December 2018

# New Mexico Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## New Board Member

Joe Anderson, PharmD, PhC, BCPS, served two complete terms as a New Mexico Board of Pharmacy member and served as the Central District representative. As a Board member, Joe served on the Board's pharmacy practice committee. He was a staunch advocate for pharmacy students and pharmacy education in the state of New Mexico. Joe will continue to serve the public as a cardiovascular pharmacotherapy clinician.

Replacing Joe as the Central District representative is Lewis Dale McCleskey, RPh. Lewis brings to the Board more than 40 years of pharmacy experience across multiple pharmaceutical platforms. The Board would like to welcome Lewis and the vast practical experience he brings to the Board.

The current makeup of the Board is:

- Richard Mazzoni, RPh, Northeast District, Board Chaiman
- Chris Woodul, RPh, Southwest District,Vice Chairman
- William "Bill" Lord, RPh, Hospital Representative
- Lewis Dale McCleskey, RPh, Central District
- Neal Dungan, RPh, Southeast District, Secretary
- Teri Rolan, RPh, Northwest District
- Michael Garringer, Public Member
- Cathleen Wingert, Public Member
- Gwen Griscom, Public Member

## 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 four newcomers to this distinguished list. They are: George Elgrably, Majed T. Faruki, Dale L. Kemper, and Paul F. Tunell. Thank you for all you do.

| | |
|---|---|
| Nick H. Brown | John A. Heaton |
| Grace Colvin | John Huffmyer |
| Kenneth L. Corazza | Lowell M. Irby |
| George E. Downs | Dale L. Kemper |
| George Elgrably | William J. Long |
| Lawrence N. Etherton | Joseph Mengoni |
| J. Ronald Ewing | Edward A. Osborne |
| Majed T. Faruki | Philip A. Parkhurst |
| Arturo Figueroa | Robert T. Shmaeff |
| Kenneth L. Fourcher | Raymond C. Sierks |
| John (Chris) C. Gallegos | Larry W. Sparks |
| Robert Ghattas | Paul F. Tunell |
| Ronald Jack Glenn | Johnny S. Volpato |
| Richard Gomez | |

## Significant Adverse Drug Events

1. A 72-year-old male patient was prescribed thyroid (pork) 90 mg, but was given levothyroxine/liothyronine 90 mg at the point of sale. The dispensing error was not noticed until the subsequent fill. After taking the medication for approximately one month, the patient complained of indigestion and drowsiness. The pharmacist attributes the error to a lack of focus and recommends familiarizing staff with all the different forms of thyroid medications stocked in the pharmacy.
2. A 30-year-old female patient was prescribed Xarelto® for deep vein thrombosis prophylaxis. A pharmacy technician sold the patient a prescription for Remeron® intended for a patient with the same first and last name. After taking one dose, the patient was admitted to the hospital for treatment of moodiness and suicidal ideation. The pharmacist attributes the error to inattention on the part of the technician due to a death in the family. The pharmacist recommends adding a middle initial to all duplicate names as company policy so that techni-

*continued on page 4*

# National Pharmacy Compliance News

**December 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.


## SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

## FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

## EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

## US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

## Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

## Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

## Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

*continued from page 1*

cians may more easily identify names that belong to multiple patients.

3. A three-year-old female patient was prescribed topiramate XR 25 mg sprinkle capsules but was given topiramate 25 mg sprinkle capsules at the point of sale. The original fill and all refills were dispensed to the patient before the error was noticed. During this time, the patient's seizures were not adequately controlled, according to the patient's mother. The pharmacist recommends using an indicator in the computer system to differentiate look-alike, sound-alike medications.
4. An 80-year-old male patient reported that he was hospitalized due to a fall that occurred as a result of taking Tikosyn® and ciprofloxacin together. The dispensing pharmacist failed to identify the drug utilization review (DUR) interaction when prompted by the computer system having thought the patient had used ciprofloxacin in the past while on Tikosyn. The pharmacist recommends that DUR blocks be put into place to prevent overriding severe drug-drug interaction until a complete profile review has occurred.
5. A 32-year-old female patient experienced mild diarrhea when she was dispensed metformin immediate release tablets in place of metformin extended release tablets. The pharmacist attributes the dispensing error to the morning rush and improper verification habits. The pharmacist recommends having the filling technician precheck the prescription after the data entry technician types it into the computer system.
6. A 35-year-old female patient was prescribed Navane® but was given generic Norvasc® in its place. The pharmacist identified the medication as Norvasc to the data entry technician who had difficulty reading the name of the medication. The patient attempted to commit suicide, possibly as a result of not having the correct medication available. The pharmacist attributes the error to not following policies regarding having a double check on all aspects of a prescription. The pharmacist recommends adhering to the policy of double checking prescriptions and contacting the physician when any aspect of the prescription is unclear during the initial check or double check.

**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.

## Regulation Changes

The following regulations have been amended:

- **16.19.29 New Mexico Administrative Code (NMAC) – Controlled Substance (CS) Prescription Monitoring Program:** Amendments were added to clarify the objective, add an audit trail definition and disclosure, clarify data submission reporting requirements, and clarify authorized users.

  Statutory Authority: Paragraphs 1 and 2 of Subsection A of Section 61-11-6, 30-31-3, 30-31-11 New Mexico Statutes Annotated (NMSA) 1978.
- **16.19.27.7 NMAC – Dishonorable Conduct:** An amendment was added to protect the health and safety of patients in New Mexico by prohibiting the solicitation of prescription business via preselected medications on prescription blanks or via prescription requests not initiated by the patient or practitioner.

  Statutory Authority: Paragraphs 1 and 12 of Subsection A of Section 61-11-6 NMSA 1978.
- **16.19.4.9 NMAC – Pharmacist:** An amendment was added to protect the health and safety of patients in New Mexico by prohibiting the solicitation of prescription business via preselected medications on prescription blanks or via prescription requests not initiated by the patient or practitioner.

  Statutory Authority: Paragraphs 1 and 12 of Subsection A of Section 61-11-6, 30-31-3, 30-31-11 NMSA 1978.

As of September 28, 2018, Drug Enforcement Administration has moved Epidiolex® to Schedule V. Epidiolex is a Food and Drug Administration-approved cannabidiol oral solution used to treat Dravet syndrome and Lennox-Gastaut syndrome.

## Disciplinary Actions

**Elizabeth Palmer, MD – License CS0017723.** Voluntary surrender. During the October 2018 Board meeting, the Board accepted a voluntary surrender of this physician's CS license. The former licensee must pay an investigative cost of $100.

**Carlos Mascarenas, CPhT – License PT00006058.** Stipulated agreement. Violation of Impaired Healthcare Provider Act. Licensee will complete a five-year contract with the Monitored Treatment Program (MTP) and will obtain MTP clearance before returning to work.

**Hobert Sharpton, DO – License CS00226097.** Stipulated agreement. In May 2018, the respondent entered into a stipulated agreement with the Alabama State Board of Medical Examiners (ASBME). During the June 2018 meeting, the New Mexico Board of Pharmacy granted a CS license to the respondent with stipulations and restrictions similar to those assigned by ASBME in May 2018.

*continued on page 5*

*continued from page 4*

**Rolando Tong, MD – License CS00208178.** Voluntary surrender. During the August 2018 Board meeting, the Board accepted the voluntary surrender of this physician's CS registration. The former licensee must pay the cost of investigation and disciplinary proceedings in the amount of $674.27.

**David Wales, RPh – License RP00006592.** Settlement agreement. During the August 2018 Board meeting, the licensee entered into a settlement agreement with the Board. The licensee must complete a five-year contract with MTP and must obtain MTP clearance before returning to work. The licensee must also pay the cost of the investigation and hearing, which amounts to $729.02.

## *2019 Pharmacy Law Update Schedule: Albuquerque*

Please contact the Board at 505/222-9830 to reserve your space for a Board-sponsored law update. The Board's law updates for the Albuquerque, NM area will be held at the Board office. Updates will be held in the morning from 9 AM to 11 AM and in the afternoon from 2 PM to 4 PM. If you wish to attend a pharmacy law update that is sponsored by the New Mexico Pharmacists Association (NMPhA) or the New Mexico Society of Health-System Pharmacists (NMSHP), please contact the organization directly to reserve a space. Please note that the dates and times for the NMPhA or NMSHP sponsored law updates vary.

To ensure you receive a certificate and the required credit for your live pharmacy law continuing education, please email or call the Board at 505/222-9830.

The dates of the Albuquerque-area law updates for 2019 are as follows:

- January 4, 2019
- February 1, 2019
- March 1, 2019
- April 5, 2019
- May 3, 2019
- June 7, 2019
- July 12, 2019
- August 2, 2019
- September 6, 2019
- October 4, 2019
- November 1, 2019
- December 6, 2019

## *2019 Pharmacy Law Update Schedule: Other New Mexico Areas*

Please contact the Board at 505/222-9830 to register and reserve your spot. Board-sponsored pharmacy law updates will be held on Tuesdays from 7 PM to 9 PM. **The only exceptions** are the reviews on July 10, 2019, and December 4, 2019, which will be held on Wednesdays. Additionally, the July 10 review will be held from 1 PM to 3 PM.

The following out-of-Albuquerque law updates are scheduled for 2019:

- **February 12, 2019**
  Eastern New Mexico University
  Roswell Occupational Technology Center
  Roswell, NM 88203
- **March 5, 2019**
  Carver Library – Ingram Room
  7th Main St
  Clovis, NM 88101
- **May 7, 2019**
  San Juan College
  Information Technology Building Room 7103
  4601 College Blvd
  Farmington, NM 87401
- **July 10, 2019**
  Toney Anaya Building – Rio Grande Room
  2550 Cerrillos Rd
  Santa Fe, NM 87504
- **September 10, 2019**
  Holy Cross Hospital
  1397 Weimer Rd
  Taos, NM 87571
- **October 8, 2019**
  Alta Vista Regional Hospital
  109 Legion Dr
  Las Vegas, NM 87701
- **November 5, 2019**
  Lea Regional Medical Center
  5419 N Lovington Hwy
  Hobbs, NM 88240
- **December 3, 2019**
  Memorial Medical Center
  2450 S Telshor Blvd
  Las Cruces, NM 88011
- **December 4, 2019**
  Mountain View Regional Medical Center
  4311 E Lohman Ave
  Las Cruces, NM 88011



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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