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News

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

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2017 Pharmacist Renewal Notices Are on the Way!

The 2017 renewal notices will be mailed in late February. You will receive a renewal notice containing your **user ID and a password,** which will allow you access to the online renewal website. If you choose not to renew online, you may request a paper renewal form from the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy office and renew by mailing the completed form and proper fees to the office. Applications for renewal must be filed no later than March 31, 2017, in order 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, 2017, must include a $50 renewal penalty 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, 2017, it will be considered lapsed. 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 (ACPE)-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.

Compliance Tips

Immunization Kits

Recently, Board inspectors have discovered numerous deficiencies with required supplies and equipment for immunization administration. As a reminder, all items in Appendix B (see below) of the joint immunization protocol are required to be **readily available and in date.**

The following items must be available in the area where vaccines are administered:

(1) A current copy of the "Protocol for Administration of Vaccines by Pharmacists."

(2) A supply of the most current federal Vaccine Information Statements for vaccines being administered or electronic access to these statements.

(3) Aqueous epinephrine USP (1:1000) in ampules, vials of solution, or prefilled devices (eg, EpiPen®). If an EpiPen is to be stocked, at least four adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) should be available.

(4) Diphenhydramine (Benadryl®) injectable solution (50 mg per mL) and oral 25 mg dosage form, to include tablets, capsules, or liquid.

(5) Syringes: 1-mL and 3-mL, 22g and 25g, and 1-inch and 1½-inch needles for epinephrine and diphenhydramine.

(6) Alcohol swabs and bandages.

(7) Blood pressure monitoring device or stethoscope and sphygmomanometer (with pediatric, adult, and extra-large cuffs).

(8) Adult- and pediatric-sized pocket masks with one-way valve.

(9) Flashlight with extra batteries (for examination of mouth and throat).

(10) Timekeeping device with ability to count seconds.

(11) Telephone access.

(12) Equipment such as a mat or a reclining chair to enable the vaccinee to sit or lie down if he or she experiences an adverse reaction to the vaccine.

Per **Regulation 99-45,** violations of the immunization protocol may result in administrative citations and penalties. Separate citations and administrative penalties may be assessed for each violation.

Technician Ratios

One of the most common violations being found in pharmacies is the lack of adherence to the technician ratio that is outlined in **Section 40-43-86(B)(4) of the South Carolina Code of Laws Unannotated.**

(b) The pharmacist-in-charge [PIC] shall develop and implement written policies and procedures to specify the duties to be performed by pharmacy technicians. The duties and responsibilities of these personnel shall be consistent with their training and experience. These policies and procedures shall, at a minimum, specify that pharmacy technicians are to be personally supervised by a licensed pharmacist who has the ability to control and who is responsible for the activities of pharmacy technicians and that pharmacy technicians are not assigned duties that may be performed only by a licensed pharmacist. One pharmacist may not supervise more than three pharmacy technicians at a time; . . . at least two

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National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

FDA Issues Final Rule Amending List of Drug Products That May Not Be Compounded

Food and Drug Administration (FDA) issued a final rule amending FDA's list of drug products that may not be compounded under certain sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that allow the marketing of unapproved compounded drugs. Drug products on the list may not be compounded because the drug products have been withdrawn or removed from the market for safety or effectiveness reasons, indicates FDA. The list may be found in the Code of Federal Regulations at Title 21, Section 216.24, at *www.ecfr.gov.*

The final rule adds 24 types of drugs to the withdrawn or removed list; modifies the withdrawn or removed list to allow one type of drug product to be compounded under certain circumstances; and clarifies that the withdrawn or removed list applies to sections 503A and 503B of the FD&C Act. The final rule is available at *www.gpo.gov/fdsys/pkg/FR-2016-10-07/pdf/2016-24333.pdf.* FDA provides more information online at *www.fda.gov/Drugs/DrugSafety/ucm524320.htm.*

Selected Medication Risks to Manage in 2017

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.*

Some medication safety risks are painfully apparent in an organization, while many others lie dormant in the system until an error or adverse event draws attention to them. ISMP thought it would be useful to describe selected medication safety risks for organizations to manage in 2017 that might otherwise fall off the radar screen.

Environmental Factors, Workflow, and Staffing Patterns – Poor Quality Lighting

Lighting is a crucial aspect of the physical environment that has been linked to medication safety.[1] Poor quality lighting has often impaired the highly visual tasks associated with medication use, thus leading to medication errors. Examples include tubing misconnections due to low lighting in a patient's room, infusion pumps that have been misprogrammed because of dim backlighting on the screens, and product selection errors in the pharmacy and patient care units caused by low lighting under a pharmacy hood or shadows around an automated dispensing cabinet (ADC).

Despite existing guidelines for lighting in health care, it has been a challenge to implement optimal lighting conditions for prescribing, dispensing, and administering medications. Recent literature reviews found that little system-wide action has been taken to increase staff awareness of the problem or improve the lighting.[1,2] This is largely because the tasks associated with medication use are varied and carried out under diverse physical conditions and in differing locations, and because there are differences in an individual's light requirements based on visual acuity and age. With an ever-increasing population of older health care providers, eye fatigue from computer work and task complexity, small font sizes on medication labels, poor background contrast, and glare or shadows have taken their toll on visual accuracy.[1,2]

Proper illumination improves both the accuracy and efficiency of medication-related tasks. Fluorescent cool white lamps or compact fluorescent lamps should be used in areas where critical tasks are performed, including on mobile medication carts, near ADCs, and in patients' rooms for nighttime administration of medications.[3,4] Administration of medications at night under low lighting to avoid disturbing the patient is an unsafe practice and should be avoided. Adjustable 50-watt high-intensity task lights are recommended when difficult-to-read prescriptions and product labels are encountered.[4] Illumination levels for computer order entry areas should be at least 75 foot-candles (fc), while 100-150 fc are needed when interpreting handwritten orders.[4] Medication preparation areas, medication verification areas, and patient counseling areas should have illumination levels between 90-150 fc.[4] Medication rooms should provide illumination at 100 fc.[4] Lighting levels should be increased if the workforce has an average age above 45 years. A magnifying glass and task light together can also significantly improve accuracy[3] and should be used on mobile medication carts (including those used with bar code medication verification systems)[4] and near ADCs.

References:

1. Chaudhury H, Mahmood A, Valente M. The effect of environmental design on reducing nursing errors and increasing efficiency in acute care settings: a review and analysis of the literature. *Environ Behav.* 2009;41(6):755-786.
2. Graves K. *Nurses' Decision Making Processes About Lighting During Medication Administration* [dissertation]. Denton: Texas Woman's University College of Nursing; 2014.
3. Grasha AF. Psychosocial factors, workload, and risk of medication errors. *US Pharm.* 2002;27(4):HS32-52.
4. United States Pharmacopeial Convention. Chapter <1066> Physical environments that promote safe medication use. *Revision Bulletin.* October 1, 2010;2-6. www.ismp.org/sc?id=1664.

DEA to Decrease Manufacturing Amount of Opioid Controlled Substances in 2017

Drug Enforcement Administration (DEA) is reducing the amount of almost every Schedule II opiate and opioid medication that may be manufactured in 2017 by 25% or more. Other medicines were reduced by more, such as hydrocodone, which will be 66% of last year's level, indicates the DEA news release. DEA notes that demand for these opioid medicines has declined based on sales data from IMS Health, a company that provides insurance companies with data on prescriptions written and prescription medications sold in the United States.

The aggregate production quota (APQ) established by the final order is the total amount of a controlled substance (CS) necessary to meet the estimated medical, scientific, research, industrial, and export needs for the year and for the maintenance

of reserve stocks. The 2017 APQ has been reduced for oxycodone, hydrocodone, fentanyl, hydromorphone, morphine, and other such medications. Much of this reduction is attributed to the elimination of a 25% buffer that was added to the APQ annually in 2013 through 2016 to guard against shortages. The purpose of quotas is to provide an adequate and uninterrupted supply for legitimate medical need of the types of Schedule I and II CS that have a potential for abuse, while limiting the amounts available to prevent diversion.

Additional details may be found in the DEA news release available at *www.dea.gov/divisions/hq/2016/hq100416.shtml* and in the final order available at *https://www.gpo.gov/fdsys/pkg/FR-2016-10-05/pdf/2016-23988.pdf*.

New CDC Brochure Offers Pharmacists Tips for Addressing Prescription Opioid Abuse and Overdose

Centers for Disease Control and Prevention (CDC) released a brochure encouraging pharmacists, who are an essential part of the health care team, to help prevent opioid abuse and overdose. The brochure, "Pharmacists: On the Front Lines," offers tips for communicating with patients who are receiving opioid therapy. In addition, the brochure offers tips on how to identify forged prescriptions and urges pharmacists to maintain collaborative working relationships with prescribers to improve patient outcomes. The brochure is available at *www.cdc.gov/drugoverdose/pdf/pharmacists_brochure-a.pdf*.

FDA Requires Boxed Warnings and Patient-Focused Medication Guides Indicating Serious Risks Related to Combined Use of Certain Opioid Medications and Benzodiazepines

FDA is requiring class-wide drug labeling changes to inform health care providers and patients of the serious risks associated with the combined use of certain opioid medications and benzodiazepines. Specifically, after an extensive review of the latest scientific evidence, FDA is requiring boxed warnings and patient-focused Medication Guides for prescription opioid analgesics, opioid-containing cough products, and benzodiazepines that provide information about the serious risks associated with using these medications at the same time. Risks include extreme sleepiness, respiratory depression, coma, and death.

FDA's news release indicates the changes are part of the agency's Opioids Action Plan, which focuses on policies aimed at reversing the prescription opioid abuse epidemic while providing patients in pain with access to effective and appropriate pain management. The public health crisis is evident through the significant rise of preventable overdose and death associated with the concurrent use of two drug classes, indicates FDA Commissioner Robert Califf, MD, in the press release, available at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm518697.htm*.

FDA's Division of Drug Information Offers CE Webinars for Students and Clinicians

FDA's Center for Drug Evaluation and Research (CDER), Office of Communications, Division of Drug Information presents a series of continuing education (CE) webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of drug shortages and prescription drug promotion. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/DDIWebinars*.

FDA Approves Labeling Changes for All Prescription Testosterone Products

In October 2016, FDA approved class-wide labeling changes for all prescription testosterone products regarding the risks associated with abuse and dependence of the drug. The changes include adding a new warning as well as updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other anabolic androgenic steroids (AAS). The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act.

Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. However, testosterone and other AAS are abused by adults and adolescents, including athletes and body builders, notes FDA. FDA indicates the new warning will "alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse." In addition, new labeling information in the Warning and Precautions section advises prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

FDA explains that abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The FDA announcement is available at *www.fda.gov/Drugs/DrugSafety/ucm526206.htm*.

Latest FDA Drug Info Rounds Training Videos Available

Drug Info Rounds, a series of online videos by FDA, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the latest Drug Info Rounds video, "Extortion Scam," pharmacists discuss steps a potential victim could take if they receive a call from individuals posing as FDA and DEA agents. Drug Info Rounds is developed with contributions from pharmacists in FDA's CDER, Office of Communications, Division of Drug Information. All Drug Info Rounds videos can be viewed on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

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of these three technicians must be state-certified. If a pharmacist supervises only one or two pharmacy technicians, these technicians are not required to be state-certified. Pharmacy technicians do not include personnel in the prescription area performing only clerical functions, including data entry up to the point of dispensing, as defined in **Section 40-43-30(14).**

(c) For the purpose of dispensing by institutional pharmacies to institutional facility in-patients the pharmacist to technician ratio may not exceed a one to three employment ratio. The allowable employment ratio for a site is determined by comparing the number of pharmacists employed at the site to the number of pharmacy technicians employed at the site. The day to day operational pharmacist to technician personal supervision ratio is to be determined by the [PIC].

Per **Regulation 99-45,** violations of the technician ratio as outlined above may result in administrative citations and penalties. Separate citations and administrative penalties will be assessed for both the permit holder and the PIC.

Compounding Logs

Another common issue being found during recent routine inspections is improper documentation of formulas and logs in relation to compounds.

Section 40-43-86(CC)

(6) The pharmacist shall ensure that there are formulas and logs maintained either electronically or manually. Formulas must be comprehensive and include ingredients, amounts, methodology, and equipment, if needed, and special information regarding sterile compounding.

The pharmacist shall ensure that components used in compounding are accurately weighed, measured, or subdivided as appropriate at each stage of the compounding procedure to conform to the formula being prepared. Any chemical transferred to a container from the original container must be labeled with the same information as on the original container and the date of transfer placed on the label.

The pharmacist shall establish and conduct procedures so as to monitor the output of compounded prescriptions, i.e., capsule weight variation, adequacy of mixing, clarity, pH of solutions, and, where appropriate, procedures to prevent microbial contamination of medications purported to be sterile.

(7) The pharmacist shall label any excess compounded product so as to reference it to the formula used and the assigned control number and the estimated beyond-use date based on the pharmacist's professional judgment, appropriate testing, or published data. The product must be stored appropriately.

At the completion of compounding the prescription, the pharmacist shall examine the prescription for correct labeling.

(8) The pharmacist shall keep records of all compounded products for a period of time as other prescriptions as required by the Board of Pharmacy. These records must be readily available for authorized inspection during the retention period at the establishment. These records are subject to duplication by photocopying or other means of reproduction as part of the inspection.

Tips for Successful Patient Searches in SCRIPTS

By Christie Frick, RPh, PMP Director

Sometimes finding a patient in the South Carolina prescription monitoring program (PMP), known as the South Carolina Reporting & Identification Prescription Tracking System (SCRIPTS), can be a challenge. The main reasons are variances in the patient's name and date of birth. Any data in the patient name field other than the name can affect the search. For example, putting quotation marks around the name or adding numbers in the name can alter search results. Entering accurate data when filling prescriptions is vital to a successful PMP.

Following the steps below will provide the best results for patient searches in SCRIPTS. Every search should begin with the patient's full name and date of birth only. If no results are found, add the patient's zip code. Adding the zip code will assist the system in identifying patients with slight variances in spelling. Finally, using a partial name search is sometimes necessary. Just remember, it is imperative to check the partial name search boxes when using a partial name, and you must use at least three characters for the first and last names. Also note, the interstate search is disabled when doing a partial name search.

Recap of best search methods:

1. Patient's full first name, last name, and date of birth.
2. Patient's full first name, last name, date of birth, and zip code.
3. Patient's partial name, using at least three characters for first and last names (check the partial name boxes), and date of birth.

If you are still unable to find the patient, please contact PMP administrators at 803/896-0688 for assistance.

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