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Missouri Board of Pharmacy News

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Pharmacist Renewals Are Almost Here

Pharmacist renewals will be mailed in August. Here are some tips for avoiding renewal delays:

- Make sure the Missouri Board of Pharmacy has your current address. Addresses can be updated online at *https://renew.pr.mo.gov/pharmacists-coa.asp*. Address changes should be submitted before **July 1.**
- Name changes cannot be processed during online renewals or on your renewal form. Instead, a written request should be submitted to the Board along with legal documentation supporting the name change (eg, marriage certificate, divorce decree). Name change requests should be submitted in writing **before July 1,** to Missouri Board of Pharmacy, 3605 Missouri Boulevard, Jefferson City, MO 65109, ATTN: Pharmacist/Intern Coordinator.
- **Do not forget your continuing education (CE):** The pharmacist CE late fee is **$1,000.** See below for **important information** on Missouri's CE changes.

Pharmacist Continuing Education

Pharmacists are required to complete 30 hours of CE every two years in order to renew their license. The Board recently revised 20 CSR 2220-7.080 to change the CE completion dates to coincide with the license expiration dates. For the 2014 renewal, CE must be completed between September 1, 2012 and October 31, 2014, to be eligible. For the future 2016 renewal, CE must be completed from November 1, 2014 to October 31, 2016.

Special Note: To renew your pharmacist license, you must attest that your CE has been completed. Although the CE deadline is October 31, 2014, **you cannot renew until your CE has been completed.**

For the 2014 renewal, the 30-hour CE requirement does not apply to renewing pharmacists who were first licensed between November 1, 2013 and October 31, 2014. However, if you hold a Medication Therapy Services (MTS), certificate please see below.

All CE must be Accreditation Council for Pharmacy Education (ACPE) or Board approved in advance to be eligible. Continuing medical education is not eligible unless approved by the Board.

20 CSR 2220-7.080(6) allows CE credit to be given for college credit earned at an accredited pharmacy, medical, or dental educational institution of higher learning. The college credit must be related to the practice of pharmacy and have been earned during the CE renewal period (September 1, 2012 through October 31, 2014). Please see the regulation for specific details.

Do you hold a pharmacist MTS certificate? If so, 20 CSR 2220-6.070 requires completion of six hours of CE related to medication therapy management at the time of your biennial pharmacist license renewal in order to renew your MTS certificate. **The six hours can be part of the 30 hours required to renew your pharmacist license.** The Board will accept approved CE related to any drug therapy or disease state management. The ACPE Universal Activity Number (UAN) would identify these as topic code "01" Drug Therapy Related (Example: ACPE UAN xxxx-xxxx-xx-xxx-x01-x).

The Board will accept CE from a MTS training certificate program completed during the CE renewal period (September 1, 2012 through October 31, 2014) to meet the MTS CE renewal requirement.

The CE exemption for persons first licensed after November 1, 2013, does not apply to the MTS renewal CE requirement. All holders of MTS certificates are required to obtain the six hours of CE in order to renew their MTS certificate.

For new pharmacy graduates, CE obtained from college credit can be used to meet the MTS renewal requirement. See the section above for details.

Lunch With the Chief!

The next **"Lunch with the Chief Inspector"** webinar will be held on **July 17, 2014,** from **noon to 1 PM.** Webinars are **free** and eligible for one hour of CE. Specific topic areas will be announced at a later date, however, the webinar will include a review of 2013-2014 regulatory changes. Mark your calendars now! Webinar registration opens approximately two weeks prior to the registration date. Watch the Board's e-mail alerts for registration details.

Have a suggestion for a webinar topic? E-mail your ideas to compliance@pr.mo.gov.

Be Alert!

Recently, the Board has reviewed several instances where controlled substance (CS) prescriptions were left unattended and stolen/diverted from the pharmacy's counter or the will-call area. In several of the instances, filled prescriptions were momentarily left in a publicly accessible area (eg, the cash register, on the pharmacy counter) while pharmacy employees briefly checked other information for the patient. In one case, the employee may have been intentionally asked to check patient information as a ploy.

Pharmacies must maintain effective controls and procedures to deter theft at all times. Medication should never be left unattended in areas accessible to the public. Physically walk through your pharmacy and check pharmacy counters to make sure drugs are not in reaching distance. It only takes a second! Be alert and aware.

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

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.

Prescription Label Recommendations

The United States Access Board, an independent federal agency established to promote equality for people with disabilities, recently published new recommendations for prescription labels for the blind, visually impaired, or elderly. The recommendations were created with the assistance of an 18-member working group that included representatives from national organizations advocating for individuals who are blind, visually impaired, and older adults, as well as industry groups representing retail, mail order, and independent community pharmacies.

According to the US Access Board:

> Persons with visual impairments who cannot read print prescription drug container labels all too often report inadvertently taking the wrong medication, the wrong amount, at the wrong time, and under the wrong instructions, thereby endangering the health and safety of themselves and family members for whom they are caregivers. Without having ready access to their prescription drug container label information, persons with visual impairments are also at risk of taking expired medications, of not being able to obtain refills in a timely manner, and of being unable to detect pharmacy errors. The majority of persons who become blind or visually-impaired do so after age 60, a time when multiple medications are often prescribed and when persons may experience physical and cognitive conditions which heighten the necessity for safe, consistent, reliable, and independent access to prescription drug container label information.
>
> The goal of the [recommendations] for accessible prescription drug container labels is to offer guidance to pharmacies on how to provide accessible prescription drug container labels to patients with visual impairments to enable them to manage their medications independently and privately and have the confidence that they are taking their medications safely, securely, and as prescribed.

The US Access Board recommendations are available online at *www.access-board.gov/guidelines-and-standards/healthcare/about-prescription-drug-container-labels/working-group-recommendations#what.* **Note: The recommendations are provided for informational purposes only; inclusion herein shall not be construed as an official Board endorsement.**

New Disciplinary Actions

Pharmacists

Jodie J. Baker, #1999141844, Holts Summit, MO. Two (2) years suspension followed by three (3) years probation. Violation of discipline involving failure to submit compliance reports to the Board; failure to complete alcohol/drug treatment program; failure to submit required documentation of such program; failure to call in daily; and did not submit to testing when selected by Board's urinalysis program. Section 338.055.2(5), (6), (13), and (15), RSMo.

Rehan A. Rana, #2005011055, Ballwin, MO. Probation for eighteen (18) months. Theft of CS by technician at pharmacy he owned and served as pharmacist-in-charge (PIC), untimely submission of Drug Enforcement Administration (DEA) and Bureau of Narcotics and Dangerous Drugs (BNDD) loss reports, failed to provide adequate security controls, and failed to supervise pharmacy personnel to assure compliance with laws/regulations. Section 338.055.2(5), (6), (13), and (15), RSMo.

Mary R. Richardson, #029924, Kansas City, MO. Revoked and cannot reapply for seven (7) years. Violation of discipline regarding failure to comply with Kansas Committee on Impaired Pharmacy Practice program, failure to enroll/activate FirstLab account, failure to submit documentation for a chemical dependency evaluation/program and documentation of support group attendance, and failure to submit compliance reports to the Board. Section 338.055.2(1), (5), (6), (13), (15), and (17), RSMo.

Richard D. Thompson, #2001016486, Springfield, MO. Public Censure. As PIC, allowed staff pharmacist to work with an expired license. Section 338.055.2(5), (6), (10), (12), and (13), RSMo.

Pharmacies

Advanced Compounding Pharmacy, #2013019680, North Hollywood, CA. Pharmacy permit issued on probation until July 7, 2018. Disciplinary action in another state regarding numerous violations of California's pharmacy laws relating to compounding records/documentation. Section 338.055.1 and .2(8), RSMo.

Entirelypets Pharmacy, LLC, #2014002635, Union City, CA. Pharmacy permit issued on probation until October 21, 2017. Disciplinary action in another state regarding practicing without a permit to do so and had dispensed prescription drugs to consumers without a good faith veterinarian examination. Section 338.055.2(8), RSMo.

HRI Pharmacy, #2014002930, Warrenville, IL. Pharmacy permit issued on probation for three (3) years. Disciplinary action in other states against PIC's pharmacist license regarding felony conviction for attempted embezzlement, misdemeanor conviction for attempted theft. Section 338.055.2(2) and (8), RSMo.

Imran Pharmacy, #2010031647, St Louis, MO. Probation for two (2) years. Theft of CS by technician, untimely submission of DEA and BNDD loss reports, and failed to provide adequate security controls. Section 338.055.2(5), (6), (13), and (15), RSMo.

The Medicine Shoppe Pharmacy, #2002009522, St Louis, MO. Probation for three (3) years. Dispensed controlled and non-controlled prescriptions for office stock, did not obtain patient-specific prescriptions for the dispensings, prescriptions received were not valid due to insufficient information, improper labeling, failure to properly document CS transfers and CS destruction, transferred CS to facility not DEA registered, shared Controlled Substances Ordering System (CSOS) password with employees, CS losses, failure to implement effective security controls. Section 338.055.2(5), (6), (13), and (15), RSMo.

The Medicine Shoppe Pharmacy, #2000148820, St Louis, MO. Probation for three (3) years. Failure to properly document CS transfers and CS destruction, improper transfer of Schedule II CS, unauthorized sharing of CSOS key with employees, reuse of medications from cassettes, OPUS cassette violations, electronic data processing system errors. Section 338.055.2(5), (6), (13), and (15), RSMo.

Walgreens #03594, Permit #005854, Branson, MO. Public Censure. Allowed pharmacists to administer vaccines without first having a signed protocol; allowed pharmacist to administer vaccine without a patient-specific prescription. Section 338.055.2(6) and (15), RSMo.

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