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News

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

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Upcoming Board of Pharmacy Vacancy

If you live in the Sixth Congressional District and are interested in serving on the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy, you must meet the following requirements:

- Reside in the Sixth Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before December 1, 2017, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Sixth Congressional District. The term begins July 1, 2018, and ends June 30, 2024.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by January 15, 2018, to all pharmacists who have notified the Board that they reside in the Sixth Congressional District; and
- Certify as true and valid all ballots postmarked before February 15, 2018, and received by the Board office before February 25, 2018.

Before March 1, 2018, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election and the name of the person who the nominee will replace on the Board. The new member, when appointed by the governor, will take office on July 1 of that year.

If you are interested in becoming a candidate for this position or have any questions, please contact the Board office.

Compliance Tips – Reporting to the Board

According to §40-43-91 of the South Carolina Pharmacy Practice Act, there are many items that are required to be reported by a permit holder or individual pharmacists and pharmacy technicians.

A permit holder is required to report to the Board within **10 working days** the occurrences of any of the following:

1. Permanent closing;
2. Change in ownership, management, location, consultant pharmacists, or pharmacist-in-charge of a pharmacy; and
3. Change in employment of pharmacists or pharmacy technicians within a pharmacy permitted by the Board.

Individual licensed pharmacists and registered pharmacy technicians are required to notify the Board within **10 days** when there is a change in employment, listing the name, address, and permit number of the permitted facility where he or she was last employed, and the name, address, and permit number of the new facility along with the effective date. Please refer to the Notification of Employment Form on the Board's website.

Any licensed pharmacist or registered pharmacy technician who changes his or her mailing address must notify the Board within **10 days,** listing his or her name, license or registration number, and new mailing address. Please refer to the Notification of Employment Form on the Board's website.

According to §40-43-84(D), all interns shall notify the Board of any changes of employment or residence address within **10 days.**

Licensees can verify their current information online via the Licensee Lookup on the Board's website. Any violations found regarding reporting requirements may result in disciplinary action. All statutes and regulations are available on the Board's website.

As a reminder, a pharmacy cannot operate without a pharmacist-in-charge.

Updated In-State Permit Applications and Notification Forms

The Board has updated the in-state permit applications and notification forms in a fillable format on the Board's website. Forms can now be completed and sent electronically. The notification forms include the Pharmacy Employee Update Form and the Notification of Employment Form.

Continued on page 4

.Pharmacy Domain Signals Safety on the Web

With only 4% of websites selling prescription drugs online following United States pharmacy laws and practice standards, consumers seeking medications online are faced with the daunting task of finding a safe site. To assist consumers and those legitimate pharmacies with an online presence, NABP has streamlined its website verification programs. As of September 1, 2017, NABP is only offering the .Pharmacy Verified Websites Program and the Verified Internet Pharmacy Practice Sites® (VIPPS®) program, providing an easy choice for safety-minded consumers and pharmacies alike. The .Pharmacy Program, which was launched in 2014, enables qualified pharmacies and pharmacy-related businesses to register a web address with the .pharmacy domain. A .pharmacy domain (pronounced "dot pharmacy") is part of a website's address like ".com" or ".biz": *www.safe.pharmacy.* It enables people to identify an online pharmacy or pharmacy-related website as safe and legitimate. Since .pharmacy is a verified domain, websites are evaluated against a set of safety standards before an applicant is approved to register the domain.

In addition to showing patients that they operate a safe website, the .pharmacy domain allows pharmacies and related entities to advertise online through Google, Bing, and Yahoo! The .Pharmacy Program replaces the e-Advertiser Approval℠ and Veterinary-VIPPS® programs for those entities that are not eligible to apply for VIPPS but want to advertise with the search engines.

For more information about the .Pharmacy Program, including the application and domain name registration process and fees, visit *www.safe.pharmacy/apply.*

Quality Processes, Risk Management, and Culture: HR-Related Policies That Conflict With a Just Culture

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.*

As health care organizations move toward a "Just Culture," one of the areas potentially overlooked is human resource (HR)-related policies and procedures. Because these policies and procedures typically describe staff expectations, individual accountability, and disciplinary processes, they must be reviewed and often revised to ensure alignment with the tenets of a Just Culture. Otherwise, the journey will be long and unsuccessful if the policies are in conflict with a Just Culture.

In a Just Culture, HR-related policies and procedures regarding safety should hold all individuals equally accountable for the quality of their behavioral choices and should not focus on errors (which are not a behavioral choice), except for the expectation to report them. Policies and procedures should reflect a tone that is proactive toward risk identification, rather than reactive to errors and adverse outcomes. They should define human error as inadvertent, with a response of consoling individuals and conducting an investigation to determine how to redesign systems to prevent errors or detect them before reaching the patient. Policies and procedures should describe how to investigate a procedural violation to determine its causes and scope, and how to coach staff who have engaged in at-risk behaviors under the mistaken, but good faith, belief that the risks were insignificant or justified. For outcome-based duties related to a business code of conduct, such as arriving to work on time and wearing identification badges, policies should be clear about expectations and the actions that will be taken when they are not met. When describing reckless behavior (actions involving a conscious disregard of what an individual knows is a substantial and unjustifiable risk), remove any reference to "negligent" or "criminal" conduct as the basis for disciplinary action. Regrettably, mere human error can result in legal action (criminal negligence), but human error is never reckless behavior. Also ensure that event reporting and investigation policies and procedures support the tenets of a Just Culture.

While HR-related policies and procedures cannot guarantee that the desired actions will be realized in practice, they are a critical step for building an organizational foundation for success. Old punitive policies risk slipping back into an unjust culture. As organizations align actual practice with a Just Culture, they also need to align supporting policies and procedures.

AMA Task Force to Reduce Opioid Abuse Promotes Safe Storage, Disposal of Opioids

The American Medical Association (AMA) Task Force to Reduce Opioid Abuse released a resource document that urges physicians and other health care providers to promote safe storage and disposal of opioids and all medications. The AMA document indicates physicians and other providers need to:

- educate patients about safe use of prescription opioids;
- remind patients to store medications out of children's reach in a safe place; and
- talk to patients about the most appropriate way to dispose of expired, unwanted, and unused medications.

The AMA resource document and additional information can be found at *www.ama-assn.org/opioids-disposal.* Options for disposing of medications safely are available in the Initiatives section of the NABP website at *www.nabp.pharmacy* under AWAR$_X$E®.

CDC Guide Shows Importance of Physicians, Pharmacists Working Together

Collaborative care by at least two practitioners working together with the patient to accomplish shared goals has been shown to improve hypertension control and cholesterol management, especially when the team involves a physician or nurse and a pharmacist, notes a new guide developed by the Centers for Disease Control and Prevention (CDC) Division for Heart Disease and Stroke Prevention, in collaboration with the American Pharmacists Association and AMA. The guide,

Creating Community-Clinical Linkages Between Community Pharmacists and Physicians, discusses the importance of community-clinical linkages specific to community pharmacists and physicians and provides a framework for how community pharmacists and physicians might approach the development of a link to help patients. In addition, the guide provides examples of existing community-clinical linkages between community pharmacists and physicians and discusses common barriers to and potential solutions for creating community-clinical linkages. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/ccl-pharmacy-guide.pdf.*

FIP Report Shows Value of Pharmacists' Role in Consumers' Self-Care

Support from pharmacists will assist consumers in better health maintenance and greater health system efficiency, indicates a recently released report from the International Pharmaceutical Federation (FIP). The report, *Pharmacy as a gateway to care: Helping people towards better health,* discusses the various factors involved in individual self-care and the evidence that pharmacists can increase value for those individuals through many opportunities because informed, engaged, and educated consumers will play a greater and critical role in caring for themselves. The definition of self-care this report adopts is that of the World Health Organization: "the ability of individuals, families and communities to promote health, prevent disease, and maintain health, and to cope with illness and disability with or without the support of a health care provider."

The report is available at *www.fip.org/files/fip/publications/2017-04-Pharmacy-Gateway-Care.pdf.*

FDA Restricts Use of Codeine and Tramadol Medicines in Children; Recommends Against Use in Breastfeeding Women

As of April 2017, Food and Drug Administration (FDA) is restricting the use of codeine and tramadol medicines in children. FDA is also recommending against the use of these medicines in breastfeeding mothers due to possible harm to their infants. Codeine and tramadol medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in this age group. These medicines should also be limited in some older children. Single-ingredient codeine and all tramadol-containing products are FDA-approved only for use in adults.

As indicated in the FDA Drug Safety Communication available at *www.fda.gov/Drugs/DrugSafety/ucm549679.htm,* FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond their 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids. FDA is now adding:

- A *Contraindication* to the drug labels of codeine and tramadol, alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label, warning against its use in children younger than 18 years to treat pain after surgery from removal of tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants.

FDA urges health care providers to report side effects involving codeine- and tramadol-containing medicines to the FDA MedWatch program at *www.fda.gov/safety/medwatch.*

AVMA Warns Pharmacists and Pet Owners About Xylitol Pharmaceutical Products

Pharmaceutical products containing xylitol may be dangerous and fatal to dogs, warns the American Veterinary Medical Association (AVMA). Xylitol stimulates an insulin release that can result in severe hypoglycemia and fatal liver damage. Pharmacists and pet owners need to be aware of and protect against xylitol toxicoses, indicates AVMA. FDA-approved gabapentin capsules and tablets do not contain xylitol, but the liquid form does. In addition, xylitol-containing media might be used in compounding products if the pharmacist is uninformed about not using it.

AVMA urges pharmacists to not use xylitol-containing products when compounding for canine patients and to contact the veterinarian if a prescribed product contains xylitol. The veterinarian may be unaware that this sweetener is in the product. AVMA also encourages pet owners and caretakers to verify with the pharmacist when picking up their dog's medication at a human pharmacy that the medication does not contain xylitol. Xylitol-containing peanut butter should not be used to help a dog take its medication.

For more information, visit *atwork.avma.org/2017/05/30/eliminate-xylitol-from-canine-prescriptions.*

CDC Publishes Guide to Help Pharmacists Initiate CPAs With Prescribers

CDC published a guide that provides pharmacists with information and resources to empower them to initiate collaborative practice agreements (CPAs) with collaborating prescribers. The guide, *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team,* contains a sample CPA and sample language that can be customized by pharmacists and prescribers using their specific state laws to create a CPA. The guide includes an overview of state laws, including which states currently allow CPAs. The guide is available at *www.cdc.gov/dhdsp/pubs/docs/CPA-Team-Based-Care.pdf.*

DEA Releases New Edition of Drugs of Abuse Resource Guide

Drug Enforcement Administration (DEA) released the 2017 edition of *Drugs of Abuse, A DEA Resource Guide,* which serves as a resource on the most commonly abused and misused drugs in the US. The latest edition, which is an update to the 2015 publication, describes the consequences of drug use, a drug's effects on the body and mind, overdose potential, origin, legal status, and other key facts. It also includes the most current information on new and emerging trends in drug misuse and abuse, including fentanyl, other opioids, and synthetic drugs. The 2017 edition can be found at *www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf.*

Continued from page 1

Once you have completed the form, you can click on the submit button at the bottom of the form. The Board requests that all forms requiring a signature be emailed to contact.pharmacy@llr.sc.gov.

South Carolina's Response to the Opioid Epidemic

Governor Henry McMaster convened the first South Carolina Governor's Opioid Summit on September 6-7, 2017. The South Carolina Department of Alcohol and Other Drug Abuse Services partnered with the Department of Labor, Licensing, & Regulation, Department of Health and Environmental Control, Department of Health and Human Services, and other key stakeholders to provide a multitrack, interdisciplinary event. Over 600 people attended, representing law enforcement, clinicians, treatment providers, insurers, faith organizations, community advocates, and families impacted by the opioid epidemic. Governor McMaster, Dr Bertha Madras of the President's Commission on Combating Drug Addiction and the Opioid Crisis, and Dr Don Teater of the Centers for Disease Control and Prevention's panel on *Guidelines for Prescribing Opioids for Chronic Pain* provided keynote addresses. Presentations are now available to download at *www.scopioidsummit.org*. The Opioid Summit was accredited to provide continuing education hours to many of the state's licensed health care professionals.

The Department of Labor, Licensing, & Regulation was heavily involved in planning the Opioid Summit. Terry Blackmon, chairperson of the Board of Pharmacy; Sam McNutt, president of the State Board of Nursing; and Stephen Gardner, president of the State Board of Medical Examiners, jointly presented "Practical Pointers for Prescribers, Pharmacists, and Impaired Professionals in South Carolina." Their panel highlighted newly released joint prescribing guidelines, which have also been adopted by the State Board of Dentistry, as well as a new website that provides information about naloxone: *www.NaloxoneSavesSC.org*. Participating pharmacies may now dispense naloxone to patients at risk of an opioid overdose and their caregivers without a prescription pursuant to a joint protocol developed by the State Board of Medical Examiners and the Board of Pharmacy. The Department of Labor, Licensing, & Regulation's licensed professionals are not immune to the disease of addiction and may seek help through the South Carolina Recovering Professional Program (RPP). Links to the Joint Revised Pain Management Guidelines, naloxone resources, and RPP are available at *www.llr.state.sc.us*.

Data Integrity for the PMP

By Christie Frick, RPh, PMP Director

The South Carolina prescription monitoring program (PMP), known as the South Carolina Reporting & Identification Prescription Tracking System (SCRIPTS), continues to experience a huge increase in use. Section 44-53-1645 of the South Carolina Code of Law Unannotated, which became effective in May of this year, states:

> A practitioner, or the practitioner's authorized delegate, shall review a patient's controlled substance prescription history, as maintained in the prescription monitoring program, before the practitioner issues a prescription for a Schedule II controlled substance.

With mandatory PMP consultation in our state, improved quality of dispensing data becomes essential. The quality of data 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 accidently placed in the patient date of birth field), numbers are transposed, or an incorrect date of birth is entered to file insurance. Considering the thousands of data elements that 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 received at SCRIPTS are from health care providers who 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 system. 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 to use the patient's correct date of birth. If a patient's date of birth is inaccurate 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.

Most recently, SCRIPTS has received many inquiries from veterinarians who cannot locate their patients in the PMP. When filling prescriptions for animals, always use the animal's first name, the owner's last name, and the animal's date of birth.

To help ensure the best PMP patient searches, please verify the patient's name and date of birth are entered correctly in your pharmacy system. Also, having a phone number is extremely helpful when trying to identify patients. Patients will often provide an accurate phone number so that they may be reached if there is a problem with their prescription. Additionally, patients tend to keep the same phone number over longer periods of time even if they move. In that instance, a phone number will be more valuable than a patient address.

This year, prescribers were issued reports that provide metrics of their prescribing habits of opioids. This report has prompted many prescribers to check their prescribing history in the PMP. 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. Prescribers are increasingly finding prescriptions that they did not issue filled under their Drug Enforcement Administration number and name. The majority of these are caused by the dispenser putting the wrong prescriber's

Continued on page 5

Continued from page 4

name on the prescription. If you are aware of an error, it must be corrected in the PMP as well as in your pharmacy dispensing system. If you are not sure how to make corrections, please contact your corporate office or call the Clearinghouse help desk at 1-844/572-4767 for assistance.

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.

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
- For animals: animal's first name, owner's last name, animal's date of birth

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