



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

Pharmacy Technician Registration Renewal by March 31, 2015

The registration renewal process is available online at www.pharmacy.ky.gov. At the completion of the application process and payment of the \$25 registration fee, you will print your certificate of registration. If you are unable to complete the process online, you may print a registration renewal application form from the Kentucky Board of Pharmacy website.

Registrations must be received in the Board office by close of business on Tuesday, March 31, 2015 (not postmarked). All online registrations must be completed before 12:01 AM (EDT), April 1, 2015. Your registration will be valid until March 31, 2016.

As a reminder, a pharmacy technician must renew his or her pharmacy technician registration and **must not apply as a new pharmacy technician**, whether he or she has changed pharmacies or is attempting to renew his or her pharmacy technician registration late.

Pharmacists-in-charge (PICs), please check that all pharmacy technicians have renewed their pharmacy technician registrations before the March 31, 2015 deadline.

Pharmacy Renewal Deadline June 30, 2015

Pharmacy permits expire June 30, 2015. A pharmacy permit can be renewed online. A postcard explaining the renewal process will be mailed to each pharmacy on or about May 1, 2015. If you want to send in a paper renewal, this form may be printed from the Board's website at www.pharmacy.ky.gov. If you have any questions concerning the renewal process, please contact the Board office. Please be reminded that if your pharmacy has an address change, relocation within the current premises of the existing permit, or ownership change, you must complete a new pharmacy application. A pharmacy application with a United States Post Office Box address only will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is June 30, 2015. All paper renewal applications must be in the Board office by the close of the day Tuesday, June 30, 2015 (not postmarked).

Board Fees

Effective January 15, 2015, the Board no longer charges a fee for the following:

- ◆ PIC changes
- ◆ Address corrections

- ◆ Reprints of all licenses, intern cards, and permits issued by the Board
- ◆ Name changes

Invoices received prior to January 15, 2015, are still valid and should be paid promptly. If you have any questions, please contact the Board office.

Regulation Updates

During 2014, two regulations were amended. First, 201 KAR 2:030 License Transfer was amended. This amended regulation no longer requires a pharmacist reciprocating from another state to have worked a year in that state. He or she can apply for a Kentucky pharmacist license by initial examination by score transfer up to 90 days after passing the North American Pharmacist Licensure Examination®. After 90 days has passed, he or she can apply for reciprocation. For more information on the regulation or the process for initial licensure by examination or reciprocation, please visit the Board's website at www.pharmacy.ky.gov.

The second regulation that was amended is 201 KAR 2:040 Registration of Pharmacist Interns. This amended regulation requires a pharmacist intern to notify the Board within 30 days of any charge of a) a felony, b) a violation of drug laws, or c) a violation of alcohol laws. To view 201 KAR 2:040, please visit the Board's website at www.pharmacy.ky.gov.

Michael A. Burleson Announcement

Michael A. Burleson, RPh, executive director of the Board, announced at the January 14, 2015 Board meeting that he would be retiring effective August 1, 2015. Mike graduated from the University of Kentucky College of Pharmacy on May 11, 1974. He became a Kentucky-licensed pharmacist in July 1974, and for the next 30 years, his pharmacy practice included working at two hospital pharmacies and three chain pharmacies, and for 19 years, he was a co-owner of an independent pharmacy in Henderson, KY. He was hired as executive director of the Board on October 1, 2004, and has held that position since that time. Mike plans on playing more rounds of golf each year and traveling with Cheryl, his wife, to the 10 states they have not visited, but most importantly, enjoying their kids and grandkids.

Bryan Proctor Announcement

Bryan Proctor recently resigned on January 23, 2015. Bryan served the Board as an administrative specialist since September 2008. Bryan accepted the position of director of ministry relations with 127 Worldwide, Inc, based out of Raleigh, NC.

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DEA Finalizes Rule on CS Prescription Drug Disposal

In September 2014, Drug Enforcement Administration (DEA) published its final rule, titled the Disposal of Controlled Substances, that allows some DEA registrants to modify their registration to become authorized collectors. Under the new rule, some DEA registrants, including retail pharmacies, hospitals/clinics with an on-site pharmacy, manufacturers, distributors, reverse distributors, and narcotic treatment programs, may modify their registration with DEA to become authorized collectors. The final rule implements the Secure and Responsible Drug Disposal Act of 2010, which authorized DEA to develop and implement regulations that would allow authorized entities other than law enforcement to collect unused and unwanted prescription drugs, including controlled substances (CS), for disposal purposes. Proper disposal of unused prescription medication is a key method of preventing and reducing prescription drug abuse. The final rule took effect on October 9, 2014.

The full rule is available on the *Federal Register* website at www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances.

System-Based Causes of Vaccine Errors

 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.

Immunizations are widely recognized as one of the most successful and cost-effective health interventions ever introduced worldwide. However, errors with vaccines can result in an unintended and unrecognized source of vulnerability. While the immediate impact of a vaccine-related error on a patient may not be serious, such errors may render the vaccine ineffective or reduce its effectiveness, leaving patients unprotected against serious diseases such as hepatitis A, hepatitis B, diphtheria, tetanus, measles, cervical cancer, and many others. In September 2012, ISMP (in cooperation with the California Department of Public Health) established the ISMP National Vaccine Errors Reporting Program (VERP) to collect data about the type of vaccine errors occurring and the reasons they occur. In ISMP's November 28, 2013 newsletter (www.ismp.org/sc?id=307), ISMP provided a summary analysis of error reports submitted to the ISMP VERP during its first year. The vaccinations that are most frequently associated with errors included *Haemophilus influenzae* type b conjugate (Hib); diphtheria and tetanus toxoids, acellular pertussis

adsorbed, and inactivated poliovirus (DTaP-IPV); tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis adsorbed (Tdap); diphtheria, tetanus toxoid, and acellular pertussis adsorbed (DTaP); hepatitis A (HepA); hepatitis B (HepB); human papillomavirus quadrivalent (types 6, 11, 16, and 18), recombinant (HPV4); zoster; and measles, mumps, rubella, and varicella (MMRV). The most common contributing factors associated with the reported vaccine errors included mistakes in choosing age-dependent formulations of vaccines intended to prevent the same diseases; unfamiliarity with the vaccine, particularly its dose, dosing schedule, age specifications, route of administration, and the vaccine's various components (eg, combination vaccines, diluents, and powder); failure to check or verify the patient's age, health record, or state registry; similar vaccine names and abbreviations; similar and confusing vaccine labeling and packaging; unsafe storage conditions (eg, stored near other similar vaccines or unwanted temperature fluctuations); and expiration dates not noticed or misunderstood.

Practice Recommendations. Involve the patient or parent(s)/caregiver(s) in a vaccine verification process by:

- 1) Documenting the vaccine name, formulation (pediatric or adult, if applicable), lot number, and expiration date on the patient's vaccine record **prior** to preparation/administration of the vaccine,
- 2) Bringing the vial and syringe or the prefilled syringe along with the immunization record into the exam room,
- 3) Asking the patient or parent/caregiver to simultaneously verify the information on the immunization record while a health care provider reads the information on the label aloud,
- 4) Asking the patient or parent/caregiver if the verified vaccine is what he or she expected to be administered (based on an immunization schedule provided to the patient or parent/caregiver previously),
- 5) Preparing and administering the vaccine immediately after verification, and
- 6) Documenting the vaccine on the patient's medical record.

FDA Warns of Growing Network of Rogue Wholesale Drug Distributors

Through a new educational program called Know Your Source, Food and Drug Administration (FDA) is warning pharmacists and other health care providers to watch for counterfeit and unapproved drugs. Aimed at protecting patients from unsafe and ineffective drugs, the program advises providers to only purchase drugs from wholesale drug distributors licensed in their state. Further, FDA offers tips to providers to protect patients, including being wary of offers too good to be true, and ensuring that all drugs received are FDA-approved medications.

Another way that pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Those wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous



review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo a site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the United States drug supply.

Additional information about the VAWD program is available in the Programs section of the NABP website. Know Your Source is available at www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm389121.htm.

PTCB Implements Changes to CE Requirements

In 2015, the Pharmacy Technician Certification Board (PTCB) will implement two changes in recertification requirements for certified pharmacy technicians (CPhTs) in accordance with its certification program changes announced in 2013. First, any continuing education (CE) hours earned by a CPhT will need to be pharmacy technician-specific in order to qualify toward recertification. Second, PTCB will reduce the number of allowable "in-service" CE hours from 10 to five. PTCB's certification program changes are intended to support and advance improved patient care and safety throughout pharmacy practice, a PTCB press release indicates. The changes are the result of a PTCB initiative that began with a 2011 summit on future directions for pharmacy technicians.

Additional information can be accessed on the PTCB website at www.ptcb.org.

Security Guidelines Available as Rate of Pharmacy Robberies Still a Concern

Nationally, pharmacy robberies dipped slightly from 745 in 2012, to 713 in 2013, according to a report compiled by *Drug Topics* using DEA statistics. The 10 states that had the most robberies are in stark contrast to other states that had no robberies (South Dakota, North Dakota, and Alaska) or as few as one or two (such as Montana and Illinois), reports *Drug Topics*. However, fueled by the prescription drug abuse epidemic, pharmacy robberies still pose a threat to the safety of personnel and customers. The report lists the top 10 states that had the most pharmacy thefts in 2013. Arizona experienced the most pharmacy robberies in 2013 with 77 incidents, and Indiana took second place with 71 robberies. The report, titled "Top 10 states for pharmacy robberies," may be found at <http://drugtopics.modernmedicine.com/drug-topics/content/tags/arizona/top-10-states-pharmacy-robberies?page=full>.

NABP partnered with DEA to create an educational pamphlet identifying key strategies pharmacists can take to secure their stores against robberies, which can be downloaded at www.deadiversion.usdoj.gov/pubs/brochures/pharmtheft.pdf. In addition, some boards of pharmacy have identified best practices for preventing pharmacy theft, and have supported these practices through regulations or recommendations for their licensees. For example, the New Jersey State Board of Pharmacy's *Pharmacy Security Best Practices* document recommends that all Schedule II and III CS be stored in a "safe or substantially constructed steel cabinet that is locked at all times," with only licensed pharmacists having access.

Additional recommendations include annual pharmacist-in-charge self-assessments and interfacing with prescribers and customers, among others. The best practices document can be downloaded from the New Jersey Consumer Affairs website at www.njconsumeraffairs.gov/press/05012013.pdf.

Private organizations have also developed resources to assist pharmacies in improving security. One such resource is the RxPATROL program, which works with law enforcement, the pharmacy community, and security professionals to maintain a database containing detailed information about pharmacy robberies and other losses. In addition, the RxPATROL website, www.rxpatrol.com, provides training videos and a pharmacy security checklist.

Further, NABP members directed the Association to convene a task force to review strategies that states have taken to prevent theft and drug diversion. The Task Force to Examine Strategies for Preventing and Reacting to Pharmacy Robberies and Thefts met on October 22-23, 2014, to discuss these issues.

Assured Brand Naproxen Tablets Recalled Due to Packaging Error

In October 2014, Contract Packaging Resources of Greensboro, NC, a drug repackaging company, issued a voluntary recall of nearly 12,000 boxes of Assured brand naproxen sodium tablets because some cartons contain bottles of 200 mg ibuprofen softgels instead, a press release posted to the FDA website indicates. The packaging error affected boxes of Assured brand naproxen sodium tablets 220 mg, 15 count (Lot Number FH4102A), which were distributed to and sold at Dollar Tree stores and on the Dollar Tree website. Contract Packaging Resources is contacting customers to arrange for replacement of all recalled products. Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm419769.htm.

Martin Avenue Pharmacy Issues Voluntary Recall for All Sterile Compounded Preparations

Martin Avenue Pharmacy, Inc. of Naperville, IL, issued a voluntary recall for all in-date compounded sterile preparations due to a lack of sterility assurance in August 2014. Following a recent FDA inspection that revealed "quality control procedures that present a risk to sterility assurance," the company issued the recall out of an abundance of caution, indicates a news release posted to the FDA website. Martin Avenue Pharmacy supplied compounded sterile preparations to offices of licensed medical professionals and individuals in multiple states including Illinois, Wisconsin, Ohio, Michigan, Florida, Alabama, and Texas until August 20, 2014. A full list of recalled products is available on the Martin Avenue Pharmacy website (registration required). FDA urges consumers and health care providers to report adverse events or side effects related to the use of these products to FDA's MedWatch Safety Information Adverse Event Reporting Program.

More information is available on the FDA website at www.fda.gov/Safety/Recalls/ucm412431.htm.

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Best wishes from the Board to Bryan; his wife, Stephanie; and their children.

DEA Disposal Regulations

The Controlled Substances Act (CSA) was amended by the Secure and Responsible Drug Disposal Act of 2010 (Disposal Act). This gave Drug Enforcement Administration (DEA) the authority to promulgate new regulations, within the framework of the CSA, to allow ultimate users to deliver unused pharmaceutical controlled substances (CS) to appropriate entities (including pharmacies) for disposal in a safe and effective manner consistent with effective controls against diversion. This took effect as of October 9, 2014. On the Board's website are three fact sheets: Disposal Regulations: Registrant Fact Sheet; Disposal Act: Long-Term Care Facility Fact Sheet; and Disposal Act: General Public Fact Sheet. Please visit the Board's website at www.pharmacy.ky.gov and then click on Important Updates.

Compliance Corner

Kentucky Religious Exemption Immunization Form

Recently, the Board office and the pharmacy and drug inspectors have received a number of calls asking the question whether a pharmacist has to sign a Kentucky religious exemption immunization form. 902 KAR 2:060 Section 3(8)(a) states that "a healthcare provider, pharmacist, local health department, or other licensed healthcare facility administering immunizations, shall, upon receipt of a written sworn statement from the parent or guardian of a child, issue a 'Certificate of Religious Exemption' from the requirements of Section 2 of this administrative regulation, in compliance with KRS 214.036."

Advanced Practice Registered Nurse Guidelines

The Board office receives many questions regarding Advanced Practice Registered Nurse (APRN) prescriptive authority for CS. APRNs, pursuant to Kentucky law, have the following prescriptive authority for CS: KRS 314.011 and 201 KAR 20:059 (see actual laws for further details).

Drug	Days or Supply	Refills
Schedule II	72 hours	No
Schedule II psychostimulants*	30 days	No
hydrocodone combinations	30 days	No

Schedule III	30 days	No
diazepam	30 days	No
clonazepam	30 days	No
lorazepam	30 days	No
alprazolam	30 days	No
carisoprodol	30 days	No
Schedule IV-V	Not to exceed six-month supply	Not to exceed six-month supply

*APRN must be certified in psychiatric-mental health and serving in a health facility or regional mental health-intellectual disability services program.

New Pharmacy and Drug Inspector

Caleb Benningfield, RPh, began working as a pharmacy and drug inspector for the Board on February 1, 2015. He is a 2008 graduate of the University of Kentucky College of Pharmacy. His pharmacy background includes work as a pharmacist in the retail community and hospital settings. He lives in Bowling Green, KY, with his wife, Laura, who is also a pharmacist. They have two children: Charlie (age three) and Emily (age eight months). Caleb will be inspecting the western region of the state.

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 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.