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Missouri Board of Pharmacy News

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Upcoming Sterile Compounding Survey

In the spring of 2014, the Missouri Board of Pharmacy will be conducting a survey of all pharmacies that hold a Class H sterile compounding pharmacy permit. The goal of the survey is to assist the Board in identifying sterile compounding activities in the state and in allocating inspection resources. Surveys will be mailed in early spring and may be completed electronically or by returning the paper survey forms.

'Lunch with the Chief Inspector'

The next **"Lunch with the Chief Inspector"** webinar will be held on **April 8, 2014,** from **noon to 1 PM.** Webinars are free and eligible for one hour of continuing education credit. Topic areas will be announced at a later date. 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.

Also mark your calendars for the following future webinar dates:

- July 17, 2014
- October 15, 2014

Compounded Drug Testing Program

In 2003, the Board began testing preparations compounded by pharmacies. All preparations are tested by an outside laboratory for potency, sterility, and endotoxins, when applicable. Pursuant to §338.150.2, RSMo, pharmacies are required to allow inspectors to collect samples during inspections and investigations. This includes both batch and patient-specific compounds present in the pharmacy at the time of the inspector's visit. The Board pays all testing costs and will reimburse the pharmacy reasonable, usual, and customary prices for samples collected. Program summaries are published in the Board's Annual Report found on the Board's website.

Technician Renewals

It is renewal time! Pharmacy technician renewal information will be mailed on March 1. To prevent delay, technician address changes should be submitted to the Board on or before February 15. Address changes can be submitted online at *https://renew.pr.mo.gov/pharmacists-coa.asp* or faxed to 573/526-3464.

Are Your Policies and Procedures Any Good?

Inspectors continue to find violations relating to incomplete, inaccurate, or missing policies and procedures. Specifically, inspectors have observed an increasing number of instances where:

- The pharmacy's policies and procedures were outdated or clearly conflicted with state or federal law.
- The written policy and procedure was distinctly different from the policy and procedure actually followed by pharmacy staff.
- Pharmacy staff were unaware of the pharmacy's policies and procedures or had never been trained on pharmacy requirements. In some instances, pharmacy staff reported never seeing the pharmacy's policies and procedures. In others, the pharmacy's policies and procedures were unopened and still in factory shrink-wrap.

Effective policies and procedures will promote consistency and prevent compliance violations. Policies and procedures should be reviewed on a regular basis and updated as needed. However, even the best policies and procedures are insufficient if pharmacy staff have not been properly trained. Relevant changes should be shared and discussed with pharmacy staff.

Generally, Missouri law requires the following policies and procedures:

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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® website at *www.AWAREfx.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 website 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 website 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*.

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Type	Regulation	Annual Review Required
General	20 CSR 2220-2.090(2)(P)	
Class C: Long-Term Care	20 CSR 2220-2.145	
Class E: Radio-pharmaceutical	20 CSR 2220-2.500	
Class F: Renal Dialysis	20 CSR 2220-2.600	
Class H: Sterile Products Compounding	20 CSR 2220-2.200	√
Class I: Consultant (in residence)	20 CSR 2220-2.010(10)	
Class J: Shared Service	20 CSR 2220-2.650	
Class L: Veterinary	20 CSR 2220-2.675	√
Class M: Specialty (bleeding disorder)	20 CSR 2220-6.100	√
Classes N & O: Automated Dispensing System	20 CSR 2220-2.900	
Technician Duties	20 CSR 2220-2.090(2)(CC)	
Prescription Deliveries	20 CSR 2220-2.013(1)	
Administration by Medical Prescription Order	20 CSR 2220-6.040	√
Electronic Record Keeping Systems	20 CSR 2220-2.083	√
Automated Filling Systems	20 CSR 2220-2.950	√

Other policies and procedures may be required by state/federal law (ie, controlled substances (CS)).

For additional information on Missouri's policy and procedure requirements, watch the video replay of the January 15 "Lunch with the Chief Inspector" webinar available on the Board's website at *http://pr.mo.gov/pharmacists-publications-resources.asp#videos.*

New Disciplinary Actions

Pharmacists

Connie M. Becker, #029549, Adrian, MO. Voluntary Surrender. Violation of discipline involving positive alcohol test, failed to call daily to Board's testing vendor, and failed to submit compliance reports to Board.

Adam R. Bohn, #2011031789, Ballwin, MO. Public Censure. Failed to sign immunization protocol before administering vaccines. Section 338.055.2(5), (6), (13), and (15), RSMo.

Timothy M. Tendick, #044904, St Louis, MO. Suspension for three (3) years, followed by five (5) years probation upon license renewal or reapplication. Pled guilty to possession of a controlled substance with intent to distribute; misappropriated prescription pads and used the prescription pads to create CS prescriptions; distributed CS in manufacturer stock bottles or prescription vials without a prescription or proper labels; unlawfully obtained/distributed non-controlled drugs from employer. Section 338.055.2(1), (2), (5), (13), (15), and (17), RSMo.

Pharmacies

M D Pharmacy, Inc, #2013015407, St Louis, MO. Permit issued on probation until September 27, 2014. Previous permit was on probation. Received drugs from non-wholesale, unlicensed drug distributors; misbranding by overfilling stock bottles; compounded prescriptions not logged; failed to maintain hard copies of CS prescriptions; failed to complete Schedule II order forms; filled prescriptions for another pharmacy without a Class J license; record-keeping violations; drug security violations; technician allowed to work and dispense without a pharmacist on duty, and counsel patients; and allowed live animal in pharmacy. Section 338.055.2(5), (6), (10), (13), and (15), RSMo.

The *Missouri Board of Pharmacy News* is published by the Missouri 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.

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