March 2016

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 SW Jackson St, Ste 1414 • Topeka, KS 66612 • *https://pharmacy.ks.gov*

New Faces at the Kansas State Board of Pharmacy

In November 2015, the Kansas State Board of Pharmacy welcomed Alexandra Blasi as the new executive secretary. Ms Blasi has worked for the state of Kansas for several years, and comes to the Board, most recently, from the Kansas Department of Commerce where she served as in-house attorney. She has a juris doctor degree and master of business administration from Washburn University, and is excited to be a part of the Board's next chapter.

The Board also appointed two new members to the Collaborative Drug Therapy Management Committee. Dean Benton and Katie Burenheide are both licensed pharmacists in Kansas with backgrounds and experience in collaborative practice. The committee shall advise and make recommendations to the Board of Pharmacy and the Kansas State Board of Healing Arts on matters relating to collaborative drug therapy management.

Proof of Qualifying Pharmaceutical Experience: Affidavits for Interns

Proof of qualifying pharmaceutical experience outside of the intern's regular school internship hours shall be evidenced by affidavits filed with the Board. It is the **intern's** responsibility to submit the completed affidavits to the Board office and maintain a copy of the affidavits for his or her own records. The affidavits should be signed by the pharmacy intern and the pharmacist preceptor who supervised the intern hours. Affidavit forms are available on the "Pharmacy Interns" page of the Board website at *http://pharmacy.ks.gov/licensing-registration/pharmacy-interns*.

The supervising pharmacist must be a preceptor in order to sign the affidavit documenting the intern hours. According to K.A.R. 68-1-3a, a preceptor may supervise no more than two individuals who are pharmacy students or interns at any time, and all hours must be worked when the pharmacy student or intern is in regular attendance at an approved school of pharmacy. A pharmacist may become a preceptor after a minimum of two years in the active practice of pharmacy. If interested in becoming a pharmacist preceptor, please email the Board office at pharmacy@pharmacy.ks.gov.

Clarification of Information Contained on Controlled Substance Prescriptions

Some of the Board's licensed pharmacies in Kansas have reported that pharmacy benefit auditors have been citing pharmacies for documenting prescription information on both the front and back of the prescription hard copy. Pharmacies are being penalized by various audit groups, and penalties are resulting in reimbursement losses because the prescription included additional information on the back.

Placing a sticker or other written information on the back of the prescription containing information required in K.A.R. 68-20-18, Information Concerning Prescriptions, has been a practice standard in Kansas for many years. However, the Board reviewed this issue at its November 2015 meeting and determined that in order to be a valid prescription, the Board only requires that all the information in K.A.R. 68-20-18(c)(2) be on the face of the prescription hard copy **or** that the pharmacist place a label containing all the required information on the back of the prescription hard copy. Thus, the Board considers the information on the back of the prescription to be part of the hard copy. K.A.R. 68-20-18 states in part:

(2) All written prescriptions for controlled substances shall meet the following requirements:
  (A) Be dated and manually signed on the day issued;
  (B) [B]ear the following information:
    (i) The full name, address, and registration number of the practitioner or mid-level practitioner;
    (ii) the name and address of the patient; and

Continued on page 4

Discontinue Use of Chen Shwezin Sterile Drug Products, FDA Warns

In October 2015, the United States Food and Drug Administration (FDA) issued a statement alerting health care providers and patients not to use drug products intended to be sterile that were made and distributed by Chen Shwezin, Inc, dba Park Compounding Pharmacy of Westlake Village, CA, because of lack of sterility assurance. Following an FDA inspection during which investigators observed unsanitary conditions, including poor sterile production practices, FDA recommended that Park Compounding Pharmacy cease sterile operations and recall all of its non-expired sterile drug products. However, the company had refused to recall its products, according to an FDA safety alert.

At this time, FDA has not received reports of any adverse events associated with the use of products from Park Compounding Pharmacy. FDA recommends that health care providers check their medical supplies, quarantine any sterile drug products from Park Compounding Pharmacy, and not administer them to patients.

More information is available in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm465582.htm.*

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

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.*

This is the final article of a three-part series on seven persistent safety gaffes of 2014.

6) Compounded Pain Creams: High Profit Margin and Danger

Some compounding pharmacies have been heavily marketing compounded pain creams directly to consumers via unsolicited calls, suggesting that the creams are more effective and safer than oral or injectable pain medications. Many of the creams contain drugs that can cause central nervous system depression or adverse cardiac effects, and most have not been FDA-approved for use in combination with each other or for topical use. Patients are charged per ingredient, with many creams containing numerous, expensive medications. Toxicity from the creams has been reported to poison control centers, including cases of accidental child exposures and intentional use for multiple family members. Patients are often unaware of the dangers with using the creams, which include unsafe packaging in containers without child-resistant closures. ISMP is specifically concerned about some statements that may be unproven, such as the products' safe use with children. Compounded pain creams need prominent warnings on labels that describe the potential for toxicity, and physicians and pharmacists who prescribe and dispense the creams must provide patients with instructions about possible adverse effects, safe storage, and proper use. ISMP believes regulatory or licensing oversight is necessary.

7) Clear Care: Still Causing Severe Eye Injuries Five Years Later

Since early 2010, ISMP has received scores of reports of painful eye injuries from patients using CLEAR CARE® Cleaning & Disinfecting Solution for contact lenses by Alcon (formerly CIBA VISION), a Novartis company, and similar store-brand products. Hundreds more can be found on Internet listservs. Located on store shelves near other lens disinfectants and solutions, these disinfecting products differ from other commonly used solutions in that they must be used with a special lens case in order to neutralize the 3% hydrogen peroxide component of the solution over at least six hours before putting the lenses back into the eyes. However, many patients have inadvertently used the solution to soak their lenses in a standard lens case, or thought the solution was saline and instilled it directly into their eyes. This has caused severe eye burning, leading many to seek out emergency medical care for corneal burns. In 2012, Alcon made a label enhancement to warn customers to use the special lens case, but the label change has been ineffective. Neither the company nor FDA's Medical Devices division have been persuaded to make effective label improvements before permanent eye injury or blindness occurs. If the labeling and packaging cannot be improved to reduce the harm being reported, perhaps these products should be pulled from the market or available only behind the pharmacy counter.

Risk of Dose Confusion and Medication Errors With Avycaz, FDA Cautions

Confusion about the drug strength displayed on the vial and carton labels has led to some dosing errors with the intravenous antibacterial drug Avycaz™ (ceftazidime and avibactam), warned FDA in September 2015. The agency explained that Avycaz was initially approved with the vial and carton labels displaying the individual strengths of the two active ingredients (2 g/0.5 g); however, the product is dosed based on the sum of the active ingredients (2.5 g). To prevent medication errors, FDA revised the labels to indicate that each

vial contains Avycaz 2.5 g, equivalent to ceftazidime 2 g and avibactam 0.5 g, according to an FDA safety alert.

As of September 2015, FDA had received reports of three medication error cases related to confusion on how the strength was displayed on the Avycaz vial and carton labels. Two cases stated that the errors occurred during preparation of the dose in the pharmacy. The third case described concern about the potential for confusion because the strength displayed for Avycaz differs from how the strength is displayed for other beta-lactam/beta-lactamase drugs. Based on the information provided in the reports, FDA is aware that at least one of the patients received a higher-than-intended dose of Avycaz. As of September 2015, no adverse events were reported.

More details are included in the FDA safety alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463595.htm.*

US Compounding, Inc, Recalls All Lots of Sterile Compounded Products

In September 2015, US Compounding, Inc, of Conway, AR, issued a voluntary recall of all lots of sterile products aseptically compounded and packaged by the company, and that remain within expiry, because of a lack of sterility assurance. The affected sterile products were distributed nationwide to patients, providers, hospitals, and clinics between March 14, 2015, and September 9, 2015. The recall does not apply to any nonsterile compounded medications prepared by US Compounding. Providers are advised to discontinue use of the products, quarantine any unused product, and contact US Compounding to arrange the return of any unused sterile compounded products using the information provided in the FDA press release, available at *www.fda.gov/Safety/Recalls/ucm464071.htm.*

The company issued this recall out of an abundance of caution. Providers who have dispensed any sterile product distributed by US Compounding should contact patients to whom product was dispensed and notify them of this recall. A list of all sterile compounded products that have been recalled is provided on FDA's website at *www.fda.gov/Safety/Recalls/ucm464072.htm.*

FDA Investigates the Risks of Using Pain Medicine Tramadol in Young Patients

As of September 2015, FDA is investigating the use of the pain medicine tramadol in young patients because of the rare but serious risk of slowed or difficult breathing. This risk may be increased in patients treated with tramadol for pain after surgery to remove their tonsils and/or adenoids. Tramadol is not FDA-approved for use in patients aged 17 years or younger; however, data show it is being used "off-label" in the pediatric population, according to the safety alert on FDA's website, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm463499.htm.*

FDA is evaluating all available information and will communicate final conclusions and recommendations to the public when the review is complete. Health care providers are encouraged to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Decreased Potency Reported in Drugs Stored in Becton-Dickinson Syringes

In September 2015, FDA expanded its alert regarding compounded or repackaged drugs stored in Becton-Dickinson (BD) general use syringes to include certain additional syringe sizes including 1 mL, 10 mL, 20 mL, and 30 mL BD syringes, and BD oral syringes. FDA's original alert applied to compounded or repackaged drugs that have been stored in 3 mL and 5 mL BD syringes. The agency expanded the alert based on BD reports that an interaction with the rubber stopper in certain lots of these syringes can cause some drugs stored in these syringes to lose potency if filled and not used immediately. BD reports that the following drugs in particular can be affected by the stoppers, but it does not know whether other drugs can be affected: fentanyl, rocuronium, neostigmine, morphine, midazolam, methadone, atropine, hydromorphone, cisatracurium, and remifentanil. This safety alert does not pertain to BD prefilled, prefillable, heparin flush, saline flush, or insulin syringes, indicates BD in an alert notice. Further, BD's alert notice also has a search tool to assist customers in determining if their lots are affected. FDA advises hospital pharmacies and staff to contact any outsourcers to determine if affected lots of BD syringes were used for compounded or repackaged products. Hospital pharmacies and staff should not administer compounded or repackaged drugs that have been stored in any of these syringes unless there is no suitable alternative available. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program.

More details are included in the FDA Safety Alert, available at *www.fda.gov/Drugs/DrugSafety/ucm458952.htm.*

MediStat Pharmacy Issues Recall of Sterile Drug Products

MediStat Pharmacy, a 503B outsourcing facility in Foley, AL, has initiated a national recall of all sterile injectable products distributed between November 1, 2014, and September 3, 2015. The recall is based on the identification of various pathogens within the compounding environment. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from MediStat, and not administer them to patients. FDA has received reports of several adverse events that are potentially associated with the drug products made by MediStat. MediStat voluntarily ceased sterile compounding operations in September 2015. FDA asks health care providers and patients to report adverse reactions or quality problems experienced with the use of these products to the FDA's MedWatch Adverse Event Reporting program.

More details are included in an FDA press release, available at *www.fda.gov/Safety/Recalls/ucm461939.htm.*

Continued from page 1

(iii) the drug name, strength, dosage form, quantity prescribed, and directions for use; and

(C) be written with ink, indelible pencil, or typewriter.

K.A.R. 68-20-18 does not specify who can add information to the hard copy, just that the prescription must bear the information in subparagraphs i-iii. It further states that a secretary or agent of the practitioner may prepare the prescription for the practitioner to sign. An important consideration is that a corresponding liability rests upon the pharmacist who fills a prescription that is not prepared in the manner required by this regulation.

Board Policy on Name Tags

According to K.A.R. 68-2-15, the following individuals shall wear a visible name tag: pharmacist, pharmacy student, intern, and pharmacy technician. There is, however, some confusion about the expectations for the information contained on the name tag. At a minimum, the name tag should include the individual's first name, but the Board also recommends including the last name or last initial. Name tags should also include the individual's designation as one of the aforementioned categories. If an individual is nationally certified or has other credentials, those may be included on the name tag (eg, CPhT, RPh, PharmD). While name tags worn by other pharmacy staff and employees are appreciated, they are not mandatory.

Continuing Education Corner

Effective January 1, 2016, the Board will no longer be offering continuing education (CE) credit for attendance at Board meetings. If you attended Board meetings prior to the effective date and have the proper documentation, CE credit will be approved **only** for those meetings.

No Grace Period for Renewals

Changes to K.S.A. 65-1632 and K.S.A. 65-1645 during the 2014 legislative session resulted in removal of the grace period for all registration, permit, and license renewals. Therefore, if the renewal application is not filed with the Board office or completed online prior to the expiration date, the existing registration, permit, or license shall lapse and become null and void on the date of its expiration. After such expiration, no new registration, permit, or license shall be granted, except upon payment of the required renewal fee plus the late penalty fee.

Upcoming Events

March 28, 2016
Collaborative Drug Therapy Management Committee Meeting
Public Area Conference Room
1701 Wheeler, Emporia, KS

April 1, 2016
Prescription Monitoring Program (PMP) Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka, KS

April 20-21, 2016
Board of Pharmacy Quarterly Meeting
University of Kansas (KU) School of Pharmacy
2010 Becker Dr, Rm 2040, Lawrence, KS

April 21, 2016 8:30 AM
Hearing on Proposed Administrative Regulations
KU School of Pharmacy
2010 Becker Dr, Rm 2040, Lawrence

May 6, 2016
PMP Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka

July 14-15, 2016
Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka

August 5, 2016
PMP Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka

October 28, 2016
PMP Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka

November 3-4, 2016
Board of Pharmacy Quarterly Meeting
Wichita, KS

January 12-13, 2017
Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka

Useful Contact Information

Kansas State Board of Pharmacy.....785/296-4056
1-888/792-6273
K-TRACS.....785/296-4056
Kansas State Board of Healing Arts.....785/296-7413
1-888/886-7205
Kansas Dental Board.....785/296-6400
Kansas State Board of Nursing.....785/296-4929
Kansas Board of Examiners in Optometry.....785/832-9986
Drug Enforcement Administration (Kansas City).....913/825-4200
Food and Drug Administration, Center for Drug Evaluation and Research.....1-855/543-3784
Kansas Pharmacists Association.....785/228-2327
Kansas Council of Health-System Pharmacists.....785/271-0208
Kansas Pharmacists Recovery Network.....785/217-7091

The *Kansas State Board of Pharmacy News* is published by the Kansas State 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.

Alexandra Blasi, JD, MBA - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager