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New Mexico Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Legislative Update

The following two bills were passed during the 2015 New Mexico Regular Legislative Session. These bills will become law on July 1, 2015.

Senate Bill 367 was signed by Governor Susana Martinez. This bill is titled "Optometrist Prescribing Powers." The bill added "optometrist" to the definition of prescriber. Wording in the bill clarified that optometrists could prescribe both topical and oral pharmaceutical agents. These pharmaceutical agents will be defined by the New Mexico Board of Optometry. The bill allows optometrists to obtain a Schedule II controlled substance (CS) registration. The only Schedule II CS that may be prescribed by an optometrist are hydrocodone-containing products.

House Bill 274 was signed by Governor Martinez. This bill is titled "Prescription Synchronization." This is a patient convenience bill. Patients on multiple medications must currently request refills whenever they run out of medication. This bill allows a prescription to be filled for less than the quantity written. This must be done with the consent of the patient. Also, the prescribing practitioner or the pharmacist must determine this to be in the best interest of the patient. The pharmacy benefit manager (PBM) cannot penalize the patient. The patient must pay a prorated copayment fee for the partial fill of the prescription, and the PBM must allow the prescription to be filled in its entirety on the chosen synchronization date. By doing this, all of the medications for a patient will be due to be refilled at the same time. This will allow only one trip to the pharmacy per filling period, whether it is one month or three months.

State Drug Inspector Position

The New Mexico Board of Pharmacy is continuing to post two positions for state drug inspector. A link for the position is on the Board's web page. If you are interested, please apply. If you have any questions regarding this position, please contact the Board office or the New Mexico State Personnel Office (SPO). Contact information for SPO is available on its website.

Regulation Change

During the April 16-17, 2015 Board meeting, Regulation 16.19.6 NMAC was altered. This is the regulation regarding retail pharmacy. New section 16.19.6.28 NMAC was added. This section regulates automated filling systems. An automated filling system is defined as an automated system used by a New Mexico pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. Please review this regulation if you will be using an automated filling system in your pharmacy. An important part of this regulation is that the process of prepacking medication is regulated. Prepacking is defined as any drug that has been removed from the original packaging of the manufacturer or a Food and Drug Administration (FDA) repackager and is placed in a properly labeled dispensing container by a pharmacy for use in an automated filling system for the purpose of dispensing to the ultimate user from the establishment in which the prepacking occurred.

Disciplinary Actions

Daniel Brandt, MD – License CS-11525. The Board accepted respondent's request to voluntarily surrender his CS registration.

Christopher Shay Driskill, MD – License CS-209142. The Board accepted respondent's request to voluntarily surrender his CS registration.

David L. Jones, CNP – License CS-208039. The Board accepted respondent's request to voluntarily surrender his CS registration. Must pay investigative costs of $100.

Lashawnda Cochran, PT – License PT-5113. Respondent obtained CS without a prescription from the pharmacy where she worked. Voluntary surrender of her pharmacy technician registration. Must pay $325 for costs of investigation.

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FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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 decisions. The latest Drug Info Rounds videos are as follows.

- In "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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Lowe's #55 Pharmacy – License PH-2516. Respondent admitted to being delinquent in reporting CS prescription information to the New Mexico Prescription Monitoring Program (PMP). Respondent shall be on probationary status for a period of six months. Respondent shall pay $100 fine.

Main Street Family Pharmacy – License PH-3262. The Board issued a notice of contemplated action to respondent regarding allegation of unlicensed activity. Respondent was allegedly wholesale distributing non-patient-specific compounded sterile preparations. Respondent did not request a hearing as required. Respondent was practicing without appropriate licensure from the Board or from FDA. As a result, respondent's New Mexico pharmacy registration was revoked by default. Respondent was ordered to pay $12,000 for the unlicensed activity. Respondent was ordered to pay $1,200 for the costs of investigation.

Maria Martinez, PT – License PT-8050. Respondent failed to comply with a judgment and order for child support. As a result, a notice of contemplated action was issued. Respondent did not request a hearing as required. Respondent's pharmacy technician registration was revoked by default. Respondent must pay $100 for investigation costs.

University Hospital Outpatient Pharmacy – License PH-1837. Respondent admitted to being delinquent in reporting CS prescription information to the PMP. Respondent shall be on probationary status for a period of six months. Respondent shall pay $100 fine.

Vida Pharmacy – License PH-2980. Respondent admitted to being delinquent in reporting CS prescription information to the PMP. Respondent shall be on probationary status for a period of six months. Respondent shall pay $100 fine.

Continuing Pharmacy Education

One of the requirements for continuing pharmacy education (CPE) is to obtain two contact hours in the area of patient safety. Beginning January 1, 2015, a minimum of two contact hours per renewal period must be in the area of safe and appropriate use of opioids. An educational program consisting of a minimum of two contact hours that addresses both patient safety as applicable to the practice of pharmacy and the safe and appropriate use of opioids will satisfy both requirements. This is not a unique requirement for New Mexico. Because of the national overdose death epidemic, many pharmacists across the country are required to meet similar requirements. Many of the web pages you visit to obtain CPE will have courses that meet the requirement. In New Mexico, medical doctors also must meet a similar requirement. The New Mexico Medical Society (NMMS), located at *www.nmms.org,* has a course that will meet the patient safety requirement in the area of opioids. The courses produced by the NMMS are Accreditation Council for Continuing Medical Education-accredited and, therefore, approved for use by New Mexico pharmacists. The cost for pharmacists to receive 5.5 hours of continuing education is $117. Please note that these hours are not considered live. A link to the course is found at *www.nmms.org/nm-medical-board-requirements.*

Inventory

Reminder: For most registrants, the annual CS inventory was due on May 1. You were allowed plus or minus four days from that date to complete the inventory. Please check your records to verify that this was done for all registered locations.

Significant Adverse Drug Events

1. A 27-year-old male was prescribed hydroxyzine 25 mg and was dispensed hydralazine 25 mg with the same instructions. The patient sought medical attention after experiencing delusions and reported taking three doses. The pharmacist indicates staffing issues and competing attention with other patients leading to this event. The patient was offered an apology, and it is recommended that additional verification of similarly appearing drug names be implemented.
2. A 66-year-old female was prescribed haloperidol 1 mg and received haloperidol 10 mg. The patient took 23 doses and contacted physician after becoming very tired and lethargic. Pharmacist cites inadequate staffing during high-volume/peak hours leading to this error.
3. A 34-year-old male with leukemia was prescribed methotrexate 10 mg with instructions to take four tablets once per week, and was dispensed methotrexate 2.5 mg with the same instructions. As a result, a new course of chemotherapy had to be initiated. The pharmacist states that the prescription was misinterpreted as 10 mg total weekly dose rather than 40 mg, and that clarification with prescriber was not sought. No specific recommendations for improvement provided.
4. A 71-year-old female with multiple comorbidities and medications was prescribed lovastatin 20 mg and was dispensed another patient's simvastatin 80 mg. The patient notified the pharmacy after taking one dose and noticing that the medication appeared different. No adverse events associated with this error were reported. The pharmacist cites technician not following workflow procedure as the cause, and has recommended holding a staff meeting to address this issue.
5. A 67-year-old female with history of hypothyroidism and hypertension was prescribed levothyroxine 100 mcg and received lisinopril 40 mg along with scheduled refill of lisinopril 40 mg in separate bottle on same visit. Low thyroid level was detected at next follow-up visit with physician, and so the patient was instructed to take double the current dose of

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levothyroxine. Malaise and a fainting episode were reported as the result of lisinopril overdose. The pharmacist was the only person staffed at the time error occurred, and so recommends filling only one prescription at a time, including final verification, and double-checking one's own work.

6. A 38-year-old female was prescribed clarithromycin and was dispensed topiramate. An unspecified adverse event resulted and the patient was treated at a local emergency department. Pharmacist recommends that staff review training procedures with particular attention on the handling of "delete reports."
7. A 42-year-old female with history of asthma was prescribed Dulera® 200/5 inhaler but was dispensed Dulera 100/5. The patient reported uncontrolled asthma symptoms some time later after error occurred. Circumstances leading to this error are unknown, and no recommendations were provided.
8. A two-and-a-half-year-old male was prescribed ranitidine 15 mg/mL with directions to take 1 mL twice daily, and was dispensed the same medication with directions to take 1 teaspoon twice daily. The patient's father gave the patient two doses of the medication and reported resulting drowsiness that resolved soon after. The pharmacist states that failure to review the electronic prescription led to this error, coupled with understaffing. It is recommended that greater vigilance during the verification/review process will avoid this type of error going forward.
9. A 49-year-old female was prescribed enoxaparin 150 mg/mL and received enoxaparin 30 mg/mL. It was reported that the patient visited the emergency room twice following the incorrect dose, presumably as a result of the error. The pharmacist indicates that barcode scanning was either not utilized or overridden, leading to the wrong dose. No specific recommendation or system changes provided.
10. A 70-year-old male hospice patient was prescribed morphine 10 mg/mL with instructions to inject 1 mL every four hours, and received a medication labeled morphine 20 mg/mL oral solution with the same instructions. The patient's nurse communicated the error both to the pharmacy and provider before any dose was given. The pharmacist states that the patient is currently prescribed both the injectable and oral morphine formulations, and the delivered medication was labeled incorrectly. No recommendations for improvement provided.
11. A 71-year-old female with history of hypertension and hypercholesterolemia was prescribed losartan 25 mg and dispensed 100 mg. The error was caught on the third refill. The patient did not report any side effects, but did provide documented improvement in blood pressure control on the higher dose. The pharmacist recommends minimizing distractions in the workflow, double-checking work, and staff education on error prevention strategies.
12. An eight-month-old male was prescribed amoxicillin 400 mg/5 mL for an ear infection, and was dispensed amoxicillin/clavulanate 400 mg/57 mg/5 mL. The error was discovered by the pharmacist during post-fill audit and the parents were contacted. It was reported that the medication had been given and diarrhea resulted. Distraction during the review/verification process is postulated as contributing factor to this error. It is recommended that entire fill process be restarted should interruptions occur.
13. A 76-year-old male with poorly controlled diabetes was prescribed Novolin® NPH and was dispensed Novolin 70/30. The patient experienced symptoms of hypoglycemia, including confusion, racing heartbeat, and sweating as a result. The pharmacist was working alone and did not double-check work when the error occurred. A software upgrade that will disallow bypassing the verification step when a pharmacist enters a prescription is recommended.
14. A 17-year-old male with attention deficit hyperactivity disorder residing in a custodial care facility was prescribed Intuniv® 2 mg and was dispensed a generic version of Dilaudid® 2 mg. The patient reported nausea, somnolence, and dizziness as a result of the mistake. The pharmacist attributes illegible prescription and failure to perform both drug review and counseling as contributing factors. The recommendation is prospective clinical review of all medications and to seek clarification on illegible prescriptions with respective prescriber.

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.

Pseudoephedrine Sales Reporting

As a reminder, retail pharmacies should be reporting over-the-counter pseudoephedrine sales to the New Mexico Methamphetamine Special Information System (NMMSIS). To gain access, you can download the application form from the Board's website. Some pharmacies within New Mexico also report to the National Precursor Log Exchange. This is permitted; however, the requirement of the Board is to report to NMMSIS.

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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