

Updates from the Kentucky Board of Pharmacy
September 29, 2023

DEA issued the Final File on the Initial Transfer of Electronic Prescriptions for Schedule II-V Controlled Substances

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 August 28, 2023.

The final rule provides clarity on existing federal regulatory requirements and clarifies what is appropriate dispensing of electronic prescriptions for controlled substances (EPCS). The final rule amends DEA regulations to allow the transfer of electronic prescriptions for controlled substances Schedule II-V 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 (1) the transfer to 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 CFR 1306.25.

Pharmacies are encouraged to contact their dispensing software vendor to determine the capability of transferring initial electronic prescriptions in compliance with the 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 Kentucky Board of Pharmacy voted to amend 201 KAR 2:165 to ensure 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 will be filed with the Legislative Research Commission by October 15, 2023, and public comments will be accepted through December 31, 2023.

DSCSA Implementation Delay

On August 30, 2023, 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](#)

[KY BOP June 2023 Newsletter](#)

[Pulse by NABP](#)

Respiratory Syncytial Virus (RSV) Vaccines in Older Adults

The Kentucky Board of Pharmacy is providing the following frequently asked questions regarding the RSV vaccines.

***the following Q&As apply to the vaccine available for adults over the age of 60*

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. [MMWR, 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. [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 cardiopulmonary resuscitation, and annually complete a minimum of 2 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 his or her liability insurance to determine if vaccines given based on shared decision making are covered.

** per CDC ACIP recommendations and guidelines

<https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm>