



Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601

Pharmacy Technician Registration Renewal by March 31, 2016

The registration renewal process is available online at www.pharmacy.ky.gov. At the completion of the application process and payment of the \$25 registration fee, you may print your certificate of registration. If you are unable to complete the process online, you may print a registration renewal application form from the Kentucky Board of Pharmacy website.

Registrations must be received in the Board office by the close of business on Thursday, March 31, 2016 (not post-marked). All online registrations must be completed before 12:01 AM (EDT), April 1, 2016. Your registration will be valid until March 31, 2017.

As a reminder, a pharmacy technician must renew his or her pharmacy technician registration and **must not apply as a new pharmacy technician**, whether he or she has changed pharmacies or is attempting to renew his or her pharmacy technician registration late.

Pharmacists-in-charge, please check that all pharmacy technicians have renewed their pharmacy technician registrations before the March 31, 2016 deadline.

Sterile Compounding Task Force

At the 2015 Board Retreat, the Board created a task force to focus on sterile compounding. The Sterile Compounding Task Force (SCTF) was composed of the following members:

- ◆ Katie Busroe, chair, Board pharmacy and drug inspector
- ◆ Michelle DeLuca Fraley, Ephraim McDowell Regional Medical Center
- ◆ John Giordullo, St Elizabeth Health System
- ◆ Larry Hadley, Board member
- ◆ Amanda Harding, Board pharmacy and drug inspector
- ◆ Tiffany Herald, Appalachian Regional Healthcare
- ◆ Barb Jolly, Sullivan University College of Pharmacy
- ◆ Tammy McDowell, Nutrishare
- ◆ Trenika Mitchell, University of Kentucky College of Pharmacy
- ◆ Laura Riley, HDM Pharmacy

- ◆ Kent Shelton, Lexington Compounding Pharmacy
- ◆ Laura Stiles, Owensboro Health Muhlenberg Community Hospital
- ◆ Robin Walters, Pikeville Medical Center, Leonard Lawson Cancer Center
- ◆ Robert McFalls, ex officio member, Kentucky Pharmacists Association (KPhA)
- ◆ Anne Policastri, ex officio member, Kentucky Society of Health-System Pharmacists

The SCTF met three times with 30 to 40 people in attendance, and several issues were discussed. United States Pharmacopeia (USP) Chapter <797> refers to a compound record on several occasions, but does not define the elements of the compound record. The SCTF unanimously recommended the Board adopt a “Best Practice Compound Record” that encompasses the elements outlined in the proposed revision of USP Chapter <797> published in September 2015. At the December 16, 2015 Board meeting, the Board unanimously adopted the Best Practice Compound Record. The Best Practice Compound Record is available as a PDF on the Board website under the Compounding Information tab on the home page.

The SCTF recommended changes to 201 KAR 2:076, Parenteral Compounding. This was to update the language of the regulation, encompassing both sterile and nonsterile compounding and reflecting current practices. The Board is considering the changes and will discuss them at the March 2016 Board meeting.

A Summary of Sterile Compounding Inspection document was created to assist with the inspection process. This one-page summary is a reference, highlighting general areas of compliance, partial compliance, and noncompliance. A summary will be provided at the conclusion of an inspection along with the Sterile Compounding Inspection Form. Both the Summary of Sterile Compounding Inspection document and the Sterile Compounding Inspection Form are available as PDFs under the Compounding Information tab on the home page of the Board’s website.

Thank you to all SCTF members and those who participated in the discussions. The agendas and minutes from the

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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: isminfo@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 remifentanyl. 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.

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SCTF are available under the Compounding Information tab on the Board website.

Compounding Update

Board pharmacy and drug inspectors will continue to perform comprehensive sterile compounding inspections in 2016. In 2015, there were 184 sterile compounding facilities in Kentucky, with 16 performing high-risk sterile compounding. In addition to the sterile compounding inspections for 2016, pharmacy and drug inspectors will be performing comprehensive nonsterile compounding inspections. Compliance with USP Chapter <795> is expected. For both sterile and nonsterile compounding inspections, multiple inspectors may be present depending on the type and volume of compounding being performed.

Board staff has created a Compounding Information section on the Board website. This will contain the agendas and minutes for the SCTF, which concluded its charge on December 17, 2015. Also available in this section are links to the Sterile Compounding and Nonsterile Compounding Inspection Forms (subject to updates) and compounding information supplied by the pharmacy and drug inspectors. The compounding information will be updated on the 15th and 30th of each month, with previous information archived and accessible below the current information. The Compounding Information section is accessible from the home page of the Board's website.

Pharmacy Renewal Deadline June 30, 2016

Pharmacy permits expire June 30, 2016. A pharmacy permit can be renewed online. A postcard explaining the renewal process will be mailed to each pharmacy on or about May 1, 2016. If you want to send in a paper renewal, this form may be printed from the Board's website at www.pharmacy.ky.gov. If you have any questions concerning the renewal process, please contact the Board office. Please be reminded that if your pharmacy has an address change, relocation within the current premises of the existing permit, or ownership change, you must complete a new pharmacy application. A pharmacy application with only a US Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is June 30, 2016. All paper renewal applications must be in the

Board office by the close of the day on Thursday, June 30, 2016 (not postmarked).

KPhA Emergency Preparedness Program

*Submitted by Leah Tolliver, RPh, Director of Pharmacy
Emergency Preparedness, KPhA*

The KPhA Emergency Preparedness Program now offers several educational opportunities. These are posted in the Resources section under Emergency Preparedness on the home page of the KPhA website. Some of the programs offer pharmacist continuing education. All programs are free of charge.

In addition, there are many other links on the page for information about emergency supply kits, preparing and restoring your business in the event of a disaster, pet disaster kits, natural disaster preparation, and much more.

To view the latest newsletter, please visit www.kphanet.org/?page=38 and scroll down to Quarterly Newsletters.

If you are not already a volunteer, please join on the Emergency Preparedness page!

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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