

April 2014

News



Oklahoma State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

4545 N Lincoln Blvd, Suite 112 • Oklahoma City, OK 73105-3413

14.09 ISMP Safety Conference

The Oklahoma State Board of Pharmacy is hosting a major continuing education (CE) program aimed at improving patient safety for pharmacists in the Oklahoma City, OK, area. The program, including lunch and Accreditation Council for Pharmacy Education (ACPE)-accredited CE, is being provided without charge by the Board to further the Board's mission of protecting the health, safety, and welfare of the citizens of Oklahoma.

Educational staff from the Institute for Safe Medication Practices (ISMP) will present four hours of ACPE-accredited CE on the topics of (1) Targeted Medication Safety Best Practices; (2) Human Factors Involved in Errors; and (3) Challenges Around High Alert Medications. The ISMP staff making the presentations will be Dr Donna Horn, RPh, DPh, the director of patient safety-community pharmacy, and Matthew P. Fricker, Jr, MS, RPh, FASHP, ISMP program director. Information presented will apply to both community retail pharmacy and hospital pharmacy practices.

The conference will be held on **Tuesday, June 17, 2014**, at the Jim Thorpe Association and Oklahoma Sports Hall of Fame Museum, Second Floor Events Center, 4040 N Lincoln Blvd, Oklahoma City. Sign-in begins at 11:45 AM. Lunch will be served at 12 PM and the CE program will start immediately after at 12:45 PM.

The Board has planned for 100 participants for the program and is accepting reservations on a first-come, first-served basis. Please e-mail sdozal@pharmacy.ok.gov with the following information to reserve a spot:

- ◆ Full name
- ◆ Oklahoma State Board of Pharmacy license number
- ◆ Daytime phone
- ◆ Birth month
- ◆ Birth day
- ◆ National Association of Boards of Pharmacy® e-Profile ID number

From the Inspector's Desk

- ◆ **14.10. Intern May Not Certify a Prescription:** Under supervision by a preceptor, interns may perform all the tasks of a pharmacist in which they are competent **except** certifying a prescription.
- ◆ **14.11. Immunization Permits:** Pharmacists must have an immunization permit to provide influenza and other vaccine immunizations. Pharmacists who immunize must maintain ongoing competency through required training such as CPR and CE. An immunization permit must be displayed with your pharmacist license. Check the Board website for immunization permit requirements and the application.
- ◆ **14.12. Nurses Are Not Allowed to Mix IV Fluids for Administration by Another Nurse:** The nurse who mixes an IV fluid must be the nurse who administers it. Mixing and labeling IV fluids for someone else to administer is considered "dispensing" by law, and under state law, only pharmacists and doctors are authorized to "dispense." Pharmacists who practice in hospitals and as consultant pharmacists for hospital drug rooms should include this information in nursing education during orientation training and as ongoing CE.

Disciplinary Actions

For more information you may view hearing minutes at www.pharmacy.ok.gov.

14.13. January 15, 2014 Board Hearing

Christina Walters, Technician #11631 – Case No. 1225: Found guilty on four counts including theft while working as a registrant; possession of a controlled dangerous substance (CDS) without a valid prescription; and furnishing fictitious, false, misleading, or fraudulent material in any application or failing to provide information relevant to the application. **Revoked.**

Walgreens Pharmacy No. 15812, #2-6267 – Case No. 1233: Respondent neither admitted nor denied guilt on

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New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *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 Error Reporting Program. Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazapryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

Compliance News to a particular state or jurisdiction should not be assumed as representing the law of such state or jurisdiction.)



can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

four counts including failing to maintain and have readily retrievable for a period of at least two years all prescription purchases and inventory records; failing to properly maintain the required inventories and records of CDS; failing to be able to print its automated data processing system refill reports; and failing to prepare and execute Drug Enforcement Administration Form 222 simultaneously in triplicate signed and dated by a person authorized to sign. **\$10,500 fine.**

Walgreens Pharmacy No. 15772, #2-6266 – Case No. 1234: Respondent neither admitted nor denied guilt on four counts including failing to establish and maintain effective controls against the diversion of prescription drugs; failing to provide effective controls and procedures to guard against theft and diversion of CDS; and failing to provide effective security procedures for handling business guests, visitors, maintenance personnel, and non-employee service personnel. **\$12,000 fine.**

Walgreens Pharmacy No. 15751, #9-6247 – Case No. 1235: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15810, #11-6252 – Case No. 1236: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15762, #2-6263 – Case No. 1237: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15763, #30-6264 – Case No. 1238: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15778, #2-6224 – Case No. 1239: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15764, #2-6222 – Case No. 1240: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15772, #2-6266 – Case No. 1241: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15808, #8-6251 – Case No. 1242: Neither admitted nor denied guilt on four counts including

failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15776, #2-6235 – Case No. 1243: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15773, #2-6223 – Case No. 1244: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15809, #2-6225 – Case No. 1245: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15780, #2-6249 – Case No. 1246: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15782, #2-6250 – Case No. 1247: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15756, #38-6234 – Case No. 1248: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15770, #2-6265 – Case No. 1249: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15811, #2-6253 – Case No. 1250: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Walgreens Pharmacy No. 15777, #2-6248 – Case No. 1251: Neither admitted nor denied guilt on four counts including failure to retain original signed order and all linked records for each order filled for two years and failure to archive records as required in 21 CFR 1305.22 (a) and (d). **\$10,500 fine.**

Cruz Ballinger, Technician #18187 – Case No. 1255: Admitted to guilt on three counts including theft while working as a registrant. **Revoked.**

Shelly Bozarth, Technician #7859 – Case No. 1256: Admitted to guilt on six counts including theft while working as

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a registrant; possession of a CDS without a prescription; abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite; and attempting diagnosis or treatment that is the legally constituted right or obligation of any practitioner of the healing arts. **Revoked.**

Cynthia Esparza, Technician #17826 – Case No. 1257: Found guilty on three counts including theft while working as a registrant. **Revoked.**

Nicol Talamantes, Technician #17808 – Case No. 1258: Found guilty on five counts including theft while working as a registrant; possession of a CDS without a valid prescription; and failing to notify the Board, in writing, within 10 days of change of employment. **Revoked.**

Cody Zimmer, Technician #11054 – Case No. 1259: Found guilty on four counts including abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite, and possession of a CDS without a valid prescription. **Revoked.**

Trinity Apothecary, #99-6362 – Case No. 1260: Found guilty of two counts including knowingly violating a Board order and failing to pay fines ordered by the Board. **Revoked.**

Wal-Mart Pharmacy No. 10-0047, #34-4508 – Case No. 1261: Respondent neither admitted nor denied guilt on three counts including failing to have a pharmacy manager who established and maintained effective controls against the diversion of prescription drugs and failing to have a pharmacy manager who supervises employees as they related to the practice of pharmacy. **\$9,000 fine.**

14.14. February 19, 2014 Board Hearing

Impaired Pharmacist #12317 – Case No. 1153: Suspension is stayed and license is placed on indefinite probation. First 1,000 hours of employment as a pharmacist shall be under the direct supervision of another pharmacist. Respondent shall attend a one-day (eight-hour) law seminar in addition to the required 15 hours of CE during the calendar years of 2014 and 2015. Ten hours of the required CE to renew his license each year must be live during the duration of his contract with Oklahoma Pharmacists Helping Pharmacists (OPHP).

Impaired Pharmacist #15171 – Case No. 1262: Admitted to guilt on eight counts including failing to participate in a rehabilitation program for the impaired as required by the Board; permitting the practice of pharmacy by someone other than a licensed pharmacist; allowing someone other than a licensed pharmacist to certify a finished prescription; the use or abuse of an illegal CDS or a positive drug screen for such illegal CDS or its metabolite; and engaging in the practice of pharmacy while incapacitated. Respondent's license is suspended for 10 years until February 19, 2024. Respondent must enter into and abide by a contract with OPHP or a similar peer assistance program.

Alex Barajas, Technician #12607 – Case No. 1263: Admitted to guilt on three counts including theft and possession of a CDS without a valid prescription. **Revoked.**

Katrina Venner, Technician #16534 – Case No. 1264: Admitted to guilt on three counts including abusing alcohol or drugs, using an illegal CDS, and/or testing positive for such substance or its metabolite. **Revoked.**

Robert French, DPh #12010 – Case No. 1265: Admitted to guilt on two counts including being convicted of a felony or pleading guilty or no contest to a felony. **Revoked.**

Calendar Notes

The Board will meet on **April 16, 2014**. The Board will be closed Monday, **May 26**, for Memorial Day and Friday, **July 4**, for Independence Day. Future Board dates will be available at www.pharmacy.ok.gov and will be noted in the *July Newsletter*.

Change of Address or Employment?

Please be diligent in keeping your information up to date and if possible, remind your co-workers and employees. This continues to be an ongoing problem and failure to notify the Board is a violation of Oklahoma pharmacy law. All pharmacists, technicians, and interns must notify the Board in writing within 10 days of a change of address or employment. Online updates through the license renewal page are also accepted as official notification.

Special Notice About the Newsletter

The *Oklahoma State Board of Pharmacy Newsletter* is an official method of notification to pharmacies, pharmacists, pharmacy interns, and pharmacy technicians registered by the Board. Please read them carefully. The Board encourages you to keep them for future reference.

Oklahoma Pharmacists Helping Pharmacists

If you or a pharmacist you care about is suffering from chemical dependency, there is a solution. OPHP is readily available for help. Pharmacists in Oklahoma, Texas, and Louisiana may call the OPHP help-line at 1-800/260-7574, ext. 5773. All calls are confidential.

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