SEPTEMBER 2024

KENTUCKY BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

Important Update: Proposed Changes to CE Requirement in 2024

The Kentucky Board of Pharmacy has voted to approve an amendment to 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). If passed, this proposed change will go into effect in 2024.

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 pending approval should not automatically be accepted as proof of completion.

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Board Issues Opinion and Declaratory Ruling for Kentucky Pharmacies Acquiring Human Compounded Products From 503B Outsourcing Facilities

On May 22, 2024, the Board issued an opinion and declaratory ruling: *Guidance for Kentucky Pharmacies Acquiring Human Compounded Products from 503B Outsourcing Facilities*. In this guidance, the Board encourages pharmacies to complete a license verification with the Board and a registration verification with Food and Drug Administration (FDA).

Outsourcing Facilities

Outsourcing facilities can only use bulk drug substances that appear on FDA's drug shortage list at the time of compounding, distribution, and dispensing, or that appear on the 503B Bulks List or Category 1 of the Bulk Drug Substances Nominated for Use in Compounding Under Section 503B of the Federal Food, Drug, and Cosmetic Act. Additionally, outsourcing facilities can only provide final, finished compounded products that have been tested to confirm that they meet the final product specifications prior to their release. If there are any adverse events from the product, the outsourcing facility must report it to FDA, and if there are any complaints, the facility should handle them according to the current Good Manufacturing Practice regulations.

Pharmacies

Pharmacies are expected to only obtain compounded products from outsourcing facilities that are legally authorized to compound and from pharmacists who are legally authorized to dispense in Kentucky. Further, pharmacies should review the drug product release date from the facilities to confirm that the products underwent quality testing. Pharmacists are expected to follow 201 KAR 2:076 for compounding policy and procedures including the reuse or resale of prescription drugs. If there are any product quality concerns, the Board expects pharmacists to report the product to the facility.

Resource for Kentucky Pharmacists Seeking Opioid CE Requirement

The Board is encouraging Kentucky pharmacists to visit the University of Kentucky College of Pharmacy website to find various webinars available for CE credit.

Updates to Board-Authorized Protocols

On July 24, 2024, the Board approved revisions for the following Board-authorized protocols:

- **Acute Influenza Infection: Chemoprophylaxis Protocol v4**
- **Self-Care Conditions: Diabetes Testing and Injection Supplies Protocol v5**
- **Self-Care Conditions: Over-the-Counter Dietary Supplement Protocol v2**
- **Self-Care Conditions: Over-the-Counter Probiotics Protocol v2**

The latest Board-approved versions have been posted on the Board's website and can be found here. Any pharmacy that has been utilizing a previously approved version is expected to use the latest version of a Board-authorized protocol to ensure compliance with 201 KAR 2:380(2)(1)(b) if the protocol was updated to align with current practice guidelines.

Updated Licensing Management Software in Progress

ThoughtSpan, LLC, the vendor selected to create a new licensing system for the Board, is making satisfactory progress in implementing this new system. The Board anticipates that 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 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 updating you as it navigates through this process.

Kentucky Board of Nursing Amends 201 KAR 20:057 Section 6(6)

Under the amendment to 201 KAR 20:057 Section 6(6), an advanced practice registered nurse (APRN) is permitted to operate under a collaborative agreement for prescriptive authority for non-scheduled/legend substances (CAPA-NS) and a collaborative agreement for prescriptive authority for controlled substances (CAPA-CS) for a period of up to 30 days if a physician's license becomes restricted or suspended.

> (6) If an APRN's CAPA-NS or CAPA-CS ends unexpectedly for reasons outside the APRN's control such as being ended by the physician without notice, the physician's license becoming no longer valid in Kentucky, or the death

Kentucky Board of Nursing Amends 201 KAR 20:057 Section 6(6)

(continued)

of a physician, the APRN may continue to prescribe for thirty (30) days, after documenting in each patient's medical record the applicant's professional determination that the continued prescribing is justified based on the individual facts applicable to the patient's diagnosis and treatment. This thirty (30) day grace period shall not be extended or occur successively.

Find out more here.

DEI Task Force Update

The Board has charged the Diversity, Equity, & Inclusion (DEI) Task Force with developing a cultural competency plan and training for pharmacists and pharmacy technicians to address DEI in pharmacy practice.

The task force will be showcasing several pharmacy podcasts. The podcasts will focus on race, the LGBTQIA+ commnuity, social determinates of health, and disabilities. We will provide conversations that will include, but are not limited to, topic definitions and real-life encounters revolving around provider/patient relationships and student relationships. The podcasts will be posted on the Board's website, and Board-approved CE will be available.

If you are interested in participating in a podcast as a guest, please reach out to pharmacy.board@ky.gov.

To learn about NABP's DEI initiative, visit its website here.

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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