KENTUCKY BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

CE Reminder

The continuing education (CE) period is March 1, 2025, through February 28, 2026. All courses and/or providers must be Accreditation Council for Pharmacy Education accredited or approved by the Kentucky Board of Pharmacy. Pharmacists shall keep valid records, receipts, and certifications of continuing pharmacy education programs completed for three years and submit the certification to the Board on request. The Board utilizes NABP's CPE Monitor® to conduct CE audits. Please check your profile periodically and prior to license renewal to avoid any discrepancies. Courses with a completion date on or after March 1, 2026, will not automatically be accepted as proof of completion.

Board Member Reappointments

Effective January 1, 2026, Governor Andy Beshear has reappointed Meredith Figg and Kimberly Croley, representing licensed pharmacists, to the Board. Further, Governor Beshear has reappointed Jason Belcher, representing citizens-at-large, to the Board. Their terms will expire on December 31, 2029.

In Memoriam – Steve Hart

The Board joins the commonwealth's pharmacy community in mourning the loss of Billy "Steve" Hart (January 29, 1958 – September 26, 2025), a devoted pharmacist, former inspector, and executive director whose impact on pharmacy practice in Kentucky was both profound and lasting. Steve's career began in community pharmacy and grew into a broad legacy that spanned retail, hospital, and consulting work. Eventually, his leadership brought him to the Board, where he first served as a pharmacy and drug inspector and later as executive director.

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In Memoriam – Steve Hart

(cont)

In these roles, Steve was widely respected for his professionalism, steady judgment, and dedication to public safety. His influence helped shape pharmacy regulations, foster transparency, and ensure the highest standards of patient care throughout the state.

A Tennessee native who came to love Kentucky as home, Steve also lived a rich life outside of pharmacy. He enjoyed golf, hunting, fishing, and cheering on the Tennessee Volunteers and St. Louis Cardinals. Most of all, he cherished time spent with his wife, Lisa, their children, and grandchildren.

The Board extends its heartfelt condolences to Steve's family, friends, and colleagues. His absence leaves a space that cannot be filled, but his legacy will continue to guide and inspire us all.

With gratitude and remembrance, we honor Steve Hart – a true steward of pharmacy and community.

Cost of Dispensing Data Collection Begins January 1, 2026, With a Reporting Deadline of February 28, 2026

Pursuant to 2025 Senate Bill 188, the Board is required to collect data from ambulatory pharmacies located in Kentucky, which will be submitted to the Department of Insurance to conduct a cost of dispensing study. Starting on January 1, 2026, and every other year thereafter, pharmacies will be required to report data from the previous calendar year prior to March 1. (eg, Data from 1/1/25 through 12/31/25 submitted by 2/28/26.) Data required for submission are found in Forms A and B.

Cost of Dispensing: Form A Required

All data shall be reported to the Board electronically through the Board's Licensure Gateway on Reporting Form A, Pharmacy Cost of Dispensing Data. Data may be submitted in the aggregate for pharmacies with multiple locations.

Pharmacy Claims Data: Form B Optional

If the pharmacy chooses to submit these data, the data should be reported to the Board electronically through the Board's Licensure Gateway on Reporting Form B, Pharmacy Claims Data.

Instructions to Submit

Beginning January 1, all pharmacies located in Kentucky will have the "Cost of Dispensing Report" option added to their Permit Options. To submit data, log in to the Licensure Gateway portal, complete the collection form in Microsoft Excel (forms will be available for download in the gateway portal), and begin the upload process. *Note: Only Excel format will be accepted.* Any pharmacy that has already submitted the forms in the portal for another pharmacy location or is exempt from reporting should select "Not Applicable" to close the report.

Which Pharmacies Are Required to Submit Data?

Ambulatory pharmacies located in Kentucky must submit data. An ambulatory pharmacy is defined as a pharmacy that is open to the general public and dispenses outpatient prescription drugs. The Board will not require an ambulatory pharmacy to submit data for pharmacies that do not bill third party plans and they may select "not

Cost of Dispensing Data Collection Begins January 1, 2026, With a Reporting Deadline of February 28, 2026 *(cont)*

applicable" to complete the reporting requirement. Lastly, pharmacies may submit data for multiple locations in one report submission. All other pharmacy locations may select "not applicable" so long as their data were already submitted. Full instructions can be found here.

Regulation Update: Pharmacy Technician Responsibilities

Recent amendments to 201 Kentucky Administrative Regulations (KAR) 2:045 and 2:165 have impacted pharmacy practice and how technicians assist pharmacists in that practice. These changes clarify technician roles, delegate new responsibilities to certified technicians, and maintain patient safety through pharmacist oversight.

201 KAR 2:045

The amendment to 201 KAR 2:045 – the administrative regulation outlining the qualifications, responsibilities, and scope for pharmacy technicians in the commonwealth – aims to clarify technician roles, ensure appropriate pharmacist oversight, and centralize requirements for initial pharmacy technician applications.

Key Changes:

1) This amendment consolidates information regarding the initial technician registration application. In addition to general identification and contact information, the applicant must also provide information concerning disciplinary actions, out-of-state licensures, national certifications, and their intent to seek registration as a charitable pharmacy technician. The most significant change to this portion of the regulation is the requirement for all technicians to register for an NABP e-Profile®.

Creating an NABP e-Profile

NABP e-Profile provides a centralized location to store career and compliance information in an easily accessible and secure platform. When preparing to register, have this information ready: legal name, profession, sex, race/ethnicity, date of birth, Social Security number, address, phone number, and any licenses. To register for an e-Profile, follow this link and the steps below.

i. After following the link, select "Individual or Business Customers."

ii. Select "Create Login."

iii. Enter a valid email address to serve as your username and follow the prompts to verify your account and create a password that meets the specified requirements.

iv. Upon successful completion of these tasks, select "Go to Login" to return to the main login screen.

v. Entering your new username and password will direct you to the NABP e-Profile dashboard.

vi. Select "Create Individual E-Profile" to set up your account.

vii. Choose your profession based on your current status.

viii. Enter personal information and contact details. Make sure to enter your name exactly as it appears on your ID.

ix. Review your information for accuracy and accept the terms and conditions.

x. Your new NABP e-Profile ID will appear on the screen.

xi. Select "Finish e-Profile" to fill in license and education details.

2) The amended regulation distinctly separates certified and registered technicians and clarifies the roles and responsibilities of each with the corresponding level of supervision required.

Registered Pharmacy Technicians

Registered technicians are those who have completed the Board's registration process but do not hold a national certification. Registered technicians may perform a wide range of functions within the pharmacy,

Regulation Update: Pharmacy Technician Responsibilities *(cont)*

including compounding activities, order entry, label preparation, counting medications, making an offer to counsel, refill authorizations with certain limitations, automated dispensing tasks, and a few additional tasks under immediate supervision as defined in Kentucky Revised Statute (KRS) 315.010 (12). A registered technician may also perform order entry from a location outside the permitted pharmacy under electronic supervision as defined in 201 KAR 2:480. Lastly, under general supervision as defined in KRS 315.010 (27), a registered technician may administer vaccines and point-of-care tests if training and CPR requirements are met, as well as stock an automated dispensing system in residential hospice facilities if a pharmacist is present on site.

Certified Pharmacy Technicians

Certified technicians may operate under general supervision and can complete all tasks assigned to registered technicians, as well as any additional task that is delegated by the supervising pharmacist, excluding tasks that involve patient counseling, drug utilization review, interpretation of orders and prescriptions, final product verification, receipt of new verbal orders or prescriptions, or any other act requiring professional judgment.

An important modification to the role of pharmacy technician involves stocking and loading an automated filling or dispensing system. With the amendment, registered technicians may only perform this action with the assistance of barcode scanning technology. If loading an automated system requires bypassing the barcode scanning technology, this action must be performed by a supervising pharmacist. Alternatively, this task may be delegated to a certified technician if, in the pharmacist's professional judgment, it can be performed safely and accurately. These changes reflect a growing emphasis on technician responsibility while ensuring patient safety through pharmacist accountability.

201 KAR 2:165

The purpose of the amendment to 201 KAR 2:165 – the regulation outlining how prescription information may be transferred between pharmacies – is to expand the tasks that may be delegated to certified pharmacy technicians. Under the amendment, a certified pharmacy technician working under the general supervision of a pharmacist may transfer a non-controlled substance prescription that has been filled and dispensed at least once. To ensure safety and accuracy, any verbal transfers given or received by a certified technician must have documentation that the prescription information was "read back and verified."

While 201 KAR 2:045 outlines the expanded responsibilities of certified pharmacy technicians, 201 KAR 2:165 establishes a mechanism for executing these responsibilities and may help reduce pharmacist workload when the task is appropriately delegated. Pharmacists and technicians should review the updated regulations closely to ensure compliance and optimize workflow in their practice settings.

FDA's Actions to Address Unapproved Thyroid Medications

Millions of Americans take thyroid hormone replacement medications to treat hypothyroidism. This medication works to replace the hormones patients need to maintain normal thyroid hormone levels and helps prevent or improve symptoms of hypothyroidism, such as fatigue, weight gain, constipation, cold intolerance, or depressed mood, among others.

Currently, there are two types of thyroid hormone replacement medicines on the market, available only by prescription:

- The most used type of therapy is synthetic (laboratory-made) medications containing only levothyroxine or liothyronine or a combination of the two. An estimated 22 million patients received prescriptions for levothyroxine dispensed by United States outpatient community pharmacies in 2024. These medications have been Food and Drug Administration (FDA) approved for decades and are marketed as branded and generic medications containing levothyroxine sodium or liothyronine sodium. Search drugs@fda for a list of FDA-approved medications.

FDA's Actions to Address Unapproved Thyroid Medications *(cont)*

- The second type of therapy is animal-derived thyroid medication, sometimes called desiccated thyroid extract, or DTE. These medications are marketed as Armour Thyroid, NP Thyroid, Nature-Thyroid, and Natural Thyroid, among others. These medications are produced from dried, ground animal thyroid glands (usually porcine, meaning from a pig). Animal-derived thyroid medications are not FDA approved, yet an estimated 1.5 million patients received prescriptions for these medications from US outpatient community pharmacies in 2024. Due to their complex biological origin, these medications contain many compounds that are uncharacterized for safety and effectiveness.

FDA has concerns with the safety and effectiveness of the unapproved animal-derived thyroid medications, which have not been reviewed by FDA to ensure safety, purity and potency, and may have quality and dosing issues. The agency has received complaints from patients and reports of adverse events related to the safety and potency of these unapproved medications.

FDA is not taking immediate action against manufacturers who make unapproved animal-derived thyroid medication to give patients time to transition to an FDA-approved medication to treat their hypothyroidism.

The agency urges patients taking these unapproved animal-derived thyroid medications to treat hypothyroidism to talk to their doctor. A primary care doctor or a professional medical society, such as the Endocrine Society or the American Association of Clinical Endocrinologists, can help identify an experienced endocrinologist, which is a specialist who supports patients with thyroid and other hormone disorders.

FDA encourages health care providers to contact patients who are taking unapproved animal-derived thyroid medication and transition them to an FDA-approved medication to treat hypothyroidism. The agency understands this could take time, and patients may have concerns with this transition.

Adapted from "FDA's Actions to Address Unapproved Thyroid Medications."

Office of Inspector General Kentucky Prescription Drug Monitoring Program KASPER Announcement Regarding Veterinarian Prescriptions

This announcement is to garner your assistance in meeting the requirements in KRS 218A.2023(b), which states, in part:

> Every practitioner or pharmacy which dispenses a controlled substance [CS] to a person in Kentucky, or to a person at an address in Kentucky, shall report to the cabinet the data required by this section, which includes the reporting of any Schedule II [CS] dispensed at a facility licensed by the cabinet and a Schedule II through Schedule V [CS] regardless of dosage when dispensed by the emergency department of a hospital to an emergency department patient.

KRS 218A.202 3(b) lists three exceptions to this requirement. None of those three exceptions apply to veterinarians. Per 902 KAR 55:110, dispensing data "shall be transmitted no later than close of business on the business day immediately following the dispensing unless the cabinet grants an extension" using the American Society for Automation in Pharmacy ASAP 4.2B or 5.0 format. Recent analysis identified limited reporting of CS prescriptions prescribed by veterinarians to the Kentucky All Schedule Prescription Electronic Reporting (KASPER) program. Please ensure that you are reporting all veterinarian Schedule II-V CS prescriptions to Kentucky's Prescription Drug Monitoring Program as required.

Reminder: If a patient is an animal, the number "000-00-0000" shall be used in the Social Security number field pursuant to 902 KAR 55:110.

Important Compounding Update

The Board is reminding licensees that the enforcement discretion period for 201 KAR 2:076, Compounding will end on December 31, 2025. Beginning on January 1, 2026, the Board will enforce the 2022 revisions to the US Pharmacopeia Chapters <795>, <797>, and <800>.

Board Actions: December 2024 – November 2025

Agreed Orders Executed 12-1-2024 – 11-1-2025

- 17-0512 – K. Humphrey 016831 AO of Rev
- 17-0499 – L. Henderson 012290 AO of Rev
- 24-0074 B – B. Wilson 010903
- 24-0074 A – Save-Rite Drugs P07482
- 24-0125 C – D. Tetrick 010357
- 24-0075 A – Gibson's LLC P07757
- 24-0075 B – A. Elliott 015553
- 24-0138 A – St Claire Medical Center P05100
- 24-0151 A – Smith Family Pharmacy P07835
- 24-0081 C – M. Beck 015670
- 24-0073 A – Smith Family Pharmacy P07835
- 24-0073 B – S. Smith 018999
- 24-0120 A – CVS P07576
- 24-0116/24-0123/24-0124 A – Henry Pharmacist Group P07616
- 24-0102 B – L. Boone 015638
- 24-0106 B – J. Dunaway 007646
- 24-0153 B – M. Andrews 013726
- 24-0153 C – C. Williams 016134
- 24-0153 D – H. Havens 020741
- 24-0178 B – E. Brown 024035
- 24-0099 B – H. Shin 022558
- 24-0173 – M. Bonomini 017266
- 24-0134 – Tailstorm Health OSF00160
- 24-0163 B – P. Wyatt 024212
- 24-0163 C – B. Graham PT00030170
- 24-0090 A – Taylor Drug Store P08063
- 25-0024 C – C. Fryar 020105
- 25-0045 E – T. Hamilton 018483
- 24-0029 A – Danhauer Chemists Inc. P00684 AO of Permit Approval
- 24-0029 A – Danhauer Chemists Inc. MG1084 AO of Permit Approval
- 25-0043 C – J. Poe 012956
- 25-0045 F – J. Stiles 009488
- 25-0058 C – T. Shipp PT00171836
- 23-0539 A – Countryside Pharmacy FL2402
- 23-0122 – T. Barbian 012681 AO of Reinstatement
- 23-0554 B – V. Craig-Geralds 011419
- 23-0128 B – J. Tran 020495
- 23-0617 A – Walmart Pharmacy #10-7611 IN3016
- 25-0038 A – Aequita Pharmacy LLC WA3091

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