OCTOBER 2022

KENTUCKY BOARD OF PHARMACY

newsletter to promote pharmacy and drug law compliance

Continuing Education Highlights

1. Kentucky requires 15 credit hours of continuing education (CE) **every calendar year.**
2. The Kentucky Board of Pharmacy audits every CPE Monitor® account **every year.**
3. Check your CPE Monitor account today to ensure that you have earned 15 CE hours. Please do not procrastinate.
4. Extension waivers are very rare. Please do not count on a waiver.

Farewell From Darla Sayre

When this *Newsletter* is published, I will no longer be working at the Board. I retired on August 1, 2022. As I look back on my years at the Board, the key to my success was my coworkers. I have been blessed to work with an amazing group of people. From Board members, executive directors, inspectors, attorneys, and office staff, these individuals allowed me to grow in experience and responsibility to build a career that I could never have imagined. Thank you to each one of you!

To all the licensees, permit holders, and registrants, it has been my pleasure to assist you throughout the years. I will occasionally stumble across a name and think, "I remember when they got licensed," or while traveling, see a pharmacy and think, "So that is where they are located."

National Pharmacy Compliance News
A Service of the National Association of Boards of Pharmacy Foundation (NABPF)

Visit NABP's website for the latest regulatory updates and news from FDA, USP, NABP, and more.

Read National News

As I begin this new chapter in my life, I pray that I have served you well. I will close with words from the song "For Good":

> It well may be that we will never meet again in this lifetime. So let me say before we part: So much of me is made of what I learned from you. You'll be with me like a handprint on my heart. And now whatever way our stories end, I know you have rewritten mine by being my friend. . . Because I knew you, I have been changed for good.

Pharmacy Requirements Under DSCSA

The Drug Supply Chain Security Act (DSCSA) was federally enacted in 2013 to protect patients from potentially counterfeit prescription medications. The law addresses the distribution of most prescription drugs from the manufacturer to the dispenser (ie, the pharmacy). The DSCSA requires pharmacies to do three things:

- **Confirm that your trading partners are appropriately licensed or registered**

  Manufacturers and repackagers are required to register with Food and Drug Administration (FDA). Third-party logistics providers (3PLs) and wholesaler distributors currently report state licensure to FDA. Pharmacists can verify this information on FDA's website. The Board requires licensure and registration for wholesale distributors and 3PLs operating within the state or shipping into Kentucky. Pharmacists can verify this information on the Board's website. Keep in mind that the Board's website lists the names of entities' parent companies, which may differ from the names that companies "do business as."

- **Receive and maintain product tracing documentation**

  With each shipment of prescription drugs, the pharmacy must receive transaction documentation including transaction information, transaction history, and a transaction statement. This information may be received electronically or by paper. The pharmacy must maintain this documentation for six years.

- **Identify, investigate, and report suspect and illegitimate drugs**

  Pharmacies must be able to identify, quarantine, and investigate suspect prescription drugs to determine if the drugs are illegitimate. If they are illegitimate, the pharmacy must then report this to the wholesaler, manufacturer, and FDA.

  Pharmacies should exercise extra vigilance in situations where there is a higher risk of suspect drugs entering the supply chain. Examples of high-risk scenarios include:

  - Drugs being sold for "too good to be true" prices.
  - Drugs in high demand due to drug shortages or public health emergencies.
  - Drugs that have historically been counterfeited or diverted (eg, HIV drugs, antipsychotics, and cancer drugs).

- Purchases from first-time or unknown suppliers, especially if done over the internet. Pharmacies should be wary of sources that send unsolicited sales offers.
- Products that arrive with missing or incomplete information, such as incomplete shipping information or missing package inserts, lot numbers, expiration dates, or National Drug Codes.
- Products that are abnormal in appearance. This may include smudged or misspelled labels, unusual coloration or shape of the package, missing security features, or dosage forms that are different in color, shape, or imprint from the normal product.
- For more information on the DSCSA and pharmacies' responsibilities, visit FDA's website. The website also includes information on pharmacies' responsibilities when selling drugs to prescribers or other pharmacies.

Useful Links

- Wholesale Distributor and Third-Party Logistics Providers Reporting (FDA Database)
- Kentucky Board of Pharmacy License Verification System
- FDA DSCSA Law and Policies Web Page
- FDA DSCSA Implementation: Identification of Suspect Product and Notification Guidance for Industry

Legend Drug Repository Program

The Kentucky Legend Drug Repository Program is intended to expand health care access to indigent, uninsured, and underinsured patients. It creates a process for the donation of non-controlled prescription drugs to be dispensed to patients who could otherwise not afford care. Kentucky Revised Statutes (KRS) 315.450 through KRS 315.460 lay out the statutory basis of the program, while 201 Kentucky Administrative Regulations (KAR) 2:440 contains the regulatory requirements that donors and authorized recipients must follow. Participation in the Legend Drug Repository Program is optional, but it presents an important opportunity to help patients overcome financial barriers to health care.

Who can donate drugs under the Legend Drug Repository Program?

A donor can be any entity that possesses state-level or federal authorization to possess drugs. Examples of eligible donors include pharmacies, clinics, and prescribers, as well as drug manufacturers, wholesalers, and distributors. There is no special registration required to donate drugs. However, donations can only be accepted by authorized recipients designated by the Board.

Which patients are eligible to receive donated drugs?

Indigent and uninsured patients have priority access to drugs dispensed through the repository program, followed by underinsured patients. However, if donated drugs are available and there are no

indigent, uninsured, or underinsured patients who need them, then authorized recipients may dispense donated drugs to patients without special financial need.

What drugs can be donated?

Authorized recipients may only accept into their inventories drugs that meet the following requirements:

1. Are in their original, unopened, sealed, and tamper-evident packaging, or have been repackaged in accordance with Section 4(4) of 201 KAR 2:440;
2. Are not classified as a controlled substance;
3. Are not visually adulterated or misbranded;
4. Are not samples;
5. Have an expiration date of 90 days or greater, unless the authorized recipient determines in their professional judgment that the drug is in high demand and can be dispensed for use prior to the drug's expiration date;
6. Are not considered to be medical supplies;
7. Do not require only being dispensed to a patient registered with the drug's manufacturer in accordance with FDA requirements, such as drugs with associated Risk Evaluation and Mitigation Strategies programs;
8. If a drug requires temperature control other than room temperature storage, it must have a United States Pharmacopeial Convention (USP)-recognized method to detect improper temperature variations. USP Chapter <1118> describes devices such as time-temperature integrators and temperature loggers that can be used to validate the temperatures experienced by a drug during storage and shipping.

Additionally, donors should remove any patient names or prescription numbers from the packaging of donated drugs.

How do I become an authorized recipient?

To receive, distribute, dispense, or administer drugs donated through the program, a pharmacy must first complete a Legend Drug Repository Authorized Recipient Form and provide it to the Board. The completed form should include the policies and procedures that the prospective authorized recipient will implement to participate in the program.

What are the responsibilities of an authorized recipient?

201 KAR 2:440 details the requirements for authorized recipients. Authorized recipients participating in the program are responsible for accepting, inspecting, and storing donated drugs; the safe distribution and dispensing of donated drugs; and proper record keeping and documentation.

Authorized recipients must only accept appropriate drugs into their repository inventory and must lawfully dispose of donations that do not meet the requirements of the program. Records must be kept of the name, strength, quantity, and donating entity for each drug accepted into

repository inventory. Donations must be kept distinct from normal inventory and stored according to manufacturer recommendations and USP Chapter <659> requirements.

When repackaging, distributing, dispensing, or administering donated drugs, authorized recipients must comply with applicable state and federal law in addition to the special stipulations of the Legend Drug Repository Program. For example, if an entity cannot legally dispense or administer drugs under normal conditions, participation in the program does not grant them special authorization to do so.

Donated drugs must be dispensed by a pharmacist pursuant to a prescription from a physician, advanced registered nurse, or physician assistant. To ensure that donated drugs reach the intended patient population, authorized recipients must use a Legend Drug Repository Patient Eligibility Affidavit Form to classify patients as indigent, uninsured, underinsured, or other. The Board provides an official form that authorized recipients may use for this purpose.

The Board's website includes a link to the Legend Drug Repository Program. This link contains the necessary forms along with a list of authorized recipients.

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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