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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 40-year-old female patient was given buprenorphine/naloxone 8/2 mg in place of brand-name Suboxone® that was written as a Dispense as Written-2 prescription. The patient reported that the generic form did not work as well for her as the brand name, and reported going without medication for a period of three days. According to the pharmacist-in-charge (PIC), the pharmacist on duty typed in the prescription for the generic form of the medication and proceeded to fill and perform the final check. The PIC recommends following protocol by allowing technicians to type and fill medications, and having the pharmacist perform the final check.
2. An approximately one-year-old male patient was prescribed a 10-day supply of amoxicillin-clavulanate suspension for an infection. When dispensed, the medication was reconstituted with too little water. The patient's mother returned to the pharmacy after five days, stating that she was out of medication and the error was noted at that time. After taking the incorrectly mixed medication, the patient experienced an upset stomach and diarrhea. According to the pharmacist, the medication was mixed by a non-certified technician who may not have been familiar with how to properly reconstitute medications. The pharmacist recommended all technicians be shown how to properly reconstitute medication, whether certified or not, as part of their initial training.
3. A 42-year-old male patient received lamotrigine 25 mg tablets that were intended for another patient. According to the pharmacist, the cashier failed to properly identify the patient by date of birth. The pharmacist was unable to make contact with the patient or the provider to verify the type of harm that occurred. As a result of the error, the pharmacist has changed how the date of birth appears on the patient leaflets (large print and highlighted).
4. A 27-year-old female patient received amiodarone 200 mg in place of APAP/codeine 300/30 mg. A second patient received APAP/codeine 300/30 in place of amiodarone 200 mg. The incorrect APAP/codeine was discovered immediately with no doses taken. Three doses of the incorrectly dispensed amiodarone were taken before the patient was made aware of the error. After taking the amiodarone for 48 hours, the patient had to follow up with her prescriber regarding adverse effects; none of which were reported to the pharmacy. The pharmacist attributes the error to a break in protocol and believes the bottles were switched after barcode verification in a dispensing robot. The pharmacist recommends only allowing one technician to work on the robot per shift and allowing fewer baskets to be staged at the robot station.

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.

Regulation Updates

- **16.19.6 New Mexico Administrative Code (NMAC) – Pharmacies: Sections 23 and 24; Amendment to Section 23 –** allows the transfer of an original, unfilled non-controlled substance (CS) prescription. Record-keeping requirements are specified, and transfer or forwarding of CS prescriptions is clarified for consistency with federal law. Amendment allowing prescription adaptation in filling a new non-CS prescription, to change the quantity, dosage, dosage form, or directions for use if it meets the intent of the prescriber, or to complete missing information; Amendment to Section 24 – a nonresident pharmacy application not successfully completed within 12 months of date received by the Board will be considered withdrawn, requiring a nonresident pharmacy as a condition of licensure to submit the procedure for ensuring proper medication storage conditions until the medication is delivered to the patient.
- **16.19.12 NMAC – Fees: Sections 12, 13, and 20; Amendment to Section 12 –** The Board may issue a CS registration for a time period determined by the Board and shorter than three years if it is consistent with the public health and safety; Amendment to Section

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National Pharmacy Compliance News

December 2020

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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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13 – increase fees from $700 to $1,000 biennially for manufacturer, wholesale drug distributor, manufacturer/repackager, repackager, and third-party logistics provider. The increased fee is due to the increased complexity and requirements of licensing associated with the Drug Supply Chain and Security Act; Amendment to Section 20 – limit CS registration delinquent renewal fees to $180.

- **16.19.20 NMAC – Controlled Substances: Sections 10, 42, and 69; Amendment to Section 10 –** reference 16.19.12 NMAC for CS registration fee, rather than duplicating language; Amendment to Section 42 – requiring electronic prescribing of CS (EPCS) prescriptions effective April 1, 2021, and specifying exceptions. EPCS is an important tool in improving the safety and quality of patient care, to protect the public via reduction of medication errors, prescription forgery, and CS diversion. Amendment to Section 69 – deschedule a drug product approved for marketing by Food and Drug Administration and which contains cannabidiol derived from cannabis and no more than 0.1% tetrahydrocannabinols.
- **16.19.30 NMAC – Compounding of Non-sterile Pharmaceuticals: Amendment to Section 9** – allows a licensed pharmacy to compound nonsterile, non-CS preparations in reasonable quantities for veterinarian office use. The office use preparation may be dispensed by a veterinarian for a patient under specific conditions, which include: the patient has an emergency condition that the compounded drug is necessary to treat, and timely access to a compounding pharmacy is not available. Up to a five-day supply can be dispensed for use in a single course of treatment.

Qualified Technician Childhood and COVID-19 Vaccine Administration and Testing

On October 30, 2020, the Board issued the **Qualified Pharmacy Technician Childhood and COVID-19 Vaccine Administration and COVID-19 Testing document,** allowing a qualified pharmacy technician under the direct supervision of a qualified pharmacist to administer Advisory Committee on Immunization Practices-recommended childhood vaccinations for ages three through 18, and coronavirus disease 2019 (COVID-19) vaccines for ages three or older. There is an additional allowance for influenza vaccine administration (age three and up). A qualified pharmacy technician may also administer COVID-19 tests. Requirements are outlined in the document. There is no change to pharmacist prescriptive authority pursuant to 16.19.26 NMAC, including age groups (eg, pharmacist vaccination is not limited to age three and up). The document is available in the FAQs section of the Board's website.

Disciplinary Actions

Angela Dagit – RP00008544. Reinstatement of pharmacist license. Respondent surrendered license on October 21, 2019, pending Monitored Treatment Program (MTP) evaluation. Respondent's license was reinstated with the following stipulations: 1) must receive MTP clearance before returning to work; 2) must complete a five-year contract with MTP; 3) must not act as PIC for one year; 4) must notify the Board and MTP within 30 days if respondent moves to another state where she will work; 5) must notify potential employers of the existence and terms of the agreement.

Buckland Pharmacy/Richard Brower – PH00001124, RP00004085. Settlement agreement. Respondents entered into a settlement agreement. Respondents agreed to the following stipulations: 1) pay a fine in the amount of $5,000 within six months; 2) license probation for a period of five years; 3) must complete 18 hours of continuing pharmacy education in the area of medication error prevention within 90 days; 4) conduct an Institute for Safe Medication Practices self-assessment and implement identified improvements; 5) submit a corrective action plan to the Board regarding proper training and supervision of all activities performed, in addition to error prevention, within 90 days.

Joe's Pharmacy – CS00207724. Voluntary surrender of CS registration. The Board accepted the surrender of this facility's CS registration.

Jesus Maholly, Jr – Pharmacy Technician Applicant. Settlement agreement. Respondent's technician application was denied. Respondent agreed not to reapply for licensure or registration with the Board, and will not engage in activity requiring Board licensure or registration.

Denver Palmer – CS00226219. Voluntary surrender of CS registration. The Board accepted the surrender of this respondent's CS registration. Respondent must pay an investigative cost of $100 within 90 days.

Walgreens Co #10808 – PH00004093. Settlement agreement. Respondent agreed to pay a fine of $4,000 within 90 days. Respondent also agreed to submission of a corrective action plan within 90 days, subject to approval by the Board's executive director.

New Mexico PMP Gateway Integration

The Board is integrating the prescription monitoring program (PMP) system into eligible health care software systems across the state. The goal is to increase PMP utilization for both prescribers of CS and pharmacists ("providers") by providing seamless access to a patient's queried PMP report. The Board currently contracts with Appriss Health for integration services, which provides a proprietary solution called PMP Gateway to integrate PMP data within a provider's workflow. Health care entities in New Mexico that employ providers who are legally authorized to prescribe, administer, or dispense CS prescriptions are eligible to apply for this integration. The

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Board, in collaboration with the New Mexico Department of Health, through federal grant funds, purchased a one-year subscription to PMP Gateway for health care entities that successfully integrate before August 31, 2021. The one-year paid subscription for a health care entity begins the date PMP Gateway integration is approved by the Board (on or before August 30, 2021). This is the second year that the Board has secured funding for PMP Gateway integration. Please note that the availability of funding after this subscription period is not guaranteed. Should the funding end after the one-year paid subscription, the licensee has the option to renew the agreement, and would be responsible for all associated fees to continue the service. More information on how to start the integration process can be found at *info.apprisshealth.com/nmgatewayintegrationrequest.*

2021 Board Meeting Dates

- Thursday, January 21 to Friday, January 22, 2021
- Thursday, April 22 to Friday, April 23, 2021
- Thursday, July 22 to Friday, July 23, 2021
- Thursday, October 21 to Friday, October 22, 2021

Meetings begin at 9 am unless otherwise noted. Each meeting agenda will be posted on the Board website at least 72 hours in advance. Additional information and the list of Board meeting dates can be found on the Board's website.

2021 Law Update Schedule

- Upcoming Albuquerque Pharmacy Law Lecture Dates:
  - January 8, 2021
  - February 5, 2021
  - March 5, 2021
  - April 2, 2021
  - May 7, 2021
  - June 4, 2021
  - July 9, 2021
  - August 6, 2021
  - September 10, 2021
  - October 1, 2021
  - November 5, 2021
  - December 3, 2021
- Upcoming Pharmacy Law Lecture Dates (Outside of Albuquerque):
  - **March 3, 2021**
    Gila Regional Medical Center
    Silver City, NM
  - **March 18, 2021**
    San Juan College (Tentative location due to COVID-19)
    Farmington, NM
  - **June 22, 2021**
    Toney Anaya Building
    Rio Grande Room
    Santa Fe, NM
  - **August 31, 2021**
    Eastern New Mexico University, Roswell
    Occupational Technology Center
    Room 20
    Roswell, NM
  - **September 14, 2021**
    Blackwater Coffee Co
    Clovis, NM
  - **September 28, 2021**
    Holy Cross Hospital
    Taos, NM
  - **October 26, 2021**
    Alta Vista Regional Hospital
    Las Vegas, NM
  - **November 16, 2021**
    Lea Regional Medical Center
    Hobbs, NM
  - **November 29, 2021**
    MountainView Regional Medical Center
    Las Cruces, NM
  - **November 30, 2021**
    Memorial Medical Center
    Las Cruces

Because of COVID-19 restrictions, some of the law update reviews may be held as webinars. 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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