



# New Mexico Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## **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 New Mexico Board of Pharmacy thanks you for your service and dedication to the profession of pharmacy and the citizens of New Mexico.

This year we have seven newcomers to this distinguished list. They are Jerry Beeman, Wilfred O. Chavez, Drexel Douglas, Edwin Gonzales, Lewis Dale McCleskey, Daniel M. Pearce, and Larry D. Quintana. Thank you for all you do.

Jerry Beeman	Nick H. Brown
Wilfred O. Chavez	Grace Colvin
Kenneth L. Corazza	Drexel Douglas
George E. Downs	Lawrence N. Etherton
Majed T. Faruki	Arturo Figueroa
Robert Ghattas	Ronal Jack Glenn
Richard Gomez	Edwin Gonzales
John A. Heaton	John Huffmyer
Lowell M. Irby	Dale L. Kemper
William J. Long	Lewis Dale McCleskey
Joseph Mengoni	Philip A. Parkhurst
Daniel M. Pearce	Larry D. Quintana

## **Significant Adverse Drug Events**

1. A 57-year-old female patient on duloxetine 30 mg was given medication for a different patient, primidone 50 mg. The patient reported taking one dose before feeling nauseous and drowsy. The error was discovered when the patient reported her symptoms to the pharmacist the next day. The pharmacist attributes the error to two

different pharmacists performing product review at the same time and switching the patient's vials/medication leaflets. The pharmacist-in-charge (PIC) recommends opening the bag when counseling to prevent similar future errors from leaving the pharmacy. As a corrective action, the PIC will only allow one pharmacist to do data verification and another to do bagging at any given time.

2. A 57-year-old male patient with a history of depression attempted to pick up his prescription for paroxetine 20 mg at a retail pharmacy. During the filling process, a technician scanned the correct bottle for filling, but filled the vial with quetiapine 200 mg tablets. After taking the incorrect medication for an undisclosed period of time, the patient required admission to the emergency room due to disorientation and slurred speech. The PIC stated that the verifying pharmacist had recently performed the final check on a quetiapine prescription, and may have had the previous prescription in mind when verifying the incorrect medication. The PIC recommends immediately returning stock bottles after filling, no more than one associate filling at a station at any given time, and having the pharmacist cancel out of the verification screen and start over if interrupted for any reason.
3. A 24-year-old female patient was prescribed Macrobid<sup>®</sup> for a urinary tract infection. During the sale of the medication, the technician updated insurance information and relabeled the incorrect bag, which was not given to the pharmacist for reverification. Prometrium<sup>®</sup> 200 mg was dispensed to the patient, of which six doses were taken. The patient reported cramping as a result of taking the incorrect medication. The PIC attributes the error to a break in procedure on the part of the technician. The PIC recommends retraining that all updates made to a verified prescription must go through the pharmacist for reverification.

*continued on page 4*

# National Pharmacy Compliance News

December 2019



**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.

## **USP Postpones Official Dates of USP General Chapters Revisions and Additions**

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- ◆ [General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations](#)
- ◆ [General Chapter <797> Pharmaceutical Compounding – Sterile Preparations](#)
- ◆ [General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging](#)

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of [Chapters <795> and <797>](#), including the section "Radiopharmaceuticals as CSPs," will remain official, according to a [notice](#) posted to the USP website.

Revisions to USP [General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings](#) are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

## **FDA Issues Statement on Compounded Bulk Drug Substances Ruling**

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the

agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

## **HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs**

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- ◆ **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- ◆ **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at <https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf>.

## **Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates**

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and

Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- ◆ Past-year abuse of psychotherapeutics decreased from 6.6 from 6.2%.
- ◆ Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- ◆ Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- ◆ Past-year abuse of opioids decreased from 4.2% to 3.7%.

“This year’s National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances,” said HHS Secretary Alex Azar. “At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz.”

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at <https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH>.

### **Additional Efforts Needed to Improve Naloxone Access, CDC Says**

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

“Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of

opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships,” the report states in its conclusion. “Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic.”

The Vital Signs report can be accessed at [www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm](http://www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm).

### **Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products**

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- ◆ Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA’s MedWatch Adverse Event Reporting program.

### **Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey**

The National Association of Boards of Pharmacy<sup>®</sup> (NABP<sup>®</sup>) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination<sup>®</sup> (NAPLEX<sup>®</sup>) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination “blueprint,” are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.



*continued from page 1*

**Disclaimer:** These suggestions are made by the pharmacist submitting the Significant Adverse Drug Event Report. The Board may not necessarily agree with these suggestions.

### **Regulation Updates**

- ◆ **16.19.5 New Mexico Administrative Code (NMAC) – Internship Training Program:** Section 7 has been amended in such a manner that the 30-semester hour requirement for licensure as a pharmacy intern has been removed. Instead, a student will now be eligible for licensure after satisfactory completion of all first semester courses. This will allow for more patient care training with the targeted outcome of better trained pharmacists.
- ◆ **16.19.12 NMAC – Fees:** Sections 1, 2, 3, 9, 13, 16, 17, 19, and 20 have been amended. Changes include administrative updates; board contact information; statutory authority; decreased pharmacy technician registration fee; waiver of registration fees for military service members and spouses for change of duty location to New Mexico; and increased fee for nonresident pharmacies that dispense compounded sterile preparations into New Mexico. The waiver of fees for military service members and spouses was implemented to minimize barriers to licensure and employment. The increased fee for nonresident sterile compounding pharmacies was implemented to offset the additional work necessary for screening applications.

### **Disciplinary Actions**

- Daniel Sheets – License PT7975.** Voluntary surrender of license. Licensee must be evaluated by the Monitored Treatment Program (MTP) prior to reapplication.
- Walgreens – License PH4507 and License PH4346.** Settlement agreement. Licensees must submit an action plan addressing the accuracy of remotely verified electronic prescriptions. Licensees must also pay a fine of \$1,000 and the cost of investigation in the amount of \$112.50.
- Diego Reyes-Dzul – License IN3685.** Default revocation of intern license. Due to violations of the Controlled Substances Act.
- Richard Brower – License RP4085.** Settlement agreement. Three-year probation period. The licensee must implement a computer verification procedure that requires pharmacist verification, final check, and documentation. The licensee must also pay a fine of \$1,000 and the cost of investigation in the amount of \$525.

**Vanessa Victorino – technician applicant.** Default denial of technician application. Due to violations of the Pharmacy Act.

**Bridget Silva – License PT9755.** Settlement agreement. Licensee agrees to revocation of her expired technician registration. May not reapply for a period of 10 years.

**Keo Vongvichith – License RP6698.** Settlement agreement. The licensee must complete continuing education (CE) in the field of medication error prevention. The licensee must also pay a fine of \$1,000 and the cost of investigation in the amount of \$300.

**Ahmad Zamanian – License RP5362.** Settlement agreement. The licensee must pay the cost of investigation in the amount of \$300. He must complete five-year MTP contract. He must have MTP clearance before returning to work. Licensee cannot serve as a PIC, preceptor, worksite monitor, or consultant pharmacist for one year.

**B. Tom White – License RP3712.** Settlement agreement. Must take and pass Multistate Pharmacy Jurisprudence Examination<sup>®</sup>. Probation for five years. During this time, may not act as a preceptor. Licensee must pay a fine of \$5,000 plus the cost of investigation in the amount of \$3,200 and the cost of hearing, which is still to be determined.

**Jerri Velasquez – technician applicant.** Default denial of technician application. Due to violations of the Pharmacy Act.

**Cory Esquibel – technician applicant.** Default denial of technician application. Due to violations of the Pharmacy Act.

**Angela Dagit – License RP8544.** Voluntary surrender. The former licensee must pay the cost of investigation in the amount of \$325.

**Phillip Meili and EZ Pharmacy – License PT12179, License PH4614.** Settlement agreement. Terms include voluntary revocation of licenses, and may not reapply for 10 years.

**Deborah Harris – License PT12122.** Voluntary surrender of technician registration.

**Kelly Kemper – License RP5290.** Decision and order. Ten years probation. Must enroll in MTP. Licensee must pay a fine of \$3,000 plus the cost of hearing in the amount of \$931.77, and cost of investigation in the amount of \$125.

**Donald Hathaway, CNP – License CS17139.** Voluntary surrender of controlled substance registration.

**Kimberlie Shofner – License PT11546.** Settlement agreement. Former licensee agreed to relinquish her

*continued on page 5*

*continued from page 4*

technician registration and will not reapply for a period of no less than 15 years.

**Marley Drug – License PH3921.** Settlement agreement. Licensee must pay a fine of \$100 for each violation, totaling \$1,900. The licensee must also pay the cost of investigation in the amount of \$450.

### **Reminders**

Upcoming pharmacy law lecture dates are as follows:

◆ **December 4, 2019**

Mountain View Regional Medical Center  
Las Cruces

◆ **December 6, 2019**

Board office  
Albuquerque, NM

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

### **Adverse Drug Event Reporting**

- ◆ 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.

### **CE Requirements**

- ◆ Pharmacists, be sure that you are completing 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 and safe/appropriate use of opioid requirements can be combined if a CE course is appropriate to cover 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.

### **2020 Board Meeting Dates**

- ◆ Thursday, January 16 to Friday, January 17, 2020
- ◆ Thursday, April 16 to Friday, April 17, 2020
- ◆ Thursday, July 23 to Friday, July 24, 2020
- ◆ Thursday, October 22 to Friday, October 23, 2020

The list of Board meeting dates can be found on the Board's website.

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Page 5 – December 2019

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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