BOARDS AND COMMISSIONS
Kentucky Board of Pharmacy
(Amended at ARRS Committee)

201 KAR 2:440. Legend drug repository.

RELATES TO: KRS 217.816, 315.191, 315.450, 315.452, 315.454, 315.456, 315.458, 315.460, 21 U.S.C. 340B, 21 U.S.C. 360-1 – 360-4, 21 U.S.C. 381 – 384g

STATUTORY AUTHORITY: KRS 315.191, 315.452, 315.458

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the Kentucky Board of Pharmacy to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. KRS 315.452 and 315.458 require the board to promulgate administrative regulations to establish the legend drug repository program. This administrative regulation establishes the legend drug repository program and the requirements to participate in the program.

Section 1. Definitions.

(1) "Authorized recipient" means a recipient:
  (a) That has received authorization from the board to participate in the legend drug repository program pursuant to Section 2 of this administrative regulation; and
  (b) Whose authorization has not been revoked by the board pursuant to Section 3 of this administrative regulation.
(2) "Board" means the Kentucky Board of Pharmacy.
(3) "Controlled substance" is defined by KRS 218A.010.
(4) "Dispense" is defined by KRS 315.010.
(5) "Distribute" is defined by KRS 315.400.
(6) "Donor" means:
  (a) Any person, including an individual member of the public who is over the age of eighteen (18), or any entity legally authorized and permitted to possess drugs, such as a wholesaler or distributor, third party logistic provider, pharmacy, clinic, surgical or health center, detention and rehabilitation center, laboratory, medical or pharmacy school, prescriber or other health care provider, or health facility; or
  (b) Government agencies and entitles that are federally authorized to possess drugs, such as:
    1. Drug manufacturers;
    2. Repackagers;
    3. Relabelers;
    4. Outsourcing facilities;
    5. Veteran Affairs hospitals;
    6. Prisons; and
    7. FDA authorized importers, such as those under 21 U.S.C. 384g or similar provisions.
(7) "Drug" is defined by KRS 315.010.
(8) "Eligible patient" means a patient:
  (a) Who is indigent, uninsured, or underinsured; and
  (b) With a need for the donated drugs not identified among indigent, uninsured, and underinsured individuals.
(9) "Health care provider" is defined by KRS 304.17A-005(23).

(10) "Health facility" is defined by KRS 216B.015(13).
(11) "Original packaging" means the packaging in which the drug was donated by the donor.
(12) "Pharmacist" is defined by KRS 315.010(17).
(13) "Recipient" means a pharmacy as defined by KRS 315.010(19).
(14) "Relabeler" means any person who owns or operates an establishment that changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name, except for establishments that do not change the original labeling, but merely add their own name.
(15) "Repackager" is defined by KRS 315.400(16).
(16) "Returns processor":
(a) Is defined by 21 U.S.C. Section 360eee(18); and
(b) Includes a reverse distributor or similar entity.
(17) "Unopened tamper-evident packaging" is defined by the United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements, and includes unopened unit-dose, multiple dose, immediate, secondary, and tertiary packaging.

Section 2. Participation in the Legend Repository Program.
(1) Donors may donate drugs to an authorized recipient. An authorized recipient may receive donated drugs from donors. Prior to the first donation from a new donor, an authorized recipient shall verify and record:
(a) That the donor meets the definition established in Section 1 of this administrative regulation;
(b) The donor's name, address, phone number, and permit or license number;
(c) That the donor will only make donations of drugs in accordance with Section 3 of this administrative regulation; and
(d) If applicable, that the donor will:
1.
a. Remove or redact any patient names and prescription numbers on donated drugs; or
b. Otherwise maintain patient confidentiality by executing a confidentiality agreement with the authorized recipient; and.
2. Complete and sign a Donor Attestation Form to be reviewed by the authorized recipient prior to acceptance of any drug by an authorized patient.
(2) Any recipient seeking to become an authorized recipient in the program shall complete and provide to the Board the Legend Drug Repository Authorized Recipient Form that includes the specific policies and procedures of the recipient for planned implementation of the repository program. The policies and procedures shall include drug acceptance, destruction, or transfer for unauthorized unaccepted drugs; quarantine of donated drugs; the electronic or written maintenance of inventory, storage, and maintenance of donated drugs; recordkeeping of dispensed drugs and patient eligibility affidavit forms; separation of donated drugs; and repackaging of donated drugs.
(3) The board may revoke the authorization of a recipient to participate in the program by issuing a written notice to the recipient. The revocation shall include references to the specific requirements that were violated and the corrective actions necessary for the recipient to resume its participation in the program.
(4) A health facility, pharmacy, pharmacist, or practitioner shall not be required to participate in the program established by this section.
(5) A drug manufacturer, repackager, or wholesaler other than a returns processor participating in this program, shall comply with the requirements of 21 U.S.C. Sections 360-1 through 360-4 relating to drug supply chain security.

Section 3. Accepting, Inspecting, and Storing Drugs.

(1) In accordance with KRS 315.454, an authorized recipient shall only accept into inventory donated drugs that:

(a)

1. Are in original, unopened, sealed, and tamper-evident packaging; or
2. Have been repackaged under this program in accordance with Section 4(4) of this administrative regulation;

(b) If in a single unit dose, have packaging that is unopened;

(c) Are not classified as a controlled substance;

(d) Are not visually adulterated or misbranded;

(e) Are not samples;

(f) Have not expired;

(g) Are not considered to be medical supplies;

(h) Do not require only being dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements, in accordance with KRS 315.460; and

(i) Have a USP-recognized method to detect improper temperature variations if the drugs require temperature control other than "room temperature storage."

(2)

(a) Donated drugs that do not meet the requirements of subsection (1) of this section shall be disposed by returning the drugs to the drug donor; destroying the drugs by incinerator, medical waste hauler, or other lawful method; or transferring the drugs to a return processor.

(b) A record of disposed drugs shall consist of the:

1. Disposal method established in paragraph (a) of this subsection;
2. The date of the disposal; and
3. The name, strength, and quantity of each drug disposed.

(c) Other records of disposal shall not be required.

(3) All drugs received but not yet accepted into repository inventory shall be quarantined in a separate, designated area.

(4)

(a) Prior to or upon acceptance of a donation or transfer into inventory, an authorized recipient shall maintain a written or electronic inventory of the donation, consisting of the:

1. Name, strength, and quantity of each accepted drug; and
2. Name, address, phone number, and permit or license number, if applicable, of the donor.

(b) This record shall not be required if the two (2) parties are under common ownership.

(c) Other records of donation shall not be required.

(5) An authorized recipient shall store and maintain donated drugs in a manner that distinguishes the drugs from other non-donated inventory and in a secure and temperature-controlled environment that meets the drug manufacturers' recommendations and USP Chapter 659, Packaging and Storage Requirements.

Section 4. Safe Distribution and Dispensing of Drugs.

(1) An authorized recipient may:

(a) Distribute donated drugs to another authorized recipient or to an entity participating in a drug donation program operated by another state;

(b) Repackage donated drugs as necessary for storage, dispensing, administration, or distribution in accordance with Section 4(4) of this administrative regulation; and

(c) Replenish drugs of the same drug name and strength previously dispensed or administered to eligible patients in accordance with 21 U.S.C. 340B.

(2) An authorized recipient shall only administer or dispense drugs that:

(a) Meet the requirements of Section 3(1) of this administrative regulation and are not visually adulterated or misbranded, as determined by a pharmacist employed by, or under contract, with the health facility or pharmacy;

(b) Are, if dispensed to a patient, repackaged into a new container or have all previous patient information on the donated container redacted or removed;

(c) Are properly labeled in accordance with KRS 217.816;

(d) Have an expiration date that will not expire before the full use by the patient based on the prescribing practitioner's directions for use; and

(e) Are:

1. Prescribed by a physician, advanced registered nurse, or a physician assistant; and
2. Dispensed by a pharmacist in accordance with KRS 315.454(1)(d).

(3) An authorized recipient shall only dispense or administer drugs to an eligible patient if permitted by KRS Chapter 315 and 201 KAR Chapter 2. Prescription drugs shall:

(a) Only be dispensed or administered to patients pursuant to a valid prescription drug order; and

(b) Have patient-specific written or electronic records maintained in accordance with KRS Chapter 315 and 201 KAR Chapter 2.

(4)

(a) Repackaged drugs shall be:

1. Labeled with the drug name, strength, and expiration date; and
2. Kept in a separate designated area until inspected and initialed by a pharmacist.

(b) If multiple packaged donated drugs with varied expiration dates are repackaged together, the shortest expiration date shall be used.

(5) The donation, distribution, transfer, receipt, or facilitation of donations, distribution, transfers, and receipt of drugs pursuant to 201 KAR Chapter 2 shall not be considered wholesale distribution and shall not require licensing as a wholesale distributor.

(6) An entity participating in a drug donation or repository program operated by another state may participate in the Kentucky program, and in the case of a pharmacy, may dispense donated drugs to residents of Kentucky. This entity shall be required to comply with all Kentucky statutes and administrative regulations.

(7) Indigent and uninsured patients shall have priority access to drugs dispensed through the repository program. If a drug is available and no indigent or uninsured patient requests dispensing of the drug, the drug shall be made available to underinsured patients before dispensing to others. All authorized recipients shall use the Drug Repository Patient Eligibility Affidavit Form provided by the board or a substantively similar physical or electronic form to confirm a patient's status as indigent, uninsured, underinsured, or other.

(8) A legend drug or supply needed to administer a legend drug that is donated for use under this program shall not be resold.

(9) All legend drugs, with the exception of controlled substances and extemporaneously compounded drugs, shall be eligible for dispensing under this program.

(10) A handling fee shall not be charged to a patient for pharmacy dispensing of a repository drug.

(11) Drugs included in a recall notice shall be considered recalled unless the drug has an affixed lot number to exclude it from the recall.

Section 5. Forms and Recordkeeping.

(1) All records required by 201 KAR Chapter 2 shall be retained in physical or electronic format, on or off the authorized recipient's premise for a period of at least five (5) years.

(a) A donor or authorized recipient may contract with one another or a third-party to create and maintain records on each other's behalf.

(b) An identifier, such as a serial number or barcode, may be used in place of any or all information required by a record or label pursuant to 201 KAR Chapter 2 if the identifier allows for this information to be readily retrievable.

1. Upon request by the board, the identifier used for requested records shall be replaced with the original information.

2. An identifier shall not be used on patient labels in conjunction with dispensing or administering a drug.

(2) An entity that chooses to participate in the program shall make all records available to audit by the board within forty-eight (48) hours.

(3) If performing any action associated with this program or otherwise processing donated drugs for tax, manufacturer, or other credit, an authorized recipient shall be considered to be acting as a returns processor and shall comply with all recordkeeping requirements for nonsaleable returns, in accordance with 21 U.S.C. 360eee.

(4) A donation, or other transfer of possession or control, shall not be construed as a change of ownership unless stated as a change of ownership by the authorized recipient. If a record of the donation's transaction information or history is required, the history shall:

(a) Begin with the donor of the drugs;

(b) Include all prior donations; and

(c) If the drugs were previously dispensed, only include drug information required to be on the patient label in accordance with KRS Chapter 315 and 201 KAR Chapter 2.

Section 6. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "USP 659 Packaging and Storage Requirements," (2021)

(b) "Legend Drug Repository Authorized Recipient Form," Form Rep. 1121A (7/20/22);

(c) "Drug Repository Patient Eligibility Affidavit Form," Form Rep. 1121B (7/20/22).

(d) "Legend Drug Donor Attestation Form," Form Rep. 1121 C (3/2026).

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. and may be accessed online at https://pharmacy.ky.gov/Forms/Pages/default.aspx.

(201 KAR 002:440. 48 Ky.R. 2131, 2758, 2956; eff. 7-20-2022; 52 Ky.R. 1736, 2032, 215, 485; eff. 9-15-2026.)

FILED WITH LRC: August 11, 2026

CONTACT PERSON: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov..