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KENTUCKY BOARD OF PHARMACY

Newsletter to Promote Pharmacy and Drug Law Compliance.

CE: Understanding Your Responsibilities Before License Renewal

Each year, the Kentucky Board of Pharmacy receives questions from pharmacists regarding continuing education (CE) requirements, CPE Monitor®, and the Board's audit process. Many of these questions arise because pharmacists mistakenly believe that receiving a certificate of completion automatically results in CE credit being reported to NABP's CPE Monitor. Unfortunately, that is not always the case.

To help pharmacists remain compliant with 201 Kentucky Administrative Regulations (KAR) 2:015, the Board offers the following guidance.

Your Responsibility as a Licensee

Kentucky pharmacists are responsible for completing the CE requirements established in 201 KAR 2:015 before renewing their licenses. At the time of renewal, pharmacists must attest that they have satisfied all applicable CE requirements. It is important to verify that your CE has been properly documented before submitting your renewal application.

Understanding CPE Monitor

For Accreditation Council for Pharmacy Education (ACPE)-accredited CE, receiving a certificate of completion does not necessarily mean that the credit has been reported to CPE Monitor.

After completing an ACPE-accredited activity, pharmacists must also complete any administrative requirements established by the provider, which may include the following:

- submitting the activity code;
- completing the required evaluation;
- verifying your NABP e-Profile® ID and date of birth; and

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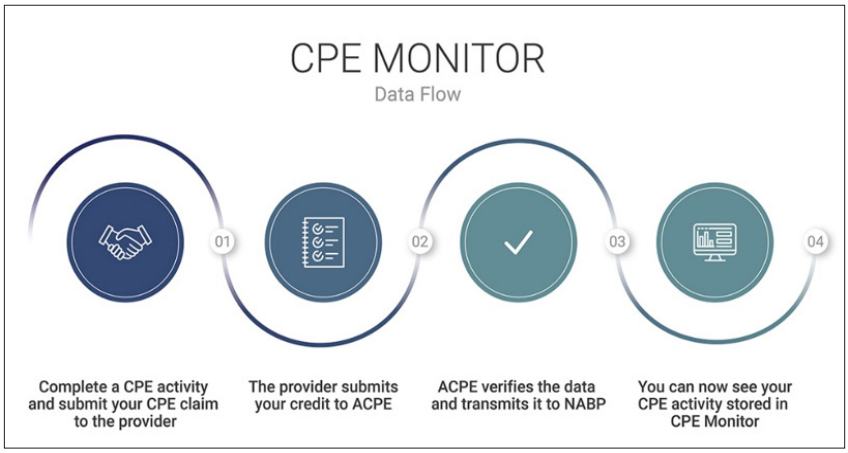
(cont)

- completing any additional provider-specific requirements.

Only after these steps have been completed can the provider report the credit to ACPE, which then validates the information and transmits the completed credit to NABP's CPE Monitor.

Providers have 60 days to report completed CE to ACPE. If the required administrative steps are not completed within the provider's reporting window, the credit may never be reported to CPE Monitor. In those circumstances, the Board cannot manually add the credit or direct NABP to do so.



Source: National Association of Boards of Pharmacy®

For this reason, pharmacists should regularly review their CPE Monitor transcript throughout the renewal cycle, rather than wait until license renewal or a Board audit.

Board-Approved CE

Certain CE activities require Board approval rather than ACPE accreditation. These activities are not automatically reflected in CPE Monitor.

To receive credit for Board-approved CE, pharmacists must submit the required, Board-approved CE application through the Kentucky Licensure Gateway upon completion of the program. The Board's Continuing Education Advisory Committee will review the application and make a recommendation to the Board if it meets the criteria for approval. Failure to submit the required application may result in the Board having no record of the completed CE during an audit.

How the Board Conducts CE Audits

The Board verifies CE compliance by using two sources:

- NABP's CPE Monitor; and
- Board-approved CE applications submitted through the Licensure Gateway.

If the Board's records do not demonstrate at least 15 hours of continuing pharmacy education (CPE), the pharmacist will receive a CE audit notification and be given an opportunity to submit documentation before an investigative case is considered.

The audit notification is intended to provide pharmacists with a final opportunity to supplement the Board's records before the matter proceeds through the disciplinary process.

Best Practices to Avoid Audit Issues

To help ensure your CE is properly documented:

- Complete all provider-required steps after attending an ACPE-accredited CE program.
- Verify that your ACPE credits appear in CPE Monitor well before renewing your license.
- Submit Board-approved CE applications through the Licensure Gateway immediately after completing the program.
- Maintain copies of all CE documentation for your records.
- Review your CE transcript before submitting your license renewal application.

Taking a few minutes to verify your CE throughout the year can help prevent unnecessary audit notifications and ensure a smooth renewal process.

Board Consumer Member Receives KPhA Meritorious Service Award

The Board is pleased to recognize consumer member Jason Belcher for receiving the 2026 Kentucky Pharmacists Association (KPhA) Meritorious Service Award at the association's annual meeting.

The KPhA Meritorious Service Award honors individuals who have demonstrated exceptional service to the association or the pharmacy profession over an extended period. While he is not a pharmacist, his dedication to protecting the public and strengthening the profession of pharmacy has made a lasting impact throughout the Commonwealth.

As the consumer member of the Board, Jason Belcher has provided a vital public perspective in the Board's deliberations and decision making. Over the past five years, he has maintained a perfect attendance record at Board meetings and has devoted countless hours to reviewing disciplinary cases, promoting accountability, and helping ensure the safe and effective practice of pharmacy across Kentucky.

His commitment to public service and thoughtful leadership have earned the respect of Board members and stakeholders alike. In recognition of his contributions, he became the first consumer member appointed to chair the Board's Case Review Panel, where he has played an important role in advancing fairness, integrity, and public trust in the regulatory process.

The impact of his service extends beyond the Board itself. Through his work, he has helped support the pharmacists and pharmacy technicians who serve Kentuckians every day, while reinforcing public confidence in the profession and the regulatory systems designed to protect patient safety.

The Board congratulates Jason Belcher on this well-deserved recognition and thanks him for his outstanding dedication, leadership, and unwavering commitment to serving the citizens of the Commonwealth.

Compounded SLIT Preparations Utilizing Allergenic Extracts: Regulatory Guidance

The Board recently reviewed an application involving the compounding and dispensing of patient-specific sublingual immunotherapy (SLIT) formulations prepared from allergenic extracts. As part of its review, the Board evaluated whether these activities would comply with the requirements applicable to pharmacies permitted to practice in Kentucky, including the federal standards governing traditional pharmacy compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

To assist in its evaluation, the Board sought guidance from the Food and Drug Administration (FDA) Compounding Policy Branch regarding the applicability of Section 503A to compounded SLIT preparations utilizing allergenic extracts.

In a written response, FDA advised that biological products subject to licensure under Section 351 of the Public Health Service Act (PHSA) are not eligible for the compounding exemptions available under Section 503A of the FD&C Act. FDA further advised that allergenic products fall within the definition of biological products under the PHSA. Additionally, FDA stated that Section 503A does not provide a legal pathway for the marketing of biological products prepared outside the scope of an approved Biologics License Application.

Based upon the information submitted during the application review process and the guidance received from FDA, the Board identified significant concerns regarding whether the compounding and dispensing of patient-specific SLIT allergen extract preparations constitute permissible pharmacy compounding activities under the

Compounded SLIT Preparations Utilizing Allergenic Extracts: Regulatory Guidance *(cont)*

standards applicable to pharmacies permitted in Kentucky.

The Board remains committed to maintaining regulatory oversight that is consistent with applicable federal law and FDA guidance. As the federal agency charged with administering and enforcing the provisions of the FD&C Act and the PHSA, FDA's interpretation of these statutes is an important consideration in the Board's evaluation of pharmacy compounding practices involving allergenic extract products.

Pharmacies should be aware that patient-specific prescriptions alone do not necessarily bring a product within the scope of Section 503A if the product is otherwise subject to federal requirements governing biological products. Licensees engaged in allergy-related services are encouraged to carefully evaluate their practices and ensure compliance with all applicable state and federal requirements.

The Board remains committed to protecting public health by promoting compliance with both state and federal law governing pharmacy practice and compounding.

Resource for Kentucky Pharmacists Seeking Opioid CE Requirement

The University of Kentucky College of Pharmacy is offering free CPE webinars discussing buprenorphine dispensing for opioid use disorder (OUD), the role of pharmacies in OUD recovery, the science behind OUD remission and recovery, and frequently asked questions about effective buprenorphine dispensing.

Board-Authorized Protocols Update

On July 15, 2026, the Board approved revisions for the Board-authorized protocol, Self-Care Conditions Protocol: Emergency Contraception V2. For the past several months the Protocol Review Committee has been working diligently to review and update this protocol to ensure it contains up-to-date clinical information and references. The latest version approved by the Board has been posted to its website for you to use and can be found here. Although it is not required by 201 KAR 2:380 to use the latest version of a board-authorized protocol, it is best practice. You can submit your fully executed protocol for the registry through the Licensure Gateway.

Kentucky PDMP Announcement

Kentucky All Schedule Prescription Electronic Reporting (KASPER), Kentucky's Prescription Drug Monitoring Program (PDMP), is pleased to announce the implementation of a new Pharmacist Dashboard, designed specifically for pharmacists-in-charge (PICs). This enhancement allows eligible PICs to monitor controlled substance reporting activity, review uncorrected file validation errors, and track compliance-related information for their pharmacy submissions. Eligible PICs may access the

Kentucky PDMP Announcement *(cont)*

dashboard within the KASPER portal by selecting "My Account Settings" and then choosing the "Pharmacy Dashboard" menu option.

The dashboard is intended to help PICs identify reporting concerns early, support timely corrections within the required compliance window, and improve the overall quality and accuracy of data submitted to KASPER.

If you have questions, please contact Misty Rose at mrose@ky.gov.

This project was supported by the 2022 Harold Rogers PDMP grant, Grant No.15PBJA-21-GG-02610-PDMP, awarded by the Bureau of Justice Assistance.

Reporting Unapproved Peptides and 'Research Chemicals'

By James Grant Wilburn, PharmD Candidate, University of Kentucky College of Pharmacy

A growing public health threat has emerged across the state due to the rise in popularity of glucagon-like peptide-1 medications for weight loss. With high demand and limited access to these medications, patients are now seeking the unapproved "research chemicals" and injectable peptides. These substances are being aggressively marketed for weight loss and anti-aging, alongside other "benefits." For the Board, ensuring that pharmacists, health care providers, and the general public know how to respond to the illicit sale and administration of these chemicals is a top priority.

Many of these products are sold under the deceptive labeling of "for research purposes only," "not for human use," or "research chemicals." This is a loophole used to bypass regulatory oversight. These substances are not FDA approved for human use. Because they bypass FDA's strict safety, efficacy, and manufacturing standards, they carry severe health risks, including dangerous immune reactions, infections, and exposure to heavy metals or bacteria. When a local wellness center or clinic administers these unapproved drugs, they are directly jeopardizing patient safety.

Because these substances are actively evading federal drug laws, prioritizing FDA reporting is crucial. If you observe the sale, compounding, or administration of these unapproved chemicals, report them immediately through the following channels:

- **FDA:** FDA holds authority over unapproved drugs and relies on public tips to track injuries and issue warnings. Use the online FDA MedWatch program to report adverse reactions, or use the agency's dedicated online portal to report the unlawful sale of medical products here.
- **Kentucky Board of Pharmacy:** If you suspect an entity is inappropriately compounding or illegally supplying unapproved peptides or "research chemicals," file a formal grievance via the Board's grievance portal.

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