DECEMBER 2024

KENTUCKY BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

Important Update: Changes to CE Requirement in 2024

The Kentucky Board of Pharmacy amended 201 Kentucky Administrative Regulations (KAR) 2:015, Continuing Education (CE). This amendment modifies the CE period from the calendar year (January 1-December 31) to the licensing year (March 1-February 28).

How will this change be implemented?

- The Board will count any Accreditation Council for Pharmacy Education (ACPE)-accredited or Board-approved CE completed in January and February 2024 toward the CE requirements for renewal in 2025.
- Pharmacists will have until the February 28 renewal deadline to complete their CE hours. Pharmacists who renew on or before the February 28 deadline should only renew their pharmacist license once their CE requirement has been met.

As a Reminder:

Pharmacists shall keep valid records, receipts, and certifications of completed continuing pharmacy education (CPE) programs for three years and submit the certification to the Board upon request. The Board utilizes the National Association of Boards of Pharmacy® CPE Monitor® to conduct CE audits. Please check your profile periodically to avoid any discrepancies. All courses and/or providers shall be ACPE accredited or Board approved. Courses with pending approval should not automatically be accepted as proof of completion.

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Governor Reappoints Jonathan Van Lahr and Anthony Tagavi to Four-Year Terms

Governor Andy Beshear reappointed Jonathan Van Lahr of Webster, KY, and Anthony Tagavi of Lexington, KY, to represent licensed pharmacists as members of the Board, serving terms expiring on December 31, 2028.

Licensing Management Software Updates Continue

ThoughtSpan Technology, LLC, the vendor selected to create a new licensing system for the Board, continues to implement this new system. The Board anticipates that this all-inclusive platform will allow the user more control of applications, modifications to records, submission of documents, and many additional capabilities available online. This will minimize the requirement for hard copy documents that the end user must submit manually to the Board office. Even transactions such as designated representative changes, address changes for individuals, employment/employee modifications, and so many more will be handled online. The Board looks forward to providing updates as it navigates through this process.

Kentucky Boards of Pharmacy, Medical Licensure, and Nursing Release Joint Statement Regarding Retail IV Therapy

Across the United States, many clinics are incorporating retail intravenous (IV) therapy business practices without considering the minimum statutory and regulatory requirements that constitute the practice of medicine, nursing, and/or pharmacy required to conduct such services. The Kentucky Board of Pharmacy, Kentucky Board of Medical Licensure, and Kentucky Board of Nursing have released a joint statement that offers guidance on performing IV therapy services pursuant to licensees' scope of practice, US Pharmacopeia (USP) <797> standards, and federal law.

The Kentucky Pharmacy Practice Act defines compounding as "the preparation or labeling of a drug pursuant to or in anticipation of a valid prescription drug order, including but not limited to packaging, intravenous admixture, or manual combination of drug ingredients." Food and Drug Administration (FDA) explains compounding as the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Individuals at IV therapy clinics engage in compounding when they add drugs or vitamins to an IV bag. Therefore, the Kentucky Board of Pharmacy requires entities to have a permit if they are compounding prescription drug orders under the supervision of the pharmacist. Physicians or advanced practice registered nurses who are compounding for immediate use or in their practice are the only exception.

If an IV therapy treatment is prepared for immediate use according to a legal prescription and within the practitioner's scope of practice, it is permitted. However, if the

Kentucky Boards of Pharmacy, Medical Licensure, and Nursing Release Joint Statement Regarding Retail IV Therapy

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preparation involves three or more different sterile products, the treatment must comply with the full requirements outlined in USP <797>.

Licensees who fail to comply with the laws of their practice could face disciplinary proceedings and sanctions by their respective boards.

The Kentucky Board of Pharmacy encourages its licensees to review the statement.

Kentucky Board Actions: January – November 2024 Summary

The cases below have been settled between the following respondents and the Board. Additional information is available on the Board's website at *www.pharmacy.ky.gov* under License/Registration Lookup.

Agreed Orders		
19-0095 A – Clinton Pharmacy, LLC P07839	23-0342 – C. Crawford 009415	23-0545 B – K. Martin 015291
20-0120 O – D. Justin 021373	23-0439 – R. Noble 021598	23-0547 – CVS #6339 P06016
22-0005 A – Owensboro Pharmacy, LLC P08149	23-0446 – D. Duda, Jr 022202	23-0548 A – CPC Animal Health TN2304
22-0014 A – Walgreens #17946 P07988	23-0506 A – Synchrony Rx at Home P08154	23-0551 – Sharp Clinical Services TPL00337
22-0069 – J. Mills 017306	23-0507 A – Outpatient Pharmacy Corp NJ2774	23-0564 – CVS #17531 P07735
22-0204 B/22-0218 B/22-0197 B /23-0121 B (Combined) – J. Price 007180	23-0514 B – R. Matthews 009527	23-0575 A – Wright Care Home Medical Supplies MG1057
23-0023 – B. George 019913	23-0516 A – Medical Arts Pharmacy P07016	23-0558 A – Reliant Care Solutions PA2857

Kentucky Board Actions: January – November 2024 Summary

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23-0052 C – M. Gruber 008865	23-0516 B – S. Billington 011296	23-0601 – Advanced Home Medical, LLC MG1040
23-0054 B – M. Francia 017762	23-0520 A – Scripts, Inc, dba Medicine Shoppe of Hyden P06302	23-0607 – S. Stevens PT00378735
23-0057 A – Kentucky CVS Pharmacy, LLC #10048 P07609	23-0520 C – K. Stewart PT00023581	24-0017 A – Dania Discount Drugs, Inc FL2417
23-0077 – K. Marsh 016029	23-0530 B – J. Nixon 011636	24-0019 C – D. Tetrick 010357
23-0125 A – Neogen Corporation W04825	23-0532 A – Janus Rx, LLC P08225	24-0022 – A. Radford 020891
23-0126 – A. Workman PT00015278	23-0532 D – S. Silverhorn PT00376529	24-0028 C/24-0069 C – J. Axmacher 023418
23-0182 – L. Gray 019448	23-0533 A – NaturalMed Apothecary, dba Core Pharmacy IL1881	24-0046 C – C. Hayes PT00274504
23-0196 – C. Coscia 011524	23-0533 B – E. Cornett 017094	24-0060 – O. Simpson 017393
23-0216 – S. Empey 018959	23-0534 C – J. Smith 007653	24-0062 C – S. Trivedi 013991
23-0326 – I. Mkparu 021671	23-0545 A – HomeMed Pharmacy IN1257	24-0117 A – Henry Pharmacist Group, dba Med Save Eminence P07616

Default Orders of Revocation	
23-0132/23-KBP-0174 – P. Patel PT00036856	22-0056/23-0514/ 23-KBP-0209 A – Franklin Pharmacy P07711

Case Study Regarding Single-Dose Medication Vials

A patient submitted a grievance regarding a pharmacy that dispensed two single-use, one mL vials of testosterone with the instructions to "inject [one-fourth] milliliter under the skin twice weekly as directed." The pharmacy had dispensed the medication with the same instructions to the patient multiple times. The patient's insurance required them to change pharmacies, and upon transferring

Case Study Regarding Single-Dose Medication Vials *(cont)*

the prescription, the new pharmacy made the patient aware that the prior pharmacy should not have dispensed the single-use vials for multiple uses due to potential harm to the patient. The patient then contacted the prior pharmacy with this information and stated that the pharmacy responded, "Not to worry because [the pharmacy] did get clearance from the manufacturer that it was okay that patients use the single-dose-only vials for multiple uses because it has the same amount of medication."

The pharmacy denies this statement about having clearance from the manufacturer. Instead, the pharmacy argued that the medication was safe because it contained the same active and inactive ingredients – including the preservative – listed on the multi-dose 10 mL testosterone vial. Centers for Disease Control and Prevention's (CDC's) guidance states that "single-use vials must be used by the same patient as part of a single case, procedure, [or] injection" and reasoned that single-use or single-dose vials are labeled as such because they do not have the preservative. The pharmacy argued that they interpreted CDC's guidance to mean that, as long as the vial contained the preservative and was used for a single patient, it was safe for multiple uses. The pharmacy further detailed that there were no instructions on the manufacturer's packaging with disposal instructions, stated that other pharmacists and pharmacies are also using this practice with single-use vials, and asked for clarification from the Board on the matter.

The Board's pharmacy and drug inspector contacted the manufacturer for response and clarification. The manufacturer confirmed that, although the single-use one mL vials and the multi-use 10 mL vials contain the same ingredients, they should not be directed for multiple uses. The manufacturer stated that if the product is labeled and approved by FDA as a single-dose vial, they can only recommend that consumers use it in accordance with FDA labeling, citing that they do not have data to support using a single dose multiple times. Specifically, once a single-dose vial is punctured, it needs to be used immediately, and if anything remains, it needs to be discarded.

The Board's Case Review Panel (CRP) ordered the issuance of letters of reprimand for each pharmacist involved, finding them in violation of Kentucky Revised Statutes 315.121(2)(d) due to engaging in conduct likely to harm the public, demonstrating a willful or careless disregard for the health, welfare, or safety of a patient, or engaging in conduct that substantially departs from accepted standards of pharmacy practice ordinarily exercised by a pharmacist stemming from the disregard of CDC and FDA guidance on single-use medication vials. Regarding the pharmacist-in-charge, the CRP found an additional violation of 201 KAR 2:205 Section 2(3)(b) due to failure to properly provide pharmacy services to the patient. The CRP dismissed the case against the permit holder, finding the pharmacists solely liable for the improper dispensing.

In sum, the Board states that single-dose medication vials shall only be used per FDA instructions for single use and shall not be administered to patients for multiple uses, regardless of whether it is for a single patient.

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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