DECEMBER 2023

KENTUCKY BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

CE Reminder

A pharmacist shall complete a minimum of 1.5 CEUs (15 contact hours) annually between **January 1 through December 31** pursuant to 201 Kentucky Administrative Regulations (KAR) 2:015 Section 5(1). Continuing education (CE) hours must be either Accreditation Council for Pharmacy Education (ACPE) accredited or approved by the Kentucky Board of Pharmacy. A pharmacist is responsible to ensure that any CE obtained from another source, such as continuing medical education, must be submitted for Board approval prior to receiving credit. For licensing years 2023 through 2028, one contact hour of the 15 contact hours shall be on the opioid epidemic or opioid use disorder. The one contact hour for licensing year 2023 will need to be completed between January 1 through December 31 of 2023. A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education (CPE) provisions, including the new requirement for 2023. The Board audits **every** CPE Monitor® account **every year.** Check your CPE Monitor account today to ensure that you have 15 CE hours.

DEA Issues Final Rule on Initial Transfer of Schedule II-V EPCS

Drug Enforcement Administration (DEA) has published the final rule, Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling, which became effective on August 28, 2023.

The final rule provides clarity on existing federal regulatory requirements and clarifies what is appropriate dispensing of electronic

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prescriptions for controlled substances (EPCS). The final rule amends DEA regulations to allow the transfer of Schedule II-V EPCS between registered retail pharmacies for initial filling, upon request from the patient, on a one-time basis, and if allowable under existing state or other applicable law.

Additionally, the final rule requires that (1) the transfer must be communicated directly between two licensed pharmacists; (2) the prescription **must remain in its electronic form;** and (3) the required prescription information must not be altered during the transmission. The record-keeping requirements for EPCS are applicable to both the transferring and receiving pharmacies for the initial fill only. The transfer of EPCS for refill dispensing is addressed by 21 Code of Federal Regulations (CFR) 1306.25.

Pharmacies are encouraged to contact their dispensing software vendor to determine the capability of transferring initial electronic prescriptions in compliance with DEA's final rule.

In accordance with 21 CFR 1306.08(g), which states "The transfer of an electronic prescription for a controlled substance in Schedule II-V for the purpose of initial dispensing is permissible only if allowable under existing State or other applicable law," the Board voted to amend 201 KAR 2:165 to ensure that it was clear that Kentucky law authorizes what DEA has now authorized in the final rule.

201 KAR 2:165 Section 2 Proposed Amendment

> a. The transfer for an initial or new dispensing of an electronic ~~of~~ prescription for schedules II-V ~~information for a controlled substance prescription, except a Schedule II controlled substance, for the purpose of refill dispensing~~ may occur if the transfer complies with the requirements of 21 C.F.R. 1306.08 ~~21 C.F.R. 1306.25.~~
>
> b. The transfer of prescription information for a controlled substance prescription for schedule III, IV, and V for the purposes of refill dispensing may occur if the transfer complies with the requirements of 21 C.F.R. 1306.25.

The regulation was filed with the Legislative Research Commission on October 11, 2023, and public comments will be accepted through December 31, 2023.

DSCSA Implementation Delay

On August 30, 2023, Food and Drug Administration (FDA) announced that it would delay enforcement of the electronic interoperable tracing of drugs down to the package level by one year to November 27, 2024. This delay is to assist trading partners in finalizing the development and refinement of their electronic systems and the processes to trace products to the package level (serialization).

Pharmacies (dispensers) are still required to:

- confirm that their trading partners are appropriately licensed or registered;
- receive and maintain product tracing documentation (either paper or electronic); and
- identify, investigate, and report suspect and illegitimate drugs.

Starting on November 27, 2024, pharmacies will have to receive product tracing documentation electronically and specific to the package level.

Resources

- FDA Guidance on Delay
- June 2023 *Kentucky Board of Pharmacy Newsletter*
- Pulse by NABP™

RSV Vaccines in Older Adults

The Board is providing the following frequently asked questions regarding the respiratory syncytial virus (RSV) vaccines.

These questions and answers apply to the vaccine available for adults over the age of 60, per Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) recommendations and guidelines.

Q. Is the RSV vaccine on the ACIP immunization schedule?

A. ACIP recommends that "adults aged ≥ 60 years may receive a single dose of an RSV vaccine, using shared clinical decision-making." See *Morbidity and Mortality Weekly Report*, July 21, 2023.

Q. How may a pharmacist administer the RSV vaccine?

A. The pharmacist must update their vaccine protocol to include the RSV vaccine or dispense a prescription from a provider (Kentucky Revised Statutes (KRS) 315.010 (22)).

Q. May a pharmacy technician administer the RSV vaccine?

A. Yes, supervised pharmacy technicians who have completed practical training accredited by ACPE that includes hands-on injection technique and the recognition and treatment of emergency reactions to vaccines, possess a current certificate in basic CPR, and annually complete a minimum of two hours of immunization-related CE accredited by ACPE may administer the vaccine (KRS 315.010 (22), 201 KAR 2:420).

Q. May a pharmacist give the RSV vaccine to someone who is not ≥ 60 years of age?

A. Yes, pursuant to a prescription and based on the pharmacist's professional judgment. A pharmacist may want to check with their liability insurance to determine if vaccines given based on shared decision making are covered.

201 KAR 2:076 Compounding

The amendments to 201 KAR 2:076 Compounding became effective on October 25, 2023. The amendments reflect the adoption by the Board of the 2022 revisions for United States Pharmacopeia (USP) <797> and USP <795> standards and include USP <800> as it relates to compounding.

Highlights of the regulation include:

- The addition of the "designated person" (definition and responsibilities).
- Definitions for "essential copy of a commercially available drug product" and "hazardous drug" and rules regarding both terms.
- The addition of a flavoring will not be considered compounding if the additive is non-expired, inert, nonallergenic, produces no effect other than the instillation or modification of flavor, and is not greater than 5% of the drug product's total volume.
- The dispensing of compounded preparations for veterinary use shall follow the requirements of 201 KAR 2:311.
- Verification of a compounded preparation shall be completed by a pharmacist after the preparation of the compound and prior to dispensing to the patient.
- Enforcement discretion – effective January 1, 2026. The Board shall enforce the 2022 revisions. Until January 1, 2026, the Board shall enforce the 2014 revision of USP <795> and the 2008 revision of USP <797>, and the Board shall not enforce USP <800>.
- Until January 1, 2026, at the request of a permit holder, the Board may inspect pursuant to the 2022 revision standards.

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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