



KENTUCKY BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Pharmacy Permit, 3PL, and Outsourcer Facility Renewals

Pharmacy permits, third-party logistics provider (3PL) licenses, and outsourcer facility licenses expire June 30, 2024. You may renew your permit/license online at www.pharmacy.ky.gov. To begin the renewal process, you must have your Kentucky permit/license number and five-digit postal code. Pharmacies must verify or provide a complete listing of all licensed or registered employees. Renewal applications may be printed from the Kentucky Board of Pharmacy website. Permit/license renewals must be received in the Board office by close of business on June 30, 2024 (not postmarked). All online renewals must be completed before 12:01 AM (EDT) on July 1, 2024. All renewals received after June 30, 2024, will be assessed a delinquent fee.

Governor Andy Beshear Appoints New Board Member

Kimberly Croley, of Corbin, KY, has been appointed to the Board to serve the vacant term expiring January 1, 2026. Dr Croley is the director of pharmacy and clinical pharmacist for Laurel Senior Living Communities in London, KY. She and her pharmacy team provide care to residents in the skilled nursing facility and two retirement/assisted living facilities. Dr Croley is a preceptor for several colleges of pharmacy, including our own University of Kentucky College of Pharmacy and Sullivan University College of Pharmacy. She has been named preceptor of the year at both schools and was also named a master preceptor in the 2017 National Master Preceptor Recognition Program by the American Association of Colleges of Pharmacy. She has been board-certified in geriatric pharmacy since 2005. Dr Croley is an active

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member of the American Pharmacists Association (APhA), serving on various committees and in the House of Delegates, and just finished a six-year stint on the Government Affairs Committee. She is an active member of the American Society for Clinical Pathology (ASCP), serving on various committees. Dr Croley has been named a fellow by both APhA and ASCP. She is also an active member of the Kentucky Pharmacists Association, serving on various committees and in multiple leadership roles, including as president twice. Dr Croley was appointed to the American Council for Pharmacy Education Board of Directors by APhA in 2020 to serve a six-year term and is currently treasurer for the board. Dr Croley has served the Kentucky Board of Pharmacy on the Advisory Council for eight years and was selected for the updated council, currently serving as chair. She has served the Board on the Regulations Committee as well.

The Board Welcomes a New Pharmacy and Drug Inspector

The Board is excited to welcome Taylor Rostova as the pharmacy and drug inspector for the greater Jefferson County area. In addition to Jefferson County, her territory includes the following counties: Bullitt, Carroll, Hardin, Meade, Oldham, and Trimble. Taylor grew up in Munfordville, KY, where she started her pharmacy career at the local pharmacy, Clark Drugs. Taylor graduated with a biology degree from Western Kentucky University in 2015. She continued her education at Sullivan University College of Pharmacy, earning her doctor of pharmacy degree. After completion of the three-year program at Sullivan College of Pharmacy, Taylor pursued a year of post-graduate training at UofL Health – Jewish Hospital. Post-residency, Taylor decided to further her post-doctorate education and obtained Board Pharmacotherapy Specialty Certification. Taylor has a passion for diverse patient care, practice management, leadership, and education. She is excited about the opportunity to leverage her skills and knowledge to support the advancement of pharmacy practice standards and ensure the delivery of safe and effective patient care across the health care landscape.

ThoughtSpan Technology

Selected by the Board, ThoughtSpan, LLC, has begun working on a new licensing system. The Board anticipates this all-inclusive platform will allow the user more control pertaining to applications, modifications to records, submission of documents, and many more capabilities available online. This will minimize the requirement of hard copy documents that the end user will need to submit manually to the Board office. Transactions such as designated representative changes, address changes for individuals, employment/employee modifications, and more will be handled online. The Board looks forward to keeping you updated as it navigates through this process.

2024 Legislative Update

House Bill (HB) 293 – An Act Relating to Kratom

This law prohibits a retailer from selling kratom to anyone under the age of 21. It would also require kratom products to be manufactured as unadulterated products, and all products would be required to be labeled with ingredients. The Kentucky Department for Public Health within the Commonwealth of Kentucky Cabinet for Health and Family Services (CHFS) will be responsible for enforcement.

SB 188 – An Act Relating to Patient Access to Pharmacy Benefits

Senate Bill (SB) 188 establishes that the minimum reimbursement requirements in the first two years will be no less than the National Average Drug Acquisition Cost (NADAC), a dispensing fee of \$10.64 for independent pharmacies, and for chain retail pharmacies, they will receive no less than the NADAC. Mail-order pharmacies would not be subject to the minimum reimbursement requirements.

After the first two years, or whenever the Department of Insurance (DOI) completes a cost-of-dispensing study, all pharmacies open to the public will be reimbursed the NADAC plus the cost of the dispensing fee determined by the study. The study will be updated every two years. The Board will work in partnership with the DOI on the development of regulations pertaining to the data required by pharmacies for this cost-of-dispensing study.

The law also prohibits pharmacy benefit managers from requiring patients to use mail-order pharmacies and from steering or incentivizing patients to use a pharmacy in which they have ownership. The bill established network adequacy requirements where a patient must have access to a pharmacy within 30 miles of the patient's home.

HB 386 – An Act Relating to Purchase Limits for Pseudoephedrine

HB 386 amends existing law on pseudoephedrine purchasing limits to eliminate the current purchase restriction of no more than 24 grams annually and allows consumers to purchase more than three packages in a single transaction. The 30-day purchasing limit of 7.2 grams remains law.

HB 829 – An Act Relating to Medical Cannabis

In the 2023 legislative session, the General Assembly passed legislation legalizing medical cannabis but delayed its implementation until January 1, 2025. HB 829 amends existing medical cannabis law to allow the CHFS Office of Medical Cannabis to issue licenses to grow, distribute, and sell medical marijuana in order to give these entities authority to be prepared to implement medical marijuana when the law takes effect on January 1, 2025. The bill added a pharmacist, appointed by the Kentucky Board of Pharmacy, to the Board of Physicians and Advisors.

HB 274 – An Act Relating to the Practice of Pharmacy

This law amends Kentucky Revised Statutes 315.010 and 315.205 to allow pharmacists to administer vaccines to children five years of age or older pursuant to prescriber-approved protocols with the consent of a parent or guardian.

Pharmacy Requirements Under DSCSA

The Drug Supply Chain Security Act (DSCSA) was federally enacted in 2013 to protect patients from potentially counterfeit prescription medications. The law addresses the distribution of most prescription drugs from the manufacturer to the dispenser (ie, the pharmacy). DSCSA requires pharmacies to do three things:

1. Confirm that your trading partners are appropriately licensed or registered.

Manufacturers and repackagers are required to register with Food and Drug Administration (FDA). 3PLs and wholesale distributors currently report state licensure to FDA. Pharmacists can verify this information on FDA's [website](#). The Board requires licensure and registration for wholesale distributors and 3PLs operating within the state or shipping into Kentucky. Pharmacists can verify this information on the Board's website. Keep in mind that the Board's [website](#) lists the names of entities' parent companies, which may differ from the names that companies "do business as."

2. Receive and maintain product-tracing documentation.

With each shipment of prescription drugs, the pharmacy must receive transaction documentation including transaction information, transaction history, and a transaction statement. This information may be received electronically or by paper. The pharmacy must maintain this documentation for six years.

3. Identify, investigate, and report suspect and illegitimate drugs.

Pharmacies must be able to identify, quarantine, and investigate suspect prescription drugs to determine if the drugs are illegitimate. If they are illegitimate, the pharmacy must then report this to the wholesaler, manufacturer, and FDA.

Pharmacies should exercise extra vigilance in situations where there is a higher risk of suspect drugs entering the supply chain. Examples of high-risk scenarios include:

- Drugs being sold for "too good to be true" prices.
- Drugs in high demand due to drug shortages or public health emergencies.
- Drugs that have historically been counterfeited or diverted (eg, HIV drugs, antipsychotics, and cancer drugs).
- Purchases from first-time or unknown suppliers, especially if done over the internet. Pharmacies should be wary of sources that send unsolicited sales offers.

- Products that arrive with missing or incomplete information, such as incomplete shipping information or missing package inserts, lot numbers, expiration dates, or National Drug Codes.
- Products that are abnormal in appearance. This may include smudged or misspelled labels, unusual coloration or shape of the package, missing security features, or dosage forms that are different in color, shape, or imprint from the normal product.

For more information on DSCSA and pharmacies' responsibilities, visit the FDA [website](#).

This [website](#) also includes more information on pharmacies' responsibilities when selling drugs to prescribers or other pharmacies.

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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