



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

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Update on DQSA

The president signed the Drug Quality and Security Act (DQSA) into law on November 27, 2013. At this time, the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy has not issued any opinions. However, the Board has been tracking this legislation since its introduction and is thoughtfully considering its application in relation to South Carolina pharmacy law.

Board representatives participated in the Inter-Governmental Working Meeting on Oversight of Compounding Pharmacies at Food and Drug Administration (FDA) in Silver Spring, MD, in March 2014. The Board is gathering information and will be analyzing how this legislation affects the practice of pharmacy in South Carolina. This will include the consideration of a memorandum of agreement between South Carolina and FDA. Please look on the Board's website for upcoming meeting dates of the Board's Compounding Committee where the legislation will be discussed. The work of the Compounding Committee will be presented to the full Board.

Approval of American Red Cross CPR Course

In accordance with the *South Carolina Board of Medical Examiners Protocol for Administration of Influenza Vaccine by Pharmacists*, the American Red Cross CPR course information and content was presented to the boards of pharmacy and medical examiners, and approved effective January 27, 2014, as an approved CPR course under the requirements of Section III(b) of the protocol for qualification as Basic Life Support Certification.

Update on Physician Assistant Prescriptive Authority for Schedule II Drugs

[28] PA PRESCRIBING QUESTION ADVISORY OPINION - The Board of Medical Examiners (BME) does not interpret the language of the PA act as amended to impose an obligation upon the pharmacy in question to verify compliance with §40-47-965. Licensees under the BME, supervising physicians and physician assistants are expected to comply with the medical practice act and are subject to discipline if they do not. Pharmacies may choose to implement their own verification procedures for prescriptions in accordance with the requirements of the Pharmacy Practice Act.

S.C. Code Ann. §40-47-965 was amended to allow physician assistants (PAs) to authorize prescriptions for an orally administered Schedule II controlled substance (CS) as defined in the federal Controlled Substances Act pursuant to the following requirements:

- (a) the authorization to prescribe is expressly approved by the supervising physician as set forth in the physician assistant's written scope of practice guidelines;
- (b) the physician assistant has directly evaluated the patient;

- (c) the authority to prescribe is limited to an initial prescription and must not exceed a seventy-two hour supply;
- (d) any subsequent prescription authorization must be in consultation with and upon patient examination and evaluation by the supervising physician, and must be documented in the patient's chart; and
- (e) any prescription for continuing drug therapy must include consultation with the supervising physician and must be documented in the patient's chart.

The PA must have a valid Drug Enforcement Administration (DEA) registration, and must prescribe in accordance with DEA rules. Schedule II CS can be prescribed if set forth in the written scope of practice guidelines. Prescriptions must meet all other state and federal laws.

Dispensing of Out-of-State Prescriptions and Orders

Please refer to South Carolina Code of Regulations R. 61-4, Section 114 for out-of-state PAs.

- (a) Prescriptions or orders for controlled substances from out-of-state practitioners may be filled in good faith by dispensers provided:
 - (1) The dispenser knows the recipient; or requires proper ID and notes such on the prescription;
 - (2) The dispenser makes a good faith inquiry concerning whether the order or prescription is legitimate;
 - (3) The prescription or order meets all of the requirements of this regulation and the Act, including whether the order or prescription is for legitimate medical purposes, and is within the regular course of practice of the practitioner;
- (4) **The practitioner who issued the prescription would ordinarily be entitled to issue prescriptions under SC law (i.e., physicians, dentists, veterinarians, and podiatrists are authorized to issue prescriptions; chiropractors, psychologists, etc, are not authorized to prescribe drugs);** and
- (5) The prescribing practitioner holds a valid individual Federal (DEA) controlled substance registration number in the state, district, or territory of origin of the prescription, or is exempt from such registration requirement under the provisions of Federal Regulation 21 CFR 1301.24.

Pharmacy Technician Renewals

The 2014 renewal notices were mailed to pharmacy technicians on or about April 15. You will be mailed a renewal notice with a **user ID** and a **password** to allow you to access the online renewal website. **If**

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New USP Webpage Answers Common Questions About USP Chapters <795> and <797>

In response to questions concerning United States Pharmacopeia-National Formulary (USP-NF) General Chapters <795> and <797>, USP has created a new frequently asked questions (FAQs) page on its website. The FAQs answer questions related to the Revision Bulletin for Chapter <795> that was issued on November 22, 2013, and became official on January 1, 2014. Among other topics, the FAQs address common questions regarding beyond-use dating and the differences between testing stability with strength (potency) or stability-inducing methods. The FAQs can be accessed at www.usp.org/support-home/frequently-asked-questions/compounding. Question four on the page includes a link to a USP article, "Strength and Stability Testing for Compounded Preparations."

Only You Can Prevent Look-Alike Sound-Alike Drug Names

 *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 Error Reporting Program. Report online at www.ismp.org. E-mail: ismpinfo@ismp.org.*

VESicare/Vesanoid Mix-Up. A prescriber's office sent an electronic prescription to the patient's pharmacy; the prescriber intended to prescribe **VESicare**® (solifenacin succinate) for overactive bladder but inadvertently selected **Vesanoid**® (tretinoin), which is used to induce remission of acute promyelocytic leukemia. The pharmacy technician entered the prescription for generic tretinoin; however, the pharmacy was unable to dispense the medication as the patient's pharmacy benefit manager required a prior authorization. The technician faxed a request and the prescriber's office replied back that VESicare was intended. Both of these products are available in 10 mg solid oral dosage forms, increasing the risk of confusion. Investigate strategies (eg, tall man letters) to differentiate these products on computer screens. Prescribers should include the indication for the drug with the prescription. As always, providing patient education, especially for new prescriptions, is a good strategy to intercept errors before they impact the patient.

Benazepril Confused With Benadryl. A pharmacist reported a mix-up between benazepril (**Lotensin**®) and **Benadryl**® (diphenhydramine). A patient faxed a request to the pharmacy to ask for her "benazpryl." The pharmacist who received the fax interpreted

it as Benadryl and placed a bottle of diphenhydramine in the bag for pick-up. Around this same time, the pharmacy went through a change in wholesaler and many manufacturers of generic products were changed. A few days later, a coworker of the patient picked up the medication (along with several others). The technician at the point-of-sale told the coworker that many of the manufacturers had changed recently and that some of the pills may look different. The patient received the diphenhydramine, filled her medication box with the capsules, and took diphenhydramine daily for three weeks before noticing she was unusually tired. When she brought the bottle back to the pharmacy, the error was recognized.

ISMP continues to receive reports of confused drug name pairs being involved in errors. ISMP wants to inform its readers of these drug name confusions so they may continue evaluating what measures they have in place to protect against these possible confusions.

Your Help Is Needed With Product Safety Testing. If you are a pharmacist, nurse, pharmacy technician, or other health care practitioner who is interested in furthering medication safety and error prevention, you can make a difference! Med-ERRS (a subsidiary of ISMP) is looking for assistance to help evaluate medication labels, drug packaging, and proposed drug names prior to submission by pharmaceutical and biotech companies for approval by Food and Drug Administration (FDA). The process is fun, simple, and easy. A small honorarium is paid. For more information or to sign up, visit www.med-errs.com and click on "Become a Reviewer."

FDA Issues Alert on Acetaminophen Products

In light of all the recent news alerts and warnings about the use of acetaminophen and acetaminophen-containing products, FDA issued a recommendation of importance to pharmacists, prescribers, and patients.

FDA recommends that health care providers consider prescribing combination drug products that contain 325 mg or less of acetaminophen. FDA also recommends that when a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit that he or she contacts the prescriber to discuss a product with a lower dose of acetaminophen. A two-tablet or two-capsule dose may still be prescribed, if appropriate. In that case, the total dose of acetaminophen would be 650 mg (the amount in two 325 mg dosage units). When making individual dosing determinations, health care providers should always consider the amounts of both the acetaminophen and the opioid components in the prescription combination drug product.

FDA, in its MedWatch Safety Alert, reports that, "There are no available data to show that taking more than 325 mg of acetaminophen per dosage unit provides additional benefit that outweighs the added risks for liver injury. Further, limiting the amount of acetaminophen per dosage unit will reduce the risk of severe liver injury from inadvertent acetaminophen overdose, which can lead to liver failure, liver transplant, and death."

In January 2011, FDA asked manufacturers of prescription combination drug products containing acetaminophen to limit the amount of acetaminophen to no more than 325 mg in each tablet or capsule by January 14, 2014. FDA requested this action to protect consumers from the risk of severe liver damage that

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can result from taking too much acetaminophen. More than half of manufacturers have voluntarily complied with FDA's request. However, some prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit remain available. In the near future, FDA intends to institute proceedings to withdraw approval of prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market.

Boards of pharmacy have received inquiries from pharmacists about remaining stock of the higher dose acetaminophen and what procedures should be followed. The FDA recommendation notes that pharmacists are advised to contact prescribers and request a change in the prescription. If the prescriber is not willing to make the change in the prescription, unfortunately, there is no clear cut recommendation at this point as to whether to dispense the higher dose acetaminophen product. It would appear that the higher dose acetaminophen-containing products will be regarded by FDA as unapproved and delisted from FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." Until this occurs, pharmacists must make a judgment regarding continuing to dispense the higher dose acetaminophen containing products in light of the FDA recommendation and concern for patient safety.

Some Rohto Eye Drops Products Recalled

The Mentholatum Company of Orchard Park, NY, has issued a voluntary recall of some Rohto® eye drop products due to a manufacturing review at the production facility in Vietnam involving sterility controls. The recall has been issued at the retail level and includes Rohto Arctic, Rohto Ice, Rohto Hydra, Rohto Relief, and Rohto Cool eye drops that were manufactured in Vietnam. Products made in other facilities are not affected by the recall. To date, there has been no evidence indicating the recalled products do not meet specifications, according to a press release.

The recalled products are sold over the counter at pharmacies and retail stores throughout the United States, and can be identified by the words "Made in Vietnam" on the side carton panel under the company name and address information as well as on the back label of the bottle. Lot numbers for the recalled products contain the letter "V." Distributors and retailers are being notified by letter to stop distributing the products and to follow the recall instructions provided by the company. Questions about the recall can be directed to The Mentholatum Company at 877/636-2677, Monday through Friday, 9 AM to 5 PM Eastern Time. FDA urges consumers and health care providers to report any adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information and Adverse Event Reporting Program. More information is available at www.fda.gov/Safety/Recalls/ucm382076.htm.

FDA Provides Compounding Law Implementation Information

FDA has provided implementation information on Title I of the recently passed Drug Quality and Security Act – known as the Compounding Quality Act – through its website.

Of note, FDA specifies that compounding entities may register as an outsourcing facility, which, under certain conditions, may be exempt from the Federal Food, Drug, and Cosmetic Act's (FD&C Act) approval and labeling requirements. Drugs produced by compounders that are not registered as outsourcing facilities must meet the conditions of Section 503A of the FD&C Act, which was amended by the new law, to qualify for certain exemptions.

The document adds, "If a compounded drug does not qualify for exemptions under either section 503A or 503B of the [FD&C Act], the compounded drug would be subject to all of the requirements of the [FD&C Act] that are applicable to drugs made by conventional manufacturers, including the new drug approval and adequate directions for use requirements." FDA also notes it will provide additional information about how the agency will interpret certain provisions of Section 503A at a later date.

The implementation information may be viewed at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm.

New e-LTP Fees Effective July 1, 2014

Supporting ongoing efforts to protect the integrity of its licensure transfer programs and to support the expansion of new technologies that are being implemented to enhance the program, the National Association of Boards of Pharmacy® (NABP®) is adjusting the fees for the Electronic Licensure Transfer Program® (e-LTP™).

Beginning July 1, 2014, the e-LTP fees will be adjusted as follows:

- ◆ The preliminary application and first state transfer fee will increase from \$350 to \$375
- ◆ Each additional state transfer will increase from \$50 to \$75
- ◆ Change of states will increase from \$50 to \$75
- ◆ Time extensions will increase from \$50 to \$75

The fees for e-LTP were last adjusted in 2010. More information about e-LTP is available in the Programs section of the NABP website at www.nabp.net. Additional questions about the fee adjustment may be directed to Neal Watson, licensure programs manager, at 847/391-4406, or at nwatson@nabp.net.



Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit www.MyCPEmonitor.net to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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you are a state-certified pharmacy technician, you must mail a copy of your current national certificate (from the Pharmacy Technician Certification Board) to the Board.

If you choose not to renew online, you may download the renewal application and renew by mailing the completed form and proper fees to the Board office. **Applications need to be received in the Board office by June 1, 2014. Pharmacy technicians who do not renew prior to June 30, 2014, will be assessed penalties and cannot work as pharmacy technicians until a 2014-2015 registration is in hand or disciplinary action may result.** 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.**

CE Reporting for Pharmacy Technicians

In order to renew online, you must certify that you have completed the required 10 hours of Accreditation Council for Pharmacy Education (ACPE) or Continuing Medical Education Category I continuing education (CE) each year. Of the 10 hours, a minimum of four hours must be “live” hours. CE must be taken **before** renewing a registration each year.

- ◆ **There are no exemptions to the CE requirement for technicians.**
- ◆ **Topics and formats of CE must include subject matter designed to maintain the professional competence of pharmacy technicians.**
- ◆ Technicians may take CE that is designated for pharmacists (P) or technicians (T).
- ◆ Use the ACPE universal program number (UPN) to determine if a CE is live (L), home (H), or combination (C). Example: Live CE will have an “L” in the UPN, eg, 430-000-092-021-L01.
- ◆ Hours completed in excess of the requirements may be carried forward in the next registration year but may not be carried forward for more than one registration year. It is the responsibility of the technician to keep up with excess hours that can be forwarded to the next registration year.

You cannot renew until you have completed the CE requirements.

After renewals are processed, a random CE audit will be conducted. If you are selected for the audit, please respond promptly. Disciplinary action will be taken if you cannot show that you completed the CE requirements or if the required CE is dated after your renewal is received in the Board office.

Facility Permit Renewals

The permit renewal notices and forms were mailed out in mid-April 2014, to the last known address on file in the Board office. If you are a permit holder and have not received your permit renewal application, contact the Board office immediately. The renewal notice you receive

will contain a **user ID** and **password** to allow you access to the online renewal website.

If you choose not to renew your permit online, you may download a renewal form from the Board’s website. Mail the completed form, along with proper fees, to the Board at PO Box 11927, Columbia, SC 29211. All applications must be received at the Board’s office prior to June 1, 2014, or a \$50 late fee will be assessed. After June 30, 2014, the facility permit will lapse.

Upon application for reinstatement, the facility will be assessed a penalty of \$10 a day until the permit is reinstated, plus the \$50 late fee and a new application fee. Depending upon the circumstances, the facility, the pharmacist-in-charge, and/or the pharmacists who practice in the pharmacy may be charged with violations of the practice act for operating without a permit pursuant to S.C. Code Ann. §40-43-83 resulting in discipline.

Pre-Printed Prescriptions

According to §40-43-86(E)(8) of the South Carolina Pharmacy Practice Act, you can have only **one drug** and set of instructions for each prescription blank. Board staff has seen an increase in the use of multiple drugs on pre-printed prescription blanks, especially in compounding pharmacies.

Common Violations on Pharmacy Inspections

- ◆ Expired drugs in active stock. §40-43-86(A)(16)(c)
- ◆ Unlabeled drugs in active stock. §40-43-86(A)(16)(c)
- ◆ Out of range refrigerator/freezer temperatures. §40-43-86(A)(16)(d)
- ◆ All supplies and equipment required for administration of influenza vaccine per state protocol must be in stock. Refer to Appendix B of the protocol. §40-43-190
- ◆ Incomplete repackaging and automated counting device logs. §40-43-86(I)(1)(b)
- ◆ Incomplete compounding logs and formulas. §40-43-86(CC)(6)
- ◆ Required documentation on prescription transfers. §40-43-86(G)

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