



Kentucky Board of Pharmacy

Published to promote compliance of pharmacy and drug law

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601



Happy Holidays!!!!
From
Kentucky Board of Pharmacy
Board Members and Staff



2018 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2018. The Kentucky Board of Pharmacy will send out a **postcard** the first week of January 2018 as a reminder (in addition, an email reminder will be sent to all pharmacists with a valid email address on file with the Board). This year the Board encourages you to renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website at www.pharmacy.ky.gov.**

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) CEUs (15 contact hours) annually between **January 1 through December 31**, pursuant to 201 Kentucky Administrative Regulations (KAR) 2:015 Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2018 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2018. The Board will send out a **postcard** the first week of February 2018 as a reminder (in addition, an email reminder will be sent to all pharmacy technicians with a valid email address on file with the Board). The Board encourages you to renew your registration online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website at www.pharmacy.ky.gov.**

Board Meeting Dates and Locations 2018

At its September 6, 2017 meeting, the Board approved the following dates and locations of the Board meetings in 2018:

- ◆ Wednesday, January 17, 2018 – Board Office*
- ◆ Wednesday, March 14, 2018 – Sullivan University College of Pharmacy
- ◆ Wednesday, May 16, 2018 – Board Office*
- ◆ Wednesday, July 11, 2018 – Board Office*
- ◆ Wednesday, September 12, 2018 – University of Kentucky College of Pharmacy
- ◆ Wednesday, October 17, 2018 – Board Office*
- ◆ Wednesday, December 12, 2018 – Board Office

*A work session will follow the Board meeting.

2018 CAPTASA Conference

The 2018 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 26-27, 2018, at the Embassy Suites in Lexington, KY. For information on this conference, please visit www.CAPTASA.org or contact David Thomas at 502/595-8059 or digsr222@gmail.com.

KASPER Reporting of Buprenorphine: Use DEA Registration

The Drug Enforcement and Professional Practices (DEPP) Branch of the Kentucky Office of Inspector General has requested that pharmacists report the Drug Enforcement Administration (DEA) registration number of the prescriber to Kentucky All Schedule Electronic Prescription Reporting (KASPER) when reporting buprenorphine and/or buprenorphine combination products, not the DATA waiver number ("X" DEA). The KASPER system is designed to run and generate report information based on the prescribers' DEA registrations. In order to compile complete and accurate

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.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_xE®.

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,

News to a particular state or jurisdiction can only be ascertained such state or jurisdiction.

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/dhbsp/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/dhbsp/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.

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reporting data, it is imperative that the DEA registration and only the DEA registration is submitted. When another number is substituted for the DEA registration, such as the DATA waiver number (X DEA), it results in incomplete and sometimes unidentifiable information.

Please contact DEPP at 502/564-2888 with any questions or concerns.

Partial Filling of Schedule II Controlled Substances

DEPP updated 902 KAR 55:095 on September 20, 2017, to allow partial filling of a prescription for a Schedule II controlled substance (CS) at the patient's or prescriber's request. There are now three situations in which a Schedule II CS prescription may be partially dispensed.

1. If the pharmacy is unable to supply the Schedule II CS, the pharmacist may make a notation of the quantity dispensed on the face of the prescription or in the electronic prescription record and dispense the remaining portion of the prescription within 72 hours of the first partial filling. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist must notify the prescriber and no further quantity can be dispensed without obtaining a new prescription.
2. A prescription for a Schedule II CS written for a patient who is in a long-term care facility (LTCF) or terminally ill may be dispensed in partial quantities if:
 - ◆ The pharmacist records on the prescription that the patient is “terminally ill” or an “LTCF patient.”
 - ◆ The pharmacist records on the back of the prescription or on another appropriate record the following:
 - ◇ Date of the partial dispensing;
 - ◇ Quantity dispensed;
 - ◇ Remaining quantity authorized to be dispensed; and
 - ◇ Identification of the dispensing pharmacist.
 - ◆ The pharmacist contacts the prescriber prior to dispensing the partial quantity if there is any question whether the patient is terminally ill. Both the pharmacist and the prescriber have a corresponding responsibility to ensure that the patient is terminally ill.
 - ◆ Total quantity dispensed in all partial dispensings does not exceed the quantity prescribed.
 - ◆ Partial dispensing occurs at the pharmacy where the original prescription is on file.
 - ◆ No dispensing occurs beyond 60 days from the date of issuance of the prescription.

3. A prescriber or a patient who is not terminally ill or in an LTCF may request that a partial quantity of a Schedule II CS prescription be dispensed as long as the following conditions are met:

- ◆ No dispensing occurs beyond 30 days from the date the prescription was issued.
- ◆ The pharmacist must record on the back of the written prescription or on another appropriate record the following:
 - ◇ Date of the partial dispensing;
 - ◇ Quantity dispensed;
 - ◇ Remaining quantity authorized to be dispensed; and
 - ◇ Identification of the dispensing pharmacist.
- ◆ Total quantity dispensed in all partial dispensings does not exceed the quantity prescribed.
- ◆ The partial dispensing occurs at the pharmacy where the original prescription is on file.

If the pharmacy computer system does not allow refills of Schedule II CS prescriptions, a new prescription number may be used for each partial dispensing.

201 KAR 2:076: Compounding

The Board has updated 201 KAR 2:076 to require compliance with the January 2014 version of United States Pharmacopeia (USP) Chapter <795> and the June 2008 version of USP Chapter <797> by January 1, 2018. The Board has created a process by which specified portions submitted by a pharmacist may be waived. The Board may waive the requirement of any specified portion of USP Chapters <795> and <797> upon a showing of good cause and in balancing the best interest of the public health, safety, and welfare. Any waiver request submitted by a pharmacist will be considered by the Board at the next regularly scheduled meeting.

Schedule II Prescriptions for LTC and Terminally Ill Patients: Update

DEPP updated 902 KAR 55:095 on September 20, 2017. Pharmacies are no longer required to obtain an original written prescription within seven days of the faxing of a Schedule II CS prescription for a long-term care (LTC) or hospice patient or for a prescription for direct parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion administration of a compounded Schedule II CS to a patient. The faxed Schedule II CS prescription may now serve as the original.

Oral Schedule II CS prescriptions are allowed for LTC and hospice patients for immediate administration. For these prescriptions, the following apply:

- ◆ The amount prescribed and dispensed must be limited to the amount adequate to treat the patient for the time period in which immediate administration is needed.

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- ◆ The prescription must be communicated by the prescriber, not by an agent.
- ◆ The prescription must contain all the required information of a Schedule II CS prescription with the exception of the prescriber's signature.
- ◆ The pharmacist must immediately reduce the prescription to writing.
- ◆ The pharmacist must make a reasonable effort to validate the prescription if the prescriber is unknown to the pharmacist.
- ◆ A written prescription must be delivered to the pharmacy within seven days of verbal authorization of the Schedule II CS for immediate administration.
 - ◇ A fax of the verbally authorized Schedule II CS is not allowed; it must be a written or e-prescription.
 - ◇ The date of the oral authorization and the statement "Authorized for Emergency Dispensing" must be on the written or e-prescription.
 - ◇ The written or e-prescription must be delivered in person, by mail, or electronically.
 - ◇ If the written or e-prescription is not delivered within seven days, the pharmacist must notify the nearest DEA office.
- ◆ Central fill pharmacies may not dispense oral Schedule II CS prescriptions.

Steve Hart Retires From State Government

Board Executive Director Steve Hart announces his retirement from the Board, effective December 31, 2017. Steve has been employed by the Board for 13

years. Steve was hired on December 1, 2004, as an inspector for Louisville, KY, and south-central Kentucky. In April 2009, Steve was promoted to inspections and investigations coordinator, a position he served until August 1, 2015, when he was appointed by the Board to his current position as executive director.

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These Newsletters will be used in administrative hearings as proof of notification.** Please read them carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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The *Kentucky Board of Pharmacy News* is published by the Kentucky Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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