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News

SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

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Kingstree Bldg, 110 Centerview Dr • PO Box 11927 • Columbia, SC 29211-1927
www.llr.state.sc.us/pol/pharmacy • 803/896-4700

2016 Pharmacist Renewal Notices Are on the Way!

The 2016 renewal notices will be mailed to you in late February. The South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy has enhanced its online renewal system to make it easier and more convenient for you to renew your license. You will receive a renewal notice with a **user ID** and a **password** that will allow you to access the online renewal website. If you choose not to renew online, you can request a paper renewal form from the Board office and renew by mailing the completed form and proper fees to that office. Applications for renewal must be filed no later than March 31, 2016, to avoid a penalty. If you do not renew online, please document the date the application is mailed. The Board recommends the paper renewal be sent via **certified mail with a return receipt requested.** Postage machines do not provide acceptable proof of mailing.

Applications submitted for renewal between April 1 and April 30, 2016, must include a penalty of $50 for late renewal in addition to evidence that the applicant meets the renewal requirements and has paid the appropriate fees. If you do not renew your license by April 30, 2016, it will lapse. You can be disciplined for unlicensed practice if you work in South Carolina with a lapsed license.

Pharmacist CE Requirements for Renewals

To renew online, you must indicate that you have completed the required 15 hours of continuing education (CE). Six of those hours must be live and 50% of the total must be in drug therapy or patient management. If you are a pharmacist administering vaccinations, you must complete at least one hour of continuing medical education Category I CE or Accreditation Council for Pharmacy Education-approved CE related to the administration of vaccines as part of your annual licensure requirements. **You cannot renew until you have completed the CE requirements.** A random CE audit will be conducted after renewals are processed. Please respond promptly if you are selected for the audit. Disciplinary action will be taken if you cannot show you completed the CE requirements or if proof of the required CE is dated **after** your renewal is received in the Board office.

Board Welcomes New Inspector

Sheila Young joined the Board staff as a pharmacist inspector on October 19, 2015. She holds a bachelor of science degree in pharmacy from Mercer University Southern School of Pharmacy. Sheila has been a pharmacist for 40 years, with 10 years specializing in sterile compounding and nonsterile compounding. She has extensive experience in pharmacy, including work in independent, retail, compounding, home health, and long-term health care settings, as well as experience as a consultant and with medical gases, durable medical equipment, and regulatory compliance with inspections and investigations. The Board and staff are happy to welcome her.

Updated Nonsterile Inspection Form Guidance

The Board developed parameters to determine when a facility qualifies for a nonsterile compounding inspection. The intent of these parameters is to apply the statutory requirements to the correct facilities without burdening those pharmacists who make "simple" compounds.

Recent feedback indicates that there is confusion over the Board's interpretation of the definition of a simple compound: "Making twenty or less compounds of an oral liquid or topical dosage form utilizing five or less non-hazardous APIs over any 30 day period (not exempt from S.C. Code Ann. §40-43-86(CC)(6), 'Formulas and Logs Maintained')."

Much of the confusion stems from a misunderstanding of what an API is. API stands for "active pharmaceutical ingredient." An API is a pure substance, usually in powder form, intended to be used in the compounding of a drug preparation and thereby becoming the active ingredient in that preparation. This differs from a manufactured or finished drug product, which contains one or more active ingredients along with other excipients (fillers, binders, dyes, flavorings, preservatives, and other materials).

The nonsterile inspection form is not intended for facilities that make simple compounds utilizing only finished drug products (eg, magic mouthwash). However, formulas and logs must be maintained, and appropriate beyond-use dating must be assigned. Pharmacists may find the questions below helpful in determining whether their pharmacy would qualify for a nonsterile compounding inspection.

- **Do you only compound oral liquid or topical dosage forms?** Yes – Next question; No – Use nonsterile form
- **Is an API part of these compounding formulas?** Yes – Next question; No – Nonsterile form does **not** apply
- **Is the API non-hazardous?** Yes – Next question; No – Use nonsterile form

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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: 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.*

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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LICENSING, & REGULATION – BOARD OF PHARMACY

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- **Do you compound 20 or less of these products within a 30-day period?** Yes – Next question; No – Use nonsterile form
- **Are you utilizing five or less APIs?** Yes – Nonsterile form does not apply to you; No – Use nonsterile form

If you answer "yes" to all of the questions, this form does not apply to your practice setting. You may access the nonsterile compounding inspection form on the Board's website, *www.llr.state.sc.us/pol/pharmacy;* on the right-hand side under Licensure Information, click on Applications and Forms. Once there, scroll down to the Inspection Report Forms subhead and click on Non-Sterile Compounding Pharmacy.

Consultant Pharmacist – Inventory Accountability at Non-Dispensing Drug Outlets

Board inspectors have discovered that some non-dispensing drug outlets do not have a system of inventory accountability in place for their legend drugs. Many of these facilities have reported that they were not aware that a record-keeping system was required.

According to South Carolina Code Annotated §40-43-86(C)(1)(b), the consultant pharmacist is responsible for "establishing and supervising the recordkeeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs." There are no specific requirements for the type of record-keeping system used as long as it can sufficiently account for the inventory on hand.

As a reminder, §40-43-91(A)(1) requires a permit holder to report to the Board " . . . within thirty working days of the discovery of the occurrence of theft or loss of drugs or devices." Proper inventory accountability facilitates this reporting requirement.

Board Meeting Calendar

The Board welcomes all interested individuals to attend Board and committee meetings held throughout the year at the Board Office in Columbia, SC. Board meeting dates are listed below.

- March 16, 2016
- June 15-16, 2016
- September 14-15, 2016
- November 16, 2016

The Board also has many special committees that meet periodically throughout the year to address specific concerns for the pharmacy community. Committee meeting dates are listed below.

- Legislative, Compounding, and Medication Integrity committees:
  - ◊ February 12, 2016
  - ◊ April 8, 2016
  - ◊ May 13, 2016
  - ◊ July 8, 2016
  - ◊ October 14, 2016
- Pharmacy Practice and Technology, Nuclear, and Pharmacy Technician committees:
  - ◊ February 25, 2016
  - ◊ April 21, 2016
  - ◊ May 26, 2016
  - ◊ July 21, 2016
  - ◊ October 27, 2016

Meetings listed below are held at the discretion of the committee chairperson.

- Compounding – Carole Russell, RPh, chairperson
- Legislative – Addison Livingston, PharmD, RPh, chairperson
- Pharmacy Practice and Technology – Terry Blackmon, RPh, chairperson
- Pharmacy Technician – Rebecca Gillespie, PharmD, RPh, chairperson
- Medication Integrity – Addison Livingston, PharmD, RPh, chairperson
- Nuclear – Spencer Morris, PharmD, RPh, chairperson
- Recovering Professionals Program – Leo Richardson, PhD
- Non-Resident Application Review – Addison Livingston, PharmD, RPh, chairperson

For more information you may check the Board's website, or if you would like to be added to the agenda distribution list for Board or committee meetings, please contact the Board office.

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