March 2014

New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

5200 Oakland Ave NE, Suite A • Albuquerque, NM 87113 • Tel: 505/222-9830 • Fax: 505/222-9845
In-State Only Toll Free: 1-800/565-9102 • *www.rld.state.nm.us/boards/Pharmacy.aspx*

Significant Adverse Drug Events

1. An 88-year-old female was prescribed 12 mcg fentanyl patch but it was dispensed as 25 mcg fentanyl patch. The patient complained of unwanted side effects such as sweatiness, agitation, and respiratory depression. The pharmacist did not catch the error and the nurse who applied the patch did not catch the error. The pharmacy will be more diligent when verifying prescriptions.
2. A pharmacy had two patients waiting to receive vaccinations. One patient was to receive Zostavax® and the other was to get a Tdap vaccination. The Zostavax was mistakenly diluted with the Tdap solution instead of the Zostavax diluent. The pharmacist called both manufacturers. The pharmacist was informed that since Tdap had no preservatives, that the Zostavax should not be affected. The pharmacist contacted the Centers for Disease Control and Prevention (CDC). The CDC reiterated what the manufacturer had stated and also suggested that the pharmacist call Food and Drug Administration (FDA). The pharmacist contacted FDA. FDA requested that the pharmacist file a report to the Vaccine Adverse Event Reporting System. The patient did not experience any pain or unwarranted effect.
3. Patient filled a prescription for levothyroxine 75 mcg. Prescription was dispensed with generic Lexapro®. The patient did not take any of the generic Lexapro.
4. A 69-year-old male patient was prescribed amiloride 5 mg tablets. Prescription was dispensed with amlodipine 5 mg. The patient complained of lethargy, edema, and swelling of the eyes. The error occurred during a telephone transfer from another pharmacy. The receiving pharmacist said that the pharmacist he was getting the transfer from said amlodipine 5 mg. The pharmacist taking the transfer did not reverify the correctness of the medication being transferred. The pharmacy had a meeting to retrain all staff on its policy for receiving transferred prescriptions, with emphasis on trying to get prescription numbers, original bottles, and repeating back information.
5. Patient was prescribed diazepam 10 mg; take one tablet one hour prior to appointment. Prescription was dispensed as diazepam 10 mg; take four tablets one hour prior to appointment. Patient became very sleepy. Pharmacist states that the directions were not checked. Pharmacist states that during counseling, the amount of tablets to take was not discussed. Pharmacist states that directions for use should be discussed during counseling.
6. A 66-year-old male who had a stroke in the past and was on warfarin fell and his broke arm. Patient was dispensed indomethacin when apparently nothing was prescribed. This was due to an error with the electronic prescribing system. Pharmacist is unsure why this happened. The pharmacy will try to determine if the error is with Surescripts. In the future, the pharmacy will pay more attention to the verification process. Also, more due diligence in patient consultation.
7. A 48-year-old female was prescribed cephalexin 250 mg; take one capsule four times a day. Prescription was dispensed cephalexin 250 mg; take one capsule daily. Patient reports that her infection got worse. Patient's prescriber wrote a new prescription for a different antibiotic (clindamycin). Pharmacist states that it was an inexperienced technician entering the information. Pharmacist reviewed the information too rapidly. The abbreviation "Q6h" or "Q6" was misinterpreted as "QD."
8. A 33-year-old female was prescribed Adderall® 10 mg for diagnosis of adult attention deficit hyperactivity disorder. Patient was dispensed amphetamine salt combo. Patient felt nauseous and could not sleep. This is a recurrent prescription for this particular patient and she only has it filled at this pharmacy. The pharmacist stated that a better job will be done to verify recurrent prescriptions, especially if there is any ambiguity.
9. A 30-year-old male was prescribed lorazepam 1 mg for anxiety. Patient was dispensed alprazolam 1 mg. The patient reported having mild dizziness as a result. The pharmacy had dispensed another patient's medication to

continued on page 4

Changes to Fentanyl Pain Patch Warnings Required by FDA

To reduce the risk of accidental exposure, Food and Drug Administration (FDA) has announced new requirements that change the appearance of fentanyl pain patch warnings to make them more visible. The change also requires new language in the warning that emphasizes the risk of death from accidental exposure, particularly in children. The announcement coincided with a Consumer Update that stressed the potential danger of improperly discarded fentanyl patches to children and pets. FDA reminded consumers of the agency's previous advice for securely storing unused patches and disposing of used fentanyl patches by folding the sticky sides together and then flushing them down the toilet. The agency also advises patients to cover in-use patches with an adhesive film to keep them from coming loose, and to regularly check patches to ensure they are securely in place. FDA offers additional information for health care providers on the "Fentanyl Transdermal System (marketed as Duragesic) Information" page, available at *www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm114961.htm*. Consumer information about safe drug disposal methods is also available on the AWAR$_X$E® Web site at *www.AWARERX.ORG*.

New: Free ISMP Medication Safety Alert! Newsletter for LTC Facilities

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 is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In July, ISMP began publishing *Long-Term Care Advise-ERR,* a new *ISMP Medication Safety Alert!* newsletter for nurses and administrators in long-term care (LTC) facilities. ISMP receives error reports that have occurred in LTC facilities. The newsletter is provided free to LTC facilities in the United States thanks in part to corporate sponsorship from Lilly and for a nominal subscription fee for pharmacies that service LTC facilities and others. Please visit ISMP's Web site at *www.ismp.org/Newsletters/longtermcare* for more information, and let your LTC facilities know about this free offer.

Here are a few excerpts from a recent issue.

Immediate Vs Extended Release Error

A physician called a LTC facility to change a resident's oxycodone order from an extended-release formulation to an immediate release formulation at the same dose and frequency. The nurse receiving the verbal order transcribed it as "Discontinue OxyContin 10 mg BID, Start OxyContin 10 mg IR BID," with "IR" meant to represent immediate release. Although Oxy**Contin**® is a brand of oxy**codone,** it is only available as an extended-release tablet. The pharmacy had previously been dispensing Oxy**Contin** for the resident, so the nurse thought she could communicate the prescriber's order by discontinuing the current Oxy**Contin** order and then ordering Oxy**Contin** as an immediate-release product. The pharmacy continued dispensing Oxy**Contin.** The differences between these products and formulations were brought to the attention of nursing staff via an in-service. To minimize the risk of confusion, do not attach modifiers such as "IR" for immediate-release or "RS" for regular strength unless it is part of the official drug name.

Errors Occur During Transitions of Care

A pharmacist reported the following hazardous situation that can occur during a hospital to LTC transfer. Residents are often admitted to a LTC facility with a list of medications printed from the hospital pharmacy computer. On these printouts, doses are expressed along with the number of tablets. For example, the printout may list hydrochlorothiazide 50 mg/2 tablets daily for an order in which the total dose was 50 mg because the hospital only stocks the 25 mg tablets. During hospitalization the patient required two tablets for each dose; however, the LTC nurse may misinterpret the order to mean two 50 mg tablets, making the total dose 100 mg, or two times more than prescribed. This issue arises every time the resident's total dose in the hospital requires more than one tablet or capsule. Discharge medication summaries and transfer orders should only list the total dose in mg or mcg and other directions for use (ie, frequency, route, drug name) to avoid misinterpretation.

2013 USP Chapter <797> Compliance Survey Shows Compliance Trends Unchanged From 2012

The 2013 United States Pharmacopoeia (USP) Chapter <797> Compliance Survey, the third annual report released since 2011, shows that the overall compliance rate of 77.2% remains nearly unchanged from the 2012 rate. Budgetary restrictions and physical plant limitations were among the top challenges to compliance by survey respondents. The report also details the

survey's findings on what types of facilities are participating in compounding, and compliance in specific domain areas such as environmental sampling and gloved fingertip sampling. Of the survey's 1,045 participants, 97% of the survey's respondents said that USP Chapter <797> "has had a positive influence on patient safety." The report notes National Association of Boards of Pharmacy® (NABP®) efforts to assist state boards of pharmacy in evaluating pharmacy compliance with USP Chapter <797> requirements for sterile compounding in their states. The report also noted that those who participated in the 2011 survey had a higher compliance score than those who did not. The survey's authors encouraged pharmacy owners with multiple areas of noncompliance to target one or two areas to improve. They also encouraged organizations that participated in the survey to make use of the free Action Plan – generated upon completion of the survey – and other free resources to "reshape" their sterile compounding practices. The full report on the survey's results is available in the October 2013 issue of *Pharmacy Purchasing & Products Magazine* and on the magazine's Web site at *www.pppmag.com/article/1403*.

FDA Recommends Schedule II Classification for Hydrocodone Combination Products

FDA planned to submit a formal recommendation to reclassify hydrocodone combination products as Schedule II controlled substances to the Department of Health and Human Services by early December 2013. FDA expects the National Institute on Drug Abuse to concur with the recommendation, indicates a statement on the FDA Web site. FDA also indicates that while "the value of and access to these drugs has been a consistent source of public debate," the agency has "been challenged with determining how to balance the need to ensure continued access to those patients who rely on continuous pain relief while addressing the ongoing concerns about abuse and misuse." Drug Enforcement Administration makes the final decision about the appropriate scheduling of these drugs. In January 2013, FDA's Drug Safety and Risk Management Advisory Committee made a recommendation that hydrocodone combination products be classified as Schedule II drugs following a 19-to-10 vote that concluded a two-day meeting during which members discussed the potential for abuse and misuse of the medications and the potential impact of rescheduling the drug products. FDA's statement on the recommendation is available at *www.fda.gov/Drugs/DrugSafety/ucm372089.htm*.

New FDA Drug Info Rounds Training Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better medication decisions. In the latest two Drug Info Rounds videos, pharmacists discuss the review and approval of new drug names and the review of marketing and advertising materials for new drugs. The videos can be viewed at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm368620.htm* and *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm371785.htm,* respectively. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, and Division of Drug Information.

CPPA Developing Specialty Pharmacy Accreditation Program

The Center for Pharmacy Practice Accreditation® (CPPA) has announced the development of a new accreditation program for specialty pharmacy practices. CPPA Executive Director Lynnae Mahaney, MBA, RPh, FASHP, VHA-CM, indicates that "CPPA will be able to develop the new specialty pharmacy standards quickly and efficiently with the existing standards development methodology, infrastructure, and network of specialty pharmacy expertise."

CPPA is a partnership between the American Pharmacists Association, the American Society of Health-System Pharmacists, and NABP. CPPA develops and implements comprehensive programs of pharmacy practice site accreditation, including the promotion, development, and maintenance of principles, policies, and standards. CPPA offers the general public and users of pharmacy services a means of identifying those pharmacies that satisfy the accreditation criteria and are focused on advancing patient care, safety, and quality.

More information may be found in the press release, available at *www.pharmacypracticeaccredit.org/news/2013/10/cppa-to-develop-specialty-pharmacy-accreditation-program*.

continued from page 1

this patient. The technician did not confirm the address of the patient picking up the prescription. The pharmacist stated that they were very busy at the time and many patients were being attended to. Pharmacist states that technicians must confirm patient address as required by procedure. Pharmacist states that new technology now in place should eliminate this type of event.

10. A 65-year-old female was prescribed trazodone 50 mg for insomnia. Patient was dispensed tramadol 50 mg. Patient felt lightheaded, dizzy, and nauseous. The pharmacy technician typed in the prescription as tramadol 50 mg. Verifying pharmacist also misinterpreted as tramadol 50 mg as well. The staff states that the error was due to unclear handwriting of physician and multiple prescriptions written on the same prescription blank. Pharmacist states that checks and balances normally catch this type of error.
11. A pharmacy, which is usually staffed with three pharmacists on certain days, had to work with only two pharmacists on a busy Monday. During this extremely busy time, a patient came in to the store and dropped off a prescription for Endocet® 7.5/325. The pharmacist incorrectly filled the prescription with Endocet 10/325. The patient noticed the error prior to taking the medication and notified the pharmacy. The patient refused to bring the medication back. Patient has a history of narcotic use. The pharmacist states that the error is due to being understaffed. Pharmacist states that he will not leave on a Monday if there are not enough pharmacists on staff.
12. A 59-year-old female with depression was prescribed citalopram. Patient was dispensed losartan 100 mg. Patient complained of headaches and anxiety. The pharmacist missed the error on the double check. To prevent future errors such as this one, the pharmacist will double check contents in the prescription bottle with the contents from the stock bottle.
13. A patient came into a pharmacy with eight new prescriptions plus two refills. Both the pharmacist and the technician were counting the medications in order to process the large order. At some point during this filling process, lamotrigine 200 mg was filled twice. This error was not caught. Pharmacist says that the lamotrigine 200 mg looks similar to the prescribed Topamax® 200 mg. Pharmacist states that all vials should be opened. Pharmacist states that you should check and match the contents of the vial with the stock bottle.

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.

Prescription Monitoring Program

A Reminder About Reporting to the PMP

New Mexico state regulations require all pharmacies (and dispensing practitioners) to submit controlled substance (CS) prescription data to the New Mexico Prescription Monitoring Program (PMP) within seven days of a prescription being filled.

As the timeliness of the PMP data is of utmost importance, compliance with this reporting is now being more strictly monitored. Pharmacies will receive a limited number of e-mail notices before their delinquency is forwarded to the Board for review (which then may lead to disciplinary action). In addition, multiple notices and/or repeated instances of delinquency are also being forwarded to the Board for review.

Therefore, it is more important than ever to get your PMP reporting processes standardized. And, of course, be sure to confirm that your e-mail address in the PMP is correct!

In the near future, the Board will be discussing daily reporting (which many states have already implemented), so having your PMP reporting processes in place and remaining compliant will help make this future transition easier.

PMP Reporting Error Correction

While on the subject of reporting to the PMP, it is very important to make sure that your submitted data has been properly processed by the PMP system. If there are errors in individual records in your upload, while the correct records will be processed, the incorrect ones will be tagged as "Outstanding Uncorrected Errors" and will need to be corrected. To find out if there are any of these errors, the day after the file has been uploaded (files are processed each evening) navigate to the Data Collection → File Upload page, then:

- Select the **View Uploaded Files tab.**
- Files with errors will have a number other than 0 in the Outstanding Uncorrected Errors column.
- Click on the appropriate file name.
- Error messages are listed under the **Description** column.
- Click on the error message.

These errors can be corrected in one of two ways:

- Correct the data in your prescription software, then regenerate the file and upload the data.
- Correct the data online via the PMP website (click on the icon to the right of each record that has an error in order to edit and correct the record).

Details on these and other data reporting issues can be found in the *PMP Data Collection Manual* in the PMP Resources section of the PMP website at *http://nmpmp.org.*

PMP User Account Permissions

And finally on the topic of the PMP, while pharmacy support staff may have their own PMP accounts, they may only use these accounts to submit prescription data to the PMP. Only pharmacists may run PMP patient request reports. There are three basic pharmacy type accounts:

- **Pharmacist:** These accounts allow for access to PMP patient request reports.
- **Dispensing Agent:** These accounts allow for only the submission of data to the PMP.

continued on page 5

continued from page 4

- **Pharmacist-in-Charge:** These accounts allow for both access to PMP patient request reports as well as the submission of data to the PMP.

Please remember that only authorized account holders can access the PMP and each user must have his or her own separate account, as sharing login information is a violation of both federal and state regulations.

For more information or for help with reporting or account access, contact the PMP staff at NM.PMP@state.nm.us or at 505/222-9847.

Nonsterile Compounding

As mentioned in a previous *Newsletter* article, during the April 18-19, 2013 Board meeting, the Board removed the section allowing for compounding of nonsterile pharmaceuticals for practitioner's office use (16.19.30.9 NMAC).

During the October 17-18, 2013 Board meeting, this regulation was clarified. Veterinarians within New Mexico were asking for a waiver to this rule. The Board stated within the regulation:

(4) Compounding veterinarian products.

(a) Products for animals may be compounded based on an order or prescription from a duly authorized veterinarian.

(b) These products are to be handled and filled the same as the human prescriptions.

The intent of this regulation revision is to allow pharmacists to compound veterinary products for the veterinarian to use in his office. Therefore, a pharmacist may compound a nonsterile product for veterinarian use.

On November 27, 2013, H.R. 3204 – Drug Quality and Security Act, was passed by Congress and signed into law by the president. The revision allows pharmacies to compound medications for bulk sale to licensees. The pharmacy, known as an outsourcing facility, must be registered with FDA. These outsourcing facilities are expected to comply with FDA rules with certain exceptions.

A list of facilities to be registered as Human Drug Compounding Outsourcing Facilities with FDA can be found on the FDA web page at *www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm.* No pharmacy registered in New Mexico has registered. However, this would be allowed. Pharmacies on this list may sell to New Mexico licensees if they license with the Board as a wholesaler.

Naloxone

During the January 16-17, 2014 Board meeting, the Board added a new section to 16.19.26 NMAC. This is the regulation allowing for Pharmacist Prescriptive Authority. The new section added is 16.19.26.13 – Naloxone for Opioid Overdose.

The new section is similar to the other preexisting sections. All pharmacists registered and practicing within New Mexico may prescribe naloxone after successfully completing an approved course of training in the area of naloxone for opioid overdose drug therapy. Thereafter, any pharmacist exercising prescriptive authority for naloxone drug therapy shall complete a minimum of 0.2 continuing education units of live Accreditation Council for Pharmacy Education-approved naloxone drug therapy related continuing education (CE) every two years. This requirement is in addition to the CE requirements required of all New Mexico pharmacists.

Prescriptive authority for naloxone drug therapy shall be exercised solely in accordance with the written protocol for naloxone drug therapy approved by the Board. A copy of the protocol is on the Board web page under the Links tab.

A course provided by the New Mexico Pharmacists Association (NMPhA) has been approved by the Board. Please contact the NMPhA to find when the next course will be offered.

All pharmacists registered and working within New Mexico may have prescriptive authority for the following after receiving the approved training and complying with the regulation:

- Vaccines
- Emergency Contraception
- Tobacco Cessation Drug Therapy
- TB Testing
- Naloxone for Opioid Overdose

Board Meeting Date Change

Because of Good Friday, the Board has rescheduled the April 2014 Board meeting. The meeting is now scheduled for Thursday, April 24, 2014 through Friday, April 25, 2014. Please mark your calendars.

Disciplinary Actions

Mary H. Albers, PA – License Number CS00019678. During the April 18-19, 2013 Board meeting, the Board accepted voluntary surrender of her CS registration. Must pay fine of $100. During the January 16-17, 2014 Board meeting, the Board reinstated CS registration.

Shirley Jojola, RPh – License Number RP00004528. A prescription for ropinirole was incorrectly filled with risperidone and dispensed to a customer at a pharmacy. Must pay fine and cost of investigation of $900. Must take CE on error reduction. On probation for one year.

Stephen Lujan – Operating Unlicensed Custodial Care Facility. During the October 17-18, 2013 Board meeting, a hearing was held. Order was signed January 15, 2014. Board found that Lujan was operating an unlicensed custodial care facility. Must pay civil penalty of $100.

Michael Means, PT – License Number PT00007195. Board accepted voluntary surrender of his pharmacy technician registration. Must pay fine of $100.

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, Inc, 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 the Foundation or the Board unless expressly so stated.

Larry Loring - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Deborah Zak - Communications Manager