June 2017

Kentucky Board of Pharmacy News

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Pharmacy Renewal Deadline June 30, 2017

Pharmacy permits expire June 30, 2017. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2017. If you want to send in a paper renewal, this form may be printed from the Kentucky Board of Pharmacy's website at *www.pharmacy.ky.gov.* Contact the Board office if you have questions concerning the renewal process. A new pharmacy application must be completed if the resident pharmacy has an address change, a relocation within the current premises of the existing permit, or a change of ownership. A pharmacy application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. All paper renewal applications must be in the Board office by the close of the day on June 30, 2017.

Craig Martin

Dr Craig Martin, MD, has been appointed by Governor Matt Bevin to the Board for a four-year term expiring December 31, 2020. Dr Martin currently serves in a joint role as director of professional practice development at the University of Kentucky for both the College of Pharmacy and HealthCare Pharmacy Services. Dr Martin resides in Georgetown, KY.

Ron Poole

Mr Ron Poole has been appointed by Governor Bevin to the Board for a four-year term expiring December 31, 2020. Mr Poole is in independent pharmacy practice, owning four pharmacies in western Kentucky. Mr Poole resides in Central City, KY.

Legislative Highlights 2017

Immunizations: Senate Bill (SB) 101, signed into law by Governor Bevin, gives pharmacists increased authority to administer vaccinations recommended by the Centers for Disease Control and Prevention via protocol beginning at age nine. Current Kentucky law allows pharmacists to administer only the flu vaccine to children starting at age nine, and this change brings all other age-appropriate vaccinations in line with the flu vaccine.

Consolidation of Prescription and Refills: SB 205, signed into law by Governor Bevin, allows a pharmacist in his or her professional judgment to consolidate a prescription for a non-controlled maintenance medication written with refills into no more than a 90-day supply. A pharmacist can currently consolidate prescription medication for a 30-day supply with two refills, but he or she must contact the prescriber before making such a change.

Pharmaceutical Drug Supply Chain: House Bill 364, signed into law by Governor Bevin, allows the Board to create classifications to parallel the Drug Quality Security Act (DQSA) of 2013. The Board will be developing the licensure requirements for third-party logistics providers, outsourcers (503B), and virtual manufacturers. The law also gives a classification for medical gas wholesalers. There will be changes in the wholesale distributor license, with the DQSA moving away from pedigrees to a track-and-trace model. Watch for more news on changes to regulations and applications over the next few weeks.

Board Reorganization

Board President Scott Greenwell and Board Executive Director Steve Hart met with the Kentucky Secretary of the Public Protection Cabinet on Tuesday, April 25, at his request. The meeting included representatives from the Kentucky Board of Chiropractic Examiners, Kentucky Board of Dentistry, Kentucky Board of Podiatry, and professional organizations representing the Board of Pharmacy. The meeting was to reveal an upcoming executive order to move the mentioned boards from general government to the Public Protection Cabinet to reorganize these boards under one executive director and general counsel, based on the state of Kentucky's response to the United States Supreme Court ruling in the North Carolina State Board of Dental Examiners case. Each board will become a five-member board through attrition of its current members. The Board of Pharmacy will also become a five-member board (four pharmacists and one consumer member). The Board will function much the same way as it has in the past. It will still be able to promulgate regulations and discipline and issue licenses and permits. The discipline and regulatory promulgation will be under the oversight of the executive director of this umbrella group. Board staff will continue to perform their duties as they currently do. There will not be an executive director at the Board level, but an administrative coordinator who will function as the current Board executive director. An administrative coordinator would not have to be a pharmacist per this order. The order is planned to be issued at the end of May 2017 or the early part of June 2017.

Gabapentin Becomes a Schedule V Controlled Substance in Kentucky

Amendments to 902 Kentucky Administrative Regulations (KAR) 55:035 were finalized and adopted on March 3, 2017. The regulation may be accessed on the Kentucky Legislative Research Commission website at *http://www.lrc.ky.gov/kar/902/055/035.htm.*

For questions, please call the Drug Enforcement and Professional Practices Branch at 502/564-7985.

continued on page 4

DEA Changes Registration Renewal Process

As of January 2017, Drug Enforcement Administration (DEA) will no longer send its second renewal notification by mail. Instead, an electronic reminder to renew will be sent to the email address associated with the DEA registration.

In addition, DEA will retain its current policy and procedures with respect to renewal and reinstatement of registration. The policy is described below.

- If a renewal application is submitted in a timely manner prior to expiration, the registrant may continue operations, authorized by the registration, beyond the expiration date until final action is taken on the application.
- DEA allows the reinstatement of an expired registration for one calendar month after the expiration date. If the registration is not renewed within that calendar month, an application for a new DEA registration will be required.
- Regardless of whether a registration is reinstated within the calendar month after expiration, federal law prohibits the handling of controlled substances or List 1 chemicals for any period of time under an expired registration.

Additional information is available on the DEA website at *www.deadiversion.usdoj.gov/drugreg/index.html.*

ISMP Medication Safety Self Assessment for Community/Ambulatory Pharmacy

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.*

Pharmacists in community and ambulatory settings can now access a newly revised tool that will help them review and improve their medication safety practices. The 2017 Institute for Safe Medication Practices (ISMP) Medication Safety Self Assessment® for Community/Ambulatory Pharmacy is designed to help pharmacies evaluate their current systems, proactively identify opportunities for improvement, and track their efforts over time.

An advisory panel of experts helped ISMP update items from the 2001 community/ambulatory self-assessment as well as add items to address new practices and processes, including the pharmacist's evolving role in immunization administration. New research findings about error prevention and emerging technologies previously not widely adopted are also covered.

The self-assessment contains items that address the use of medications in the clinical setting, many of which are on the ISMP list of high-alert medications. Many of the items included represent system improvements and safeguards that ISMP has recommended in response to analysis of medication errors reported to the ISMP Medication Errors Reporting Program, problems identified during on-site consultations with health care organizations, and guidelines in medical literature.

The self-assessment is divided into 10 key elements that most significantly influence safe medication use. Each element is defined by one or more core characteristics of a safe pharmacy system that further define a safe medication use system. Each core characteristic contains individual self-assessment items to help evaluate success with achieving each core characteristic.

ISMP recommends that each pharmacy site convene its own team of staff members (ie, pharmacist(s), technician(s), and student pharmacist(s)) to complete this comprehensive assessment and use the information as part of its ongoing safety and quality improvement efforts. An online form has been provided to help participants organize and score their responses. **Important:** The self-assessment should be completed in its entirety by staff and managers who work within the pharmacy, not by off-site managers on behalf of the pharmacy.

When the self-assessment is completed, respondents can generate reports showing how their pharmacy answered each item and how they scored on each as a percentage of the maximum possible score. The pharmacy can then use its scores to identify and prioritize opportunities for its safety plan of action.

ISMP is not a regulatory or standards-setting organization. As such, the self-assessment characteristics represent ideal practices and are not purported to represent a minimum standard of practice. Some of the self-assessment criteria represent innovative practices and system enhancements that are not widely available in pharmacies today. However, the value of these practices in reducing errors is grounded in expert analysis of medication errors, scientific research, or strong evidence of their ability to reduce errors.

To view, download, and print the PDF of the assessment, which includes the introduction, instructions for use, self-assessment items, and definitions, visit *https://www.ismp.org/Survey/NewMssacap/Index.asp.*

CDC Publishes Resource to Foster Use of JCPP Pharmacists' Patient Care Process

A publication intended to encourage the use of the Joint Commission of Pharmacy Practitioners (JCPP) Pharmacists' Patient Care Process was released by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention. In *Using the Pharmacists' Patient Care Process to Manage High Blood Pressure: A Resource Guide for Pharmacists,* CDC calls on pharmacists and other health care providers to implement the Pharmacists' Patient Care Process model to reduce heart disease and stroke in the United States. Pharmacists can have a positive effect on population health by providing patient care services and participating in collaborative practice agreements and continuing education (CE) programs, notes the CDC publication. The publication is available at *www.cdc.gov/dhdsp/pubs/docs/pharmacist-resource-guide.pdf.*

The National Association of Boards of Pharmacy® (NABP®) is a member of JCPP and endorses the Pharmacists' Patient Care Process. In its September 2015 newsletter (page 167), NABP discusses integrating the JCPP Pharmacists' Patient Care Process to improve medication outcomes and promote consistency in patient care service delivery. Additional information about JCPP is available at *https://jcpp.net.*

FDA Issues Final Guidance on Repackaging Drugs by Pharmacies and Registered Outsourcing Facilities

In January 2017, Food and Drug Administration (FDA) issued a final guidance for industry titled, "Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities." This guidance describes the conditions under which FDA does not intend to take action for violations of certain provisions of the Federal Food, Drug, and Cosmetic Act when a state-licensed pharmacy, a federal facility, or an outsourcing facility repackages certain human drug products. The guidance is available at *www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM434174.pdf.*

Electronic or written comments may be submitted at any time for this final guidance following the instructions provided in the *Federal Register,* which can be found at *www.federalregister.gov/documents/2017/01/13/2017-00723/repackaging-of-certain-human-drug-products-by-pharmacies-and-outsourcing-facilities-final-guidance.*

CriticalPoint Launches QP503A Certification Program for Sterile Compounding in 2017

In 2017, CriticalPoint, LLC, launched its QP503A certification program for sterile compounding personnel. Specifically, CriticalPoint is offering the QP503A Certification and the QP503A Master Certification, which may be earned after obtaining the basic QP503A Certification. Participants will gain vital knowledge and skills to successfully plan, develop, and operate a 503A pharmacy sterile compounding operation.

The QP503A Certification involves a didactic program of home study, live training, and practicum activities accompanied by required objective personnel and cognitive testing. The QP503A Master Certification requires participants to demonstrate their ability to apply their QP503A Certification training in actual work settings and produce measurable changes in sterile compounding processes resulting in improved patient safety.

Additional details about these programs and the certification requirements are available online at *www.criticalpoint.info/wp-content/uploads/CriticalPoint-QP503A-Certification.pdf.*

PTCB Suspends Implementation of Planned 2020 Accredited Education Requirement for Pharmacy Technicians

The Pharmacy Technician Certification Board (PTCB) is suspending the implementation of the accredited education requirement for pharmacy technicians. In 2013, PTCB announced that the requirement would take effect in 2020, but PTCB has "determined that additional deliberation and research are needed to address stakeholder input, develop supporting policy, and conduct further study of technician roles," said Larry Wagenknecht, BPharm, chair of the PTCB Board of Governors, and chief executive officer of the Michigan Pharmacists Association, in a news release. The role of pharmacy technicians is evolving, and PTCB is taking steps to support the pharmacy community.

PTCB recently completed a job analysis study to collect data on current roles and responsibilities of pharmacy technicians across all practice settings to update PTCB's Pharmacy Technician Certification Exam and is in the process of developing advanced certification programs. In addition, PTCB hosted an invitational conference in February 2017 where pharmacy leaders and stakeholders examined entry-level standards and provided information to help determine future plans for implementing PTCB program changes.

PTCB's news release is available at *www.ptcb.org* in the News Room section.

ASOP Global Spreads Awareness About Illegal Online Drug Sellers and Counterfeit Medications

Alliance for Safe Online Pharmacies (ASOP Global) partnered with several nonprofit organizations, including NABP, to launch a campaign to raise awareness of illegal online drug sellers and counterfeit medications. The campaign encourages dialogue among health care providers and patients regarding where patients purchase their medications, especially if patients are buying them online.

After offering the CE course "Internet Drug Sellers: What Providers Need to Know" to over 1,000 health care providers, ASOP Global found that less than 10% of providers reported they were "very aware" counterfeit prescription drugs are being sold on the internet and only 1.4% said they regularly discuss the risks of illegal internet drug sellers with patients. ASOP Global Executive Director Libby Baney said, "After completing the course, however, there was a ten-fold increase in the expected frequency in which providers planned to discuss the risks associated with buying prescription medicines online with their patients and what they can do to avoid physical and financial harm."

For more information about the campaign, visit *www.BuySafeRx.pharmacy.*

New Interactive Map Tracks Pharmacist Vaccination Laws

A new resource – an interactive 50-state map tracking pharmacist vaccination laws between 1990 and 2016 – was published by The Policy Surveillance Program, A LawAtlas Project. The map, which is available at *http://lawatlas.org/datasets/pharmacist-vaccination,* explores laws that give pharmacists authority to administer vaccines and establish requirements for third-party vaccination authorization, patient age restrictions, and specific vaccination practice requirements, such as training, reporting, record keeping, notification, malpractice insurance, and emergency exceptions. The Policy Surveillance Program is administered by Temple University Beasley School of Law.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

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continued from page 1

Effective July 1, 2017, all gabapentin products will be Schedule V controlled substances (CS) in Kentucky. All applicable provisions of Kentucky Revised Statutes (KRS) Chapter 218A, 902 KAR Chapter 55, and other licensure Board regulations will apply to gabapentin. Please review all CS security, storage, record keeping, inventory, prescribing, and dispensing requirements. This document is not intended to be an all-inclusive overview.

Authorized practitioners **must** be properly licensed and registered with Drug Enforcement Administration (DEA) to order the dispensing of a CS. Therefore, only DEA-registered practitioners may issue prescriptions for gabapentin or order the direct administration or dispensing of gabapentin to a patient. After July 1, 2017, any existing orders for gabapentin (including prescription refills) issued by a practitioner **without** a DEA registration will no longer be valid and **may not** be administered or dispensed. Existing orders for gabapentin that were issued by a practitioner **with** a DEA registration will not be affected, except that existing gabapentin prescriptions will expire after five refills or six months from the date the prescription was issued, whichever comes first. It will not be legal to distribute gabapentin samples in Kentucky. Please note that physician assistants are not authorized to prescribe CS in Kentucky.

How Does Moving Gabapentin to Schedule V Affect Prescribing Practitioners?

- Advanced practice registered nurses will no longer be able to prescribe gabapentin unless they have a DEA license.
- Gabapentin dispensed in Kentucky will appear on Kentucky All Schedule Electronic Prescription Reporting (KASPER) reports.
- Prescribers must comply with the legal standards for prescribing CS promulgated by their licensure board.
- Prescribers may issue written or oral prescriptions for gabapentin.
- Written prescriptions must be issued on a CS Security Prescription Blank or transmitted to a pharmacy using a certified electronic prescribing application.
- Prescriptions for gabapentin may include up to five refills and expire six months after the date issued.
- Prescriptions for gabapentin may not be pre-signed or post-dated.

How Does Moving Gabapentin to Schedule V Affect Dispensing Practitioners?

- Only authorized practitioners may directly dispense CS to patients. In Kentucky, no mid-level practitioners are authorized to directly dispense CS.
- Practitioners who directly dispense gabapentin **from** their stock **to** a patient, including both administering and dispensing, shall transmit the required dispensing data to the KASPER system in accordance with KRS 218A.202 and 902 KAR 55:110.
- Practitioners must perform an initial gabapentin inventory on or after July 1, but before July 30, 2017.
- Practitioners must include gabapentin in their biennial CS inventory.
- Practitioners must comply with the legal standards for dispensing CS that were promulgated by their licensure board.

How Does Moving Gabapentin to Schedule V Affect Pharmacies?

- Pharmacies must perform an initial gabapentin inventory on or after July 1, but before July 30, 2017.
- Pharmacies must include gabapentin in their biennial CS inventory.
- Dispensing data for gabapentin must be transmitted to the KASPER system in accordance with KRS 218A.202 and 902 KAR 55:110.
- Gabapentin dispensing data will not successfully upload to KASPER if the prescriber does not have a DEA number, so please ensure that your computer system reflects the correct prescriber data.
- Refills on existing gabapentin prescriptions **may** be filled if the prescriber is authorized to prescribe Schedule V CS **and** the prescriber has a DEA number **and** the prescription has not been refilled more than five times **and** the prescription was written less than six months prior.

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.

Steve Hart, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Amy Suhajda - Communications Manager