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News

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

*Published to promote compliance of pharmacy and drug law*

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## Board Elects Officers

At its June 2016 meeting, the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy elected Carole S. Russell, RPh, of Charleston, SC, as its chairperson. Russell is the pharmacist representing the First Congressional District.

Terry A. Blackmon, RPh, of New Zion, SC, representing the Sixth Congressional District, was elected vice chairperson. Each will serve a one-year term from July 1, 2016, until June 30, 2017.

## Congratulations to Board Appointee

The Board would like to congratulate Robert (Rob) Hubbard, RPh, of Clemson, SC, on his recent reappointment to the Board by Governor Nikki Haley.

Hubbard's six-year term will expire on June 30, 2022. He represents the Third Congressional District and will continue to provide valuable expertise regarding independent community pharmacy practice as well as experience as a consultant pharmacist, providing immunizations and compounding services. The Board would like to extend its gratitude to Hubbard for his continued hard work and commitment to the citizens of South Carolina and the profession of pharmacy.

## Board Welcomes New Staff Members

Doug Murray, PharmD, joined the Board staff as a pharmacist inspector on June 2, 2016. Murray received his bachelor of science degree and later his doctor of pharmacy degree from the University of South Carolina College of Pharmacy. He has spent the last 37 years with KershawHealth Medical Center, serving as the director of pharmacy for the last 21. Murray brings with him extensive experience in hospital, clinical, and consultant pharmacy, as well as extensive training and certification in leadership.

Traci Collier, PharmD, joined the Board staff as assistant administrator on April 18, 2016. Collier holds a doctor of pharmacy degree from Campbell University College of Pharmacy and Health Sciences. She has more than 20 years of experience as a pharmacist, with experience in retail, ambulatory care, and pharmacy systems, as well as pharmacy administration and management.

The Board and staff are happy to welcome both Murray and Collier and look forward to working with them in their new roles.

## Data Integrity for the Prescription Monitoring Program

*By Christie Frick, RPh, PMP Director*

The South Carolina prescription monitoring program (PMP), known as the South Carolina Reporting & Identification Prescription Tracking System (SCRIPTS), has experienced a huge increase in use in 2016. Since several third-party payers are now requiring providers to verify controlled substance history through the PMP before issuing a prescription, improved quality of dispensing data becomes essential. The quality of data that is sent to a PMP is dependent on the accuracy and completeness of the information provided by the dispenser. There are times when data is entered in the wrong field (eg, the date when a prescription is filled or dispensed may be accidentally placed in the patient's date of birth field), numbers are transposed, or an incorrect date of birth is entered to file insurance. Considering the thousands of data elements most pharmacies record daily, the data provided to a PMP is usually of good quality. However, the slightest error or omission may impact how a patient receives care.

Many of the questions SCRIPTS receives from health care providers are due to the fact that they cannot find a patient in the PMP. The most common reasons are variations in the patient's name and date of birth. Therefore, it is very important that dispensers be cognizant of what information they have in their pharmacy systems. It is best to use a patient's legal name instead of a nickname. Any notes or numbers in the patient name field will transfer to the PMP, making it difficult to find the patient. It is also important that the patient's correct date of birth is used. If a patient's date of birth is inaccurately recorded with an insurance company and pharmacy claims are denied, please have the patient correct it with the insurance company instead of using the incorrect date of birth in the pharmacy system.

To help ensure the best PMP patient searches, please verify the patient's name and date of birth are entered correctly in

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## FDA Calls for Review of Opioids Policy, Announces Action Plan

As part of a broad national campaign to address opioid abuse, dependence, and overdose, Food and Drug Administration (FDA) Deputy Commissioner for Medical Products and Tobacco, Dr Robert Califf, along with other FDA leaders, developed a comprehensive action plan to reassess the agency's approach to opioid medications. The objective of the plan is to "focus on policies aimed at reversing the epidemic, while providing patients in pain access to effective relief," indicates the FDA news release. FDA's plan is to:

- Re-examine the risk-benefit paradigm for opioids and ensure that the agency considers their wider public health effects;
- Convene an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties;
- Assemble and consult with the Pediatric Advisory Committee regarding a framework for pediatric opioid labeling before any new labeling is approved;
- Develop changes to immediate-release (IR) opioid labeling, including additional warnings and safety information that incorporate elements similar to the extended-release/long-acting (ER/LA) opioid analgesics labeling that is currently required;
- Update Risk Evaluation and Mitigation Strategy requirements for opioids after considering advisory committee recommendations and review of existing requirements;
- Expand access to, and encourage the development of, abuse-deterrent formulations of opioid products;
- Improve access to naloxone and medication-assisted treatment options for patients with opioid use disorders; and
- Support better pain management options, including alternative treatments.

FDA will also seek guidance from outside experts in the fields of pain management and drug abuse. The National Academies of Sciences, Engineering, and Medicine has been asked by FDA to help develop a framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of opioid misuse and abuse. The news release is available on FDA's website at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm484765.htm.*

## More Selected Medication Safety Risks to Manage in 2016

*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.*

### Manufacturer Drug Labeling, Packaging, Nomenclature – Per Liter Electrolyte Content on Various Sizes of Manufacturers' IV Bags

The way electrolyte concentrations are expressed on intravenous (IV) bags in volumes less than or greater than one liter has tripped up many practitioners over the years. Concentrations are listed per liter, not per container volume. For example, a 250 mL 0.9% sodium chloride injection container label lists the sodium chloride content as 154 mEq/1,000 mL, rather than 38.5 mEq/250 mL. Commercially available parenteral nutrition products available in containers greater than one liter also express the electrolyte ingredients "per liter."

An error occurred while a pharmacist was preparing a bag of 3% sodium chloride after the pharmacy unexpectedly ran out of the commercially available bags. The pharmacist mistakenly set the proportion up as 154 mEq/0.9% = x/3% and calculated that he needed 513 mEq of sodium chloride, when he actually only needed 256-257 mEq of sodium chloride for a 500 mL bag (77 mEq/0.9% = x/3%).

For single- and multiple-dose injectables, the United States Pharmacopeial Convention (USP) requires the strength per total volume as the primary, prominent display on the label, followed in close proximity by the strength per mL enclosed in parentheses. This should apply to large volume parenterals as well. Until it does, pharmacists who calculate electrolyte quantities should seek out an independent double check. Sufficient quantities of commercially available products should be used whenever possible. For products that routinely require admixture, an instruction sheet should be available to guide the process.

### Patient Education – Discharging Patients Who Do Not Understand Their Discharge Medications

Despite the importance of teaching patients about the medications to take after discharge, studies suggest health care providers are not successfully preparing patients for the transition home. Between 30% and 70% of patients make a medication error in the immediate weeks following hospitalization,[1-5] and the Centers for Medicare & Medicaid Services reports an average national hospital readmission rate of 17.5% to 19.5%.[6] The discharge process is often rushed and interrupted, making it difficult to ensure patients know what medications to take, the correct doses, and how to take them after discharge. Immediately prior to discharge is not an ideal time for education either, as patients may be overwhelmed with the amount of information being provided at once.

Medication errors that occur during the first few weeks after discharge from the hospital can cause significant harm. In fact, one study showed that almost a quarter of all post-discharge errors were considered serious or life-threatening, and that

most of these errors happened within the first 14 days after discharge.[5] The highest predictors of post-discharge errors included low health literacy and low subjective numeracy (self-reported measure of the ability to perform mathematical tasks and the preference for numerical versus prose information (ie, ordinary words)).[4]

Perhaps this risk is best addressed with a redesigned discharge process that facilitates the most effective means of teaching patients about their medications, initiating education earlier in the hospital stay, and providing post-discharge support.

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## USP Publishes Chapter on Handling Hazardous Drugs in Health Care Settings

A new general chapter, <800> *Hazardous Drugs—Handling in Healthcare Settings,* has been published as part of a suite of health care quality standards included in the *United States Pharmacopeia – National Formulary (USP–NF)* by USP to help prevent and/or limit hazardous drug exposures in health care. The standard applies to all health care personnel, such as physicians, nurses, veterinarians, pharmacists, and technicians, and all health care facilities where hazardous drugs are handled or manipulated, including their storage and distribution. Health care facilities have more than two years to conform to the new requirements and have until July 1, 2018, to implement the new standard, indicates a USP press release, which is available at *www.usp.org* in the News section. General Chapter <800> is available in both the First Supplement to *USP 39–NF 34* and the *USP Compounding Compendium.*

## FDA Provides Training Video on Keeping Medications Safe in Emergency Situations

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. In the February 2016 Drug Info Rounds video, "Emergency Preparedness – Keeping Medications Safe," pharmacists discuss educating patients about having a plan in place for emergency medication and medical supplies and the resources available for pharmacists to use when advising their patients. Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, 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.*

## FDA Requires Class-Wide Labeling Changes for IR Opioid Analgesics

FDA is requiring class-wide safety labeling changes for IR opioid pain medications, which will include a new boxed warning about the serious risks of misuse, abuse, addiction, overdose, and death. The announcement is part of the agency's effort to educate prescribers and patients about the potential risks related to opioid use. FDA is also requiring several safety labeling changes across all prescription opioid products to include additional information on the risk of these medications. The new requirements are part of a plan to reassess the agency's approach to opioid medications. The plan is focused on reversing the epidemic of abuse and overdose while still providing patients in pain access to effective relief, indicates the FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm491739.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery.*

Further, FDA is requiring updated labeling for all opioids (both IR and ER/LA products) to include safety information about potentially harmful drug interactions with other medicines that can result in a serious central nervous system condition called serotonin syndrome. In addition, updated labeling will include information about opioid effects on the endocrine system, including a rare but serious disorder of the adrenal glands (adrenal insufficiency) and decreased sex hormone levels (androgen deficiency). More information about these risks is available in FDA's Drug Safety Communication announcement, available at *www.fda.gov/Drugs/DrugSafety/ucm489676.htm.*

## FDA Issues Alert Regarding All Unexpired Sterile Drug Products Produced by Medaus Pharmacy

On April 1, 2016, FDA alerted health care providers and patients not to use products marketed as sterile from Medaus Pharmacy in Birmingham, AL. Insanitary conditions, including poor sterile production practices, were identified by FDA investigators during a recent inspection at Medaus' facility. The affected products were distributed nationwide and internationally. The alert applies to all unexpired drug products that are intended to be sterile. Health care providers should check their medical supplies, quarantine any drug products marketed as sterile from Medaus, and not administer them, indicates the FDA Safety Alert, available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsForHumanMedicalProducts/ucm493871.htm.*

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your pharmacy system. Also, having a phone number is extremely helpful when trying to identify a patient. A patient will often provide an accurate phone number so that he or she may be reached if there is a problem with his or her prescription. Additionally, a patient tends to keep the same phone number over longer periods of time even if he or she moves. In that instance, a phone number will be more valuable than a patient address. Also, prescribers now have access to a list of prescriptions that were dispensed under their Drug Enforcement Administration number. It is imperative that special attention is paid to the selection of the appropriate prescriber to ensure that the correct prescriber is selected in the pharmacy system.

With your assistance in entering complete and accurate information to be transmitted to the PMP, SCRIPTS will continue to be a valuable health care tool to assist providers and dispensers in patient care. Inaccurate information could impede a patient's ability to receive appropriate care.

Below is a prescription accuracy checklist.

- Patient's legal name in name field (no numbers, symbols, or nicknames)
- Correct gender
- Date of birth
- Phone number
- Suffix in correct field
- Correct prescriber

## Assigning Beyond-Use Dates for Nonsterile Compounded Products

*By Carole S. Russell, RPh, Chairperson of Compounding Committee*

The Board's Compounding Committee received a request for clarification on assigning beyond-use dates (BUDs) (expiration dates) to nonsterile compounds. The newly posted Non-Sterile Compounding Inspection Form states:

- BUDs are assigned from the day of preparation.
- BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of an [active pharmaceutical ingredient] and not later than six (6) months.
- BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).
- BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.
- BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.
- Extended BUDs are supported by testing data and professional judgment.

The Compounding Committee recommended to the full Board that compounders consider the last bullet point above and rely on literature citations and their own testing data and professional judgment to extend the expiration dates of nonsterile compounded products past those recommended by United States Pharmacopeia Chapter <795> as stated above. Therefore, reliable references on compounded formulation expirations may be considered for extension of BUDs.

The full Board accepted the recommendation of the Compounding Committee at its June 15, 2016 meeting. The Non-Sterile Compounding Inspection Form may be found on the Board website.

## Flu Season Is Approaching

Please review the current "Protocol for Administration of Vaccines by Pharmacists" and appendixes to familiarize yourself with the qualifications to administer vaccines by the protocol and the requirements of supplies and equipment to have on hand. The protocol may be found by visiting the Board website, *www.llr.state.sc.us/pol/pharmacy,* and clicking "Joint Pharmacist Administered Immunization Protocol (pdf)." Pharmacist inspectors will be inspecting to monitor compliance with the protocol.



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