist reported that a new technician manually filled the prescription, which would normally have been filled by the robot system, and did not document the different National Drug Code for the pharmacist to check. The pharmacist failed to notice the mistake on final check. The pharmacist recommends retraining and coaching the technician to follow filling procedures.
3. A 42-year-old male patient received 750 mcg Belbuca® films instead of the 75 mcg films that were prescribed. After taking two doses, the patient reported feeling drunk, and the error was discovered during a televisit with his prescriber. The pharmacist attributes the error to lack of notification by the computer system for an irregular dose, and the faxed image that made the data harder to read. The pharmacist recommends having internal alerts for drugs that have multiple doses with high variance in mcg or mg strength.
4. A 77-year-old male patient received generic Augmentin® 500 mg tablets in place of amoxicillin 500 mg tablets, to be taken four times daily. The patient reported an upset stomach and vomiting after taking four doses. The pharmacist attributes the error to multiple look-alike, sound-alike medications in the computer during data entry. The pharmacist recommends reviewing data entry and data review procedures with all staff.
5. A 66-year-old male patient reported receiving spironolactone 50 mg instead of the expected 25 mg tablets. After taking the medication for 14 days, the patient reported weight gain. The error was discovered at the time of refill. The pharmacist attributes the error to not immediately putting away stock bottles after use in filling prescriptions. The pharmacist recommends a procedure of immediately putting away a stock bottle after use to reduce the risk of filling a prescription with the wrong medication.
6. A 48-year-old female patient received chlorthalidone 25 mg tablets in place of chlordiazepoxide 25 mg capsules. A second prescription for chlordiazepoxide was filled correctly several months later. The patient reported feeling dizzy and tired with both medications. The pharmacist attributed the error to look-alike, sound-alike drug names and recommended that both technicians and reviewing pharmacists watch these medications closely.
7. A 45-year-old male patient received lamotrigine 25 tablets that were intended for someone else. After taking the medication for approximately one month, the patient reported pain in his abdominal area that required a physician visit. According to the pharmacist, the lamotrigine was bagged with multiple other prescriptions that were correctly filled and labeled for

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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 Releases MOU on Human Drug Compounding Regulation and Oversight

Acknowledging the vital role states play in reducing the risks associated with compounded drugs, Food and Drug Administration (FDA) has made available a Final Standard Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products, intended to be entered into between the agency and the states. The release of the MOU is required as part of its submission to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1995. The MOU was developed in close consultation with the National Association of Boards of Pharmacy® (NABP®), as described in the Federal Food, Drug, and Cosmetic Act. The agency also engaged with states, pharmacies, associations, pharmacists, and other stakeholders.

Among the issues addressed in the MOU is the definition of the statutory term "inordinate amounts," which refers to compounded drugs that are distributed interstate. In addition, the MOU includes the risk-based oversight model from the 2018 revised draft MOU. States that sign the document agree to identify pharmacy compounders that distribute inordinate amounts (greater than 50%) of compounded drug products interstate, as well as report certain information to FDA about those compounders. FDA also provided clarity in the MOU on state investigations of complaints associated with compounded drugs distributed out of state. States that enter into the MOU will investigate complaints about drugs compounded at a pharmacy within their state and distributed outside of the state and advise FDA when they receive reports of serious adverse drug experiences or serious product quality issues, like drug contamination.

To help states to better investigate these issues, FDA has also announced an agreement with NABP to make an information sharing network available to the states. Through this network, states will be able to obtain information from pharmacies in their states and transmit that information to FDA.

"We anticipate the final MOU, once signed, will help to facilitate increased collaboration between the FDA and the states that sign it," said Janet Woodcock, MD, Director, Center for Drug Evaluation and Research, in an FDA Voices article. "Working together, we can help promote quality compounding practices and better address emerging public health concerns that may affect patients."

FDA Clarifies Compounding Rules, Offers Flexibility to Help Ease Drug Shortages During COVID-19 Pandemic

FDA noted it will use discretion in enforcing certain standards related to 503A and 503B compounding in an effort to ease drug shortages during the coronavirus disease 2019 (COVID-19) pandemic. During an American Pharmacists Association (APhA) webinar on April 30, 2020, the agency clarified it will "look to 503B compounders to grapple with drug shortages" and "turn to 503A compounders to fill in the gaps."

In addition, the agency clarified that medications on the FDA drug shortage list are effectively considered "not commercially available," which frees 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. FDA also does not intend to take action if a 503A facility fills orders for a compounded drug that is essentially a copy of an approved drug that has been discontinued and is no longer marketed.

In April 2020, FDA issued a temporary guidance that granted flexibility for pharmacists to compound certain necessary medications under 503A for nonspecific patients hospitalized due to COVID-19. In addition, a temporary guidance was issued that granted enforcement flexibility for 503B outsourcing compounding facilities for drugs in shortage for patients hospitalized during the COVID-19 public health emergency. The guidance documents stipulate the conditions compounders must meet and are available at *https://www.fda.gov/media/137125/download.*

More information on these compounding rule clarifications is available in a May 5, 2020 press release on the APhA website.

CMS Allows Pharmacies to Temporarily Enroll as Clinical Diagnostic Laboratories for COVID-19 Testing

Centers for Medicare & Medicaid Services (CMS) has released a document detailing a process that allows pharmacies to temporarily enroll as independent clinical diagnostic laboratories. This process will allow those

facilities to seek Medicare reimbursement for COVID-19 tests, making it easier for them to provide that service during the pandemic.

"Up until this point in time, most pharmacies could only offer this as a cash service because they were not considered providers through CMS, and really a lot of the third-party payers really didn't have an interest in a fee-for-service type model," said Michael E. Klepser, PharmD, FCCP, pharmacy professor at Ferris State University, in an interview with *Bloomberg Law.* "The fact that CMS is saying we're now authorizing or allowing pharmacists to get reimbursed for these is a great door opening at the federal level and that's a huge, huge thing."

Chain pharmacies such as CVS, Walgreens, and Rite Aid are offering drive-through testing at many pharmacies throughout the country.

FDA Issues Updated Guidance for Compounding Pharmacies Experiencing PPE Shortages

FDA has issued an update for its guidance to pharmacy compounders that may experience shortages of personal protective equipment (PPE) during the COVID-19 pandemic. As compounders typically utilize PPE when performing sterile compounding, the updated guidance clarifies that the drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom. This policy has been adopted to ensure patients continue to have access to medicines they need during the pandemic, and to reduce the risks of compounding when standard PPE is not available.

In addition to FDA guidance, United States Pharmacopeial Convention has previously issued an informational document for compounders regarding garb and PPE shortages during the pandemic. The document includes recommendations for conserving garb and PPE and what steps might be considered in the case of shortages of garb and PPE used for both sterile and nonsterile compounding.

The updated guidance can be accessed through FDA's website by visiting *www.fda.gov/media/136841/download.*

HHS Expands Telehealth Access in Response to COVID-19

In an effort to prevent and respond to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) has awarded $20 million to increase telehealth access and infrastructure for health care providers and families. The funds, which are awarded through the Health Resources and Services Administration (HRSA), will increase capability; capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents, and families; and assist telehealth providers with cross-state licensure.

"This new funding will help expand telehealth infrastructure that is already being used during the pandemic to provide essential care, especially to the most vulnerable, including pregnant women and children with special health care needs," said HHS Secretary Alex Azar in a press release. "This funding will also help clinicians use telehealth nationally by streamlining the process to obtain multi-state licensure."

HRSA's Maternal and Child Health Bureau awarded a total of $15 million to four recipients; each award supports a key area in maternal and child health, including pediatric care, maternal health care, state public health systems, and family engagement for children with special health care needs. HRSA's Federal Office of Rural Health Policy awarded a total of $5 million to two recipients through the Licensure Portability Grant Program, which will assist telehealth clinicians nationally on licensure and credentialing to meet emerging needs related to COVID-19.

Criminals Found Posing as CDC Representatives to Steal Money and Information

Centers for Disease Control and Prevention (CDC) is warning the general public of a new type of phone and phishing scam by criminals posing as CDC representatives, often requesting donations. According to CDC, most of these fraudulent activities are being conducted by phone, utilizing software to "spoof" phone calls to make them appear as if they are coming from phone numbers that may look familiar. CDC advises consumers to avoid answering calls from numbers they do not recognize, and to avoid sharing personal information over the phone. In addition, CDC notes that no federal agency will request donations from the general public. Suspicious phone calls may be reported to the Federal Communications Commission.

More information on the scams is available on the CDC website at *https://www.cdc.gov/media/phishing.html.*

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the patient. At the point of sale, patient information was only verified off the foremost leaflet, which was correct. As a result of the dispensing error, the pharmacist contacted his software vendor to change how name and date of birth appear on labeling to make it more easily identifiable and recognizable at the point of sale.

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.

Fifty-Year Pharmacists

The following is the current list of pharmacists who have been licensed by the state of New Mexico for at least 50 years and who also maintain an active license. The Board thanks you for your service and dedication to the profession of pharmacy and the citizens of New Mexico.

This year there are three newcomers to this distinguished list. They are Richard Haverland, Allan Ludwick, and Robert Roybal. Thank you for all you do.

Jerry Beeman	Nick H. Brown
Wilfred O. Chavez	Grace Colvin
Kenneth L. Corazza	Drexel Douglas
George E. Downs	Majed T. Faruki
Arturo Figueroa	Robert Ghattas
Ronald Jack Glenn	Richard Gomez
Edwin Gonzales	Richard A. Haverland
John A. Heaton	John Huffmyer
Lowell M. Irby	Dale L. Kemper
William J. Long	Allan Ludwick
Lewis Dale McCleskey	Daniel M. Pearce
Larry D. Quintana	Robert Roybal

Counseling as a Veiled Offer

All new prescription drug orders require a pharmacist or pharmacist intern to personally offer to counsel on that will enhance or optimize drug therapy with each patient or the patient's agent. According to the Institute for Safe Medication Practices (ISMP), current counseling rates are only at 8-42%. In New Mexico, approximately one in 12 errors reported to the Board are medications that went to the incorrect patient. Simply asking, "do you have any questions?" may not be an effective offer of counseling, as patients may not know what to ask. In addition, using a show-and-tell as part of the patient offer to counsel (eg, this is your levothyroxine for your thyroid), is recommended both for patient understanding and to catch wrong patient errors. Please keep the following in mind regarding patient counseling:

- The offer of counseling on a new prescription must come from a pharmacist or pharmacist intern.
- A patient may not know what questions to ask or what relevant information is needed regarding a medication.
- A patient may feel like they do not want to bother a visibly busy pharmacist; however, it is your responsibility as a pharmacist to create a counseling session if needed.
- It is good practice, and an ISMP recommendation, to make the patient a participant in the counseling session. As a pharmacist, have the patient tell you basic necessary information (eg, this is your lisinopril; so I can best give you information, would you please tell me how you take it and what for?). You are there to help fill in any gaps or reiterate important information.
- Please open the vial and show the patient the medication at the point of sale. This is a means by which a counseling session can be initiated, and is a good way to prevent errors – including wrong patient errors – from leaving the pharmacy.

Remember, patient counseling is a requirement, and is important for patient safety. For counseling requirements, please see 16.19.4.16 New Mexico Administrative Code (NMAC).

Naturopathic Doctor, Prescriptive Authority

The Board promulgated regulations regarding the scope of practice for naturopathic doctors, 16.10.22.11 NMAC, which became effective in March 2020. After passing a pharmacy examination authorized by the rules of the Board of Medicine, naturopathic doctors may prescribe, administer, dispense, and order the following:

- All legend drugs; and
- Controlled substances (CS) in Schedules III, IV, and V of the New Mexico Controlled Substances Act (including testosterone products), **excluding** all benzodiazepines, opioids, and opioid derivatives.

The naturopathic doctor scope of practice **does not include** Schedule II CS.

For more information, please refer to 16.10.22 NMAC.

Reminder: PMP Utilization Requirements

Prescription monitoring program (PMP) report review alone **does not** fulfill the medical record review

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requirement of consultant pharmacists in certain settings, including clinics. Medical record review is comprised of, but not limited to: ". . . eliminating unnecessary drugs, and establishing the medical necessity of drug therapy, by identifying over-utilization or under-utilization, therapeutic duplication, drug-disease contraindications, drug-drug contraindications, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, appropriate medication indication, and/or clinical abuse/misuse." While PMP review may be a part of medical record review, it does not encompass the entirety of the requirement. Consultant pharmacists are reminded to conduct medical record reviews that meet the requirement of the regulation, which may include PMP report review.

For more information, refer to 16.19.4.11 NMAC and 16.19.4.16 NMAC.

Disciplinary Actions

Michael Toon – RP00004915. Settlement agreement. Respondent agrees to pay a fine and cost of investigation in the amount of $1,200 and provide evidence of successful continuing education (CE) completion.

Monument Pharmacy – PH00003835. Settlement agreement. Respondent agrees to pay a fine and cost of investigation in the amount of $1,500 and must fully comply with relevant statutes and regulations while licensed in New Mexico.

Claudia Marechal – RP00006344. Settlement agreement. Respondent agrees to pay a fine and cost of investigation in the amount of $1,100 and provide evidence of successful CE completion.

David Elliott – CS00005724. Voluntary surrender of CS registration.

Arlene Brown – CS00007020. Voluntary surrender of CS registration.

Howard Schwartz – CS00209132. Voluntary surrender of CS registration.

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

Upcoming Law Updates

- Upcoming pharmacy law lecture dates are as follows:
  - **Friday, September 4, 2020**
    Webinar. Registration closes on September 2
  - **Friday, October 2, 2020**
    Board Office
    Albuquerque, NM
  - **Friday, November 6, 2020**
    Board Office
    Albuquerque
  - **Tuesday, November 17, 2020**
    Carlsbad Medical Center
    Carlsbad, NM
  - **Tuesday, December 1, 2020**
    MountainView Regional Medical Center
    Las Cruces, NM
  - **Wednesday, December 2, 2020**
    Memorial Medical Center
    Las Cruces
  - **Friday, December 4, 2020**
    Board Office
    Albuquerque

Because of the coronavirus disease 2019 restrictions, some of the law update reviews have been given in webinar format. The most up-to-date information on review format and 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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