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# New Mexico Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

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## The Board Is Hiring – Have You Seen Larry?

Because neither has the New Mexico Board of Pharmacy staff. Larry Loring retired December 31, 2014, after being the Board's executive director. Larry worked for the Board for 24 years. During that time, Larry was instrumental in the development of the New Mexico Prescription Monitoring Program (PMP). As a result, New Mexico is no longer number one in overdose deaths. If you see Larry, thank him for a job well done. Replacing Larry as executive director is Ben Kesner.

There are currently two open state drug inspector positions available. By the time this *Newsletter* is published, the positions should be posted. If interested, you must apply through the New Mexico State Personnel Office. A link to the job position offer will be placed on the Board's home page.

## Flu Shot Renewal

Pharmacists who exercise their right to prescribe vaccines under the Pharmacist Prescriptive Authority Act must receive additional continuing education more than that required of a pharmacist who does not wish to participate. The regulation states: "Any pharmacist exercising prescriptive authority for vaccines shall complete a minimum of 0.2 CEU of live ACPE approved vaccine related continuing education every two years." Because your pharmacist registration must be renewed every two years, as long as you receive the two additional hours each renewal period, you are in compliance. Failure to complete the additional hours during a renewal period will result in your having to complete the initial training again if you wish to continue to vaccinate.

## Significant Adverse Drug Events

1. A 34-year-old female was prescribed hydralazine 10 mg, but was dispensed hydralazine 100 mg. After taking the first dose, the patient became very lethargic and dizzy, so she called to question the dose. Pharmacist recommends watching for similar sounding drugs with multiple strengths.
2. A nursing home patient was prescribed warfarin 1 mg with instructions to take 4½ tablets (4.5 mg) daily, and was dispensed warfarin 5 mg with the same instructions. The patient experienced a gastrointestinal bleed and was transported to the hospital for treatment. Pharmacist recommends including total dose on the prescription label and having pharmacists only verify orders that they did not enter themselves.
3. A 49-year-old female with a history of depression was prescribed escitalopram 20 mg daily, but was dispensed escitalopram 10 mg daily. After taking 33 doses of the incorrect strength, the patient noticed the error on the bottle. She did report an increase in depressive symptoms. Pharmacist recommends counseling patient on drug name and strength at checkout, and not overriding barcode scanning of stock bottles during the filling process.
4. A 38-year-old female with a history of hypertension, asthma, and hypothyroidism was prescribed metoprolol ER 25 mg every evening, and was dispensed metoprolol ER 200 mg every evening. The error was caught by the pharmacist on the third refill. The patient did not report experiencing any adverse effects. Pharmacist indicated that the pharmacy got rushed and staff was involved in too many things. No recommendations for improvement were provided.
5. A 37-year-old female with mild depression was prescribed paroxetine 30 mg and was dispensed another patient's prescription instead. The patient noticed the error and did not take any of the medication. Pharmacist indicated that the pharmacy clerk was in a hurry to leave for the day. Pharmacist recommends verifying date of birth, address, phone number, and all necessary demographics before checking out the patient.
6. A 58-year-old female with menopausal symptoms was prescribed an unnamed medication and received a different patient's medications. The patient was contacted before any incorrect medications were taken. Pharmacist recommends ensuring medications are bagged correctly after patient consultation.
7. A 49-year-old female was prescribed imipramine 50 mg daily and was dispensed another patient's medication, medroxyprogesterone 10 mg daily. Patient complained of nausea and vomiting and had to miss a day of work after taking one dose. Pharmacist recommends verifying name, address, telephone, and date of birth prior to dispensing.

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## DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.*

## System-Based Causes of Vaccine Errors

*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. *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. *Email: ismpinfo@ismp.org.*

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter *(www.ismp.org/sc?id=307),* ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

**Practice Recommendations.** Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
5) Preparing and administering the vaccine immediately after verification, and
6) Documenting the vaccine on the patient's medical record.

## FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous

review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm*.

## PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at *www.ptcb.org*.

## Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at *http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full.*

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at *www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf*. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access. Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at *www.njconsumeraffairs.gov/press/05012013.pdf.*

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, *www.rxpatrol.com*, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

## Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.*

## Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc, of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm412431.htm*.

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8. A 65-year-old male was prescribed lamotrigine 100 mg #450 and was dispensed lamotrigine 100 mg #390 and lamotrigine 150 mg #60. Patient stated the only side effect he experienced was dizziness. Pharmacist recommends scan verifying all stock bottles against the prescription label and spacing bottles on shelf to prevent confusion between strengths. Also visually check every stock bottle pulled from the shelf before pouring into amber vial, and visually check dispensed drug when dispensing large quantities.
9. A 71-year-old female with a history of anxiety was prescribed Ativan® 0.5 mg and was dispensed alprazolam 0.5 mg. The patient did not experience any adverse effects, and the error was caught when a refill was requested from the prescriber. Pharmacist recommends paying attention to the right medication, the right patient, and the right dose prior to dispensing. Also endorses the use of bins to keep prescriptions separate and that the pharmacist concentrate on one patient's prescriptions at a time.
10. Six inpatients of various age, gender, and diagnoses were prescribed hydrocodone/acetaminophen 5/325 mg and received oxycodone/acetaminophen 5/325 mg due to a packaging error. The two drugs involved were temporarily not available in manufacturer unit-dose packaging. No adverse events were reported as a result. Pharmacist recommends using tall man lettering and adding trade name, when appropriate, to unit-dose labeling.
11. A 55-year-old female patient was prescribed oxycodone 10 mg and was dispensed oxycodone 20 mg. She reported feeling sick to her stomach, and noticed the error after taking five doses. Pharmacist recommends double-checking all prescriptions before filling and counseling patients with drug name, dose, and instructions.
12. A 61-year-old female with an acute respiratory infection was prescribed Levaquin® 500 mg once daily, and was dispensed levetiracetam 500 mg once daily. The patient reported continuing symptoms of infection and feeling very tired, and her daughter brought her to the emergency room due to difficulty breathing. The patient ingested only one tablet of levetiracetam and other than drowsiness, the attending physician felt that the one wrong tablet contributed to no other problems. Pharmacist recommends spacing look-alike/sound-alike drugs on the shelves to prevent confusion. In this case, the levetiracetam was moved to a new location under the brand name Keppra®.
13. A 91-year-old female experienced numbness and tingling in both hands, both arms, and up to her shoulders after receiving Fluarix® Quadrivalent PFS. Before administering the vaccine, the pharmacist verified that the patient had received the flu shot before and did not want the high-dose vaccine. The patient did not report any pain immediately after the vaccine was given. Two weeks later, the patient called and reported numbness and tingling in her arms. The patient's primary care doctor was consulted, and said it was a side effect of the flu vaccine.

**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.

## Board Members

Please welcome Cathleen Wingert. Cathleen has been appointed by Governor Susana Martinez as a public member to the Board. Cathleen replaces Allen Carrier. Allen served on the Board for two full terms. During that time, he was involved in many aspects of the profession of pharmacy. The Board members and staff would like to thank Allen for his service and all he has done to better the profession of pharmacy.

The current list of Board members is as follows:

- Danny Cross, RPh, Southeast District, Board Chairperson
- Amy Buesing, RPh, Hospital Representative, Board Vice Chairperson
- LuGina Mendez-Harper, RPh, Northwest District, Secretary
- Joe R. Anderson, RPh, Central District
- Richard B. Mazzoni, RPh, Northeast District
- Buffie Saavedra, Public Member
- Cathleen Wingert, Public Member
- Chris Woodul, RPh, Southwest District
- Anise Yarbrough, Public Member

## Hydrocodone-Containing Products

Hydrocodone-containing products have gone through two recent changes. Change number one is that the amount of acetaminophen in the brand name tablets has been reduced. Change number two is that these products are now a Schedule II controlled substance (CS). Most generics that are available have different strengths of acetaminophen, but a pharmacist may contact the practitioner to verify a strength change. A pharmacist may not call the practitioner to change the medication, such as hydrocodone to morphine. In this case, the Schedule II drug, hydrocodone, does not change. You do not need to send the patient back to the practitioner to receive a new handwritten prescription.

## Pharmacy Technicians

Please remember that pharmacy technicians must be registered with the Board prior to working as a pharmacy technician. After registering, the pharmacy technician has one year to become certified. Failure to become certified within one year will cause the technician to not be able to renew his or her registration unless he or she is enrolled in a Board-recognized technician training program. Numerous pharmacy technicians have been allowed to work after their registration has expired. Allowing this may result in disciplinary action against the supervising pharmacist and the pharmacist-in-charge (PIC).

## Prescription Monitoring Program

Public hearing of proposed changes to 16.19.29 NMAC (the rule affecting the PMP) took place during the January 2015 Board meeting. This was a substantial rewrite of the rule and involved changes to the required reporting of data to the PMP, disclosure of such data, registration for access to the program, as well as a multitude of language and clarification edits. Most importantly for pharmacies and pharmacists is the change requiring CS prescription data to be reported to the PMP **within one business day** of a prescription being filled. Also specified in the regulation is the requirement that corrections to information submitted to the PMP be addressed. This includes: (1) File upload or "Outstanding Uncorrected Errors" as defined in the *PMP Data Reporting Manual;* (2) Prescriptions that were not dispensed to the patient must be voided from the PMP; and (3) Incorrect information in prescription records submitted to the PMP must be corrected as soon as

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possible after the dispenser has been notified. The rule also refers to the *PMP Data Reporting Manual* as the reference for data requested to be reported as well as the required format. The most current version of this manual can always be found at *http://nmpmp.org* under PMP Resources. The changes are scheduled to go into effect in March. Two other changes will be addressed in the near future. Clarification of required data fields will be added to 16.19.29 NMAC, and the data reporting format will move to American Society for Automation in Pharmacy 4.2 format. For more information, contact the PMP director at nm.pmp@state.nm.us.

The January Board meeting also saw the presentation of the second set of cases for action by the Board regarding failure and/or delinquency in reporting to the PMP. Dispensers have been required to report the filling of CS prescriptions since the inception of the program in July 2005. Compliance with this reporting has been more strictly monitored by the PMP director. For the past year, courtesy emails have been sent as reminders to those delinquent in reporting. The Board decided that those dispensers delinquent three or more times within six months should be presented as cases. In October, the first set of these cases was presented. It is important to remember that while dispensers may receive reminders of their failure and/or delinquency in reporting, these are merely a courtesy. Dispensers are required to know of and be compliant with reporting to the PMP or be subject to similar action by the Board.

## *Getting the Right Practitioner*

The Board received a call from a practitioner who had discovered numerous fraudulent prescriptions filled using his credentials. Upon investigation, the practitioner's former place of employment had continued using the same prescription pads from when the practitioner worked there. The pads still had his name on them. Pharmacy personnel had chosen an incorrect practitioner when filling the prescriptions. The prescriptions were later verified as legitimate. To avoid problems, please select the correct practitioner when filling a prescription.

## *Regulation Changes*

In addition to the PMP change discussed in a separate article on pages 4-5 of this *Newsletter,* during the January Board meeting, the Board made four additional regulation changes. These changes are discussed briefly below. To view the regulations in their entirety, please visit the Board's web page.

### 16.19.36 NMAC – Compounded Sterile Preparations

Scope expanded to include any licensee who might handle sterile products. Changed objective to reflect United States Pharmacopeia – National Formulary General Chapters numbered below 1,000. Term "batching" added to definitions from United States Pharmacopeia Chapter <795>. Documentation required was updated to reflect that records must be kept for three years. Training requirements updated to include more site-specific control and freedom for institutions and PICs.

### 16.19.5 NMAC – Internship Training Program

Registration as an intern allowed after the completion of 30 semester hours in a college of pharmacy curriculum or its equivalent.

### 16.19.6.23.D(5) NMAC – Prescriptions

A pharmacy may not refuse to transfer original prescription information to another pharmacy that is acting on behalf of a patient.

### 16.19.12 NMAC – Fees

Registration as an intern and intern renewal changed to $25 per year.

## *Disciplinary Actions*

**American Specialty Pharmacy – License PH-3437.** Respondent admits to being delinquent in reporting CS prescription information to the PMP. Respondent's New Mexico nonresident pharmacy license shall be on probationary status for a period of six months. Respondent shall pay $100 fine.

**California Pharmacy & Compounding – License PH-3136.** Respondent admits to being delinquent in reporting CS prescription information to the PMP. Respondent's New Mexico nonresident pharmacy license shall be on probationary status for a period of six months. Respondent shall pay $100 fine.

**Martin Fritsch, PT – License PT-3097.** The Board will reinstate respondent's pharmacy technician registration after receiving an application and take no further action provided that respondent agrees to be an active participant in the New Mexico Monitored Treatment Program until successfully completing.

**Healthy Options, Inc, dba Postal Prescriptions – License PH-1994.** Respondent admits to being delinquent in reporting CS prescription information to the PMP. Respondent's New Mexico nonresident pharmacy license shall be on probationary status for a period of six months. Respondent shall pay $100 fine.

**Brittney Keiter, PT – License PT-9125.** Respondent voluntarily surrendered her registration as a pharmacy technician.

**Michael's Prescription Corner – License PH-2509.** Respondent admits to being delinquent in reporting CS prescription information to the PMP. Respondent's New Mexico resident pharmacy license shall be on probationary status for a period of six months. Respondent shall pay $100 fine.

**Lea Van Wart, PT – License PT-6804.** On November 18, 2014, the Board received a signed Voluntary Surrender of Pharmacy Technician form from registrant. At this time, respondent admitted to knowingly filling forged prescriptions. Must pay investigative costs in the amount of $1,000.

## *Reminder*

Tramadol is considered to be an opiate. Please remember this when accepting a new therapy for a telephoned prescription. The maximum allowed to be telephoned in as a new therapy is 10 days.



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