BOARDS AND COMMISSIONS
Kentucky Board of Pharmacy
(Amendment)

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 to 360-4, 21 U.S.C. 381 to 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 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 that has received authorization from the board to participate in the legend drug repository program pursuant to Section 2 and whose authorization has not been revoked by the board pursuant to Section 3.

(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 that is over the age of 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) An individual who is indigent, uninsured, or underinsured; and

(b) Other patients, if a need for the donated drugs is 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 the following:
(a) That the donor meets the definition provided in Section 1;
(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; and
(d) If applicable, that the donor will:
1. Remove or redact any patient names and prescription numbers on donated drugs; or
2. Otherwise maintain patient confidentiality by executing a confidentiality agreement with the authorized recipient.
3. 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);
(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 an expiration date of ninety (90) days or greater, unless the drug:
1. Is in high demand, as determined by the professional judgement of the authorized recipient; and
2. Can be dispensed for use prior to the drug's expiration date;
(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 Section 3(1) shall be disposed by returning it to the drug donor, destroying it by incinerator, medical waste hauler, or other lawful method, or transferring it to a return processor.
(b) A record of disposed drugs shall consist of the:
1. Disposal method described 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 them 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).
(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) 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 this chapter 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 Patient Eligibility Affidavit Form provided by the board or a substantively similar physical or electronic form when confirming 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 specified in a recall notice shall be considered recalled unless the drug has an affixed lot number to exclude it from the recall.

(12) An authorized recipient may dispense a therapeutic equivalent drug product under the following conditions:

(a) The ordering practitioner has indicated "formulary compliance approval" on the prescription, in one (1) of the following ways:

1. In the practitioner's own handwriting; or

2. By checking a "formulary compliance approval" box on a preprinted form;

(b) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:

1. That the pharmacist engaged in formulary compliance; and

2. Of the therapeutic equivalent drug product that was dispensed.

(c) The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative.

Section 5. Forms and Recordkeeping.

(1) All records required by this chapter shall be retained in physical or electronic format, on or off the authorized recipient's premise for a period of five (5) years. A donor or authorized recipient may contract with one another or a third-party to create and maintain records on each other's behalf. 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 this chapter if it allows for this information to be readily retrievable. Upon request by the board, the identifier used for requested records shall be replaced with the original information. An identifier shall not be used on patient labels when 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 is 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 specified 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)~~[05/2017]~~;

(b) "Legend Drug Repository Authorized Recipient Form," Form Rep. 1121A (12/2021);

(c) "Legend Drug Repository Patient Eligibility Affidavit Form," Form Rep. 1121B (12/2021).

(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.

CHRISTOPHER HARLOW, PharmD, Executive Director

APPROVED BY AGENCY: March 9, 2026

FILED WITH LRC: March 10, 2026 at 3:15 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on May 22, 2026, at 9:00 a.m. EST via a Zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted

through May 31, 2026. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Christopher Harlow

Subject Headings:Pharmacy; Colleges and Universities; Education and Professional Standards.

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes and governs the legend drug repository program for pharmacies and other entities legally entitled to possession prescription drugs in the Commonwealth and sets forth requirements relating to the ability of a pharmacy or other authorized entity to accept drugs as part of the legend drug repository program.

(b) The necessity of this administrative regulation:
KRS 315.458 directs the Board to create, by administrative regulation, a legend drug repository program.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This regulation establishes the legend drug repository program and sets forth requirements to ensure the program is safe for participants.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
This regulation sets forth the framework of the program and ensures the intent of the legislature is followed.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
This amendment expands the definition of "donor" to include individuals over the age of 18 and allows individuals, not just licensed entities- to donate eligible prescription drug to the legend drug repository program and thereby increasing the potential supply of donated medications for populations in need. This expansion will also reduce the barriers for participation in the program.

(b) The necessity of the amendment to this administrative regulation:
This amendment is necessary because one of the noted barriers from the one participating program in the state is that individuals cannot donate their medications or the medications of deceased loved ones. Often, these potential donors are referred to bordering states that allow individuals to donate qualifying medications.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 315.458 states that the Board shall promulgate regulations to establish the program which includes setting forth the criteria for acceptance of and processing of the donated medications. This authority would include establishing criteria for who can donate into the program and how those medications should be inspected for safety.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment will expand the eligibility of who can donate to the program and thereby increase the ability of donated medications to help those Kentuckians that need this healthcare resource. The requirements for inspection will remain the same.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No. This builds upon the prior legislation that was enacted to create the legend drug repository program.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

Statewide this regulation affects pharmacies or individuals seeking authorization as legend drug recipients; healthcare facilities and providers that may participate as donors or dispensing sites; drug manufacturers, wholesalers, repackagers, outsourcing facilities, return processors or other authorized entities that may donate drugs; and as amended, individual members of the public over the age of 18 who may donate eligible medications (if passed). It also impacts eligible patients who may receive donated drugs and the Kentucky Board of Pharmacy as the administering and auditing agency.

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment:

Pharmacies and pharmacists will have to familiarize themselves with new amended language in the regulation. However, there has been no significant changes beyond the updated standards.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

There are no expected costs for the parties to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

The amendment may increase participation in the legend drug repository and thereby make more meaningful impact for those that are in need in the Commonwealth. The amendment may also contribute to a reduction in pharmaceutical waste in the state. (6) Provide an estimate of how much it will cost to implement this administrative Regulation:

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

No costs will be incurred.

(b) On a continuing basis:

No costs will be incurred.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:

Board revenues from pre-existing fees provide the funding to enforce the regulation.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No increase in fees or funding will be required because of this new regulation.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not establish fees or directly or indirectly increase any fees.

(10) TIERING: Is tiering applied?

Tiering is not applied because the regulation is applicable to all pharmacists and sponsors that desire approval for continuing education credit.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation:
KRS 315.450 – 315.460; 201 KAR 2:440.

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:
KRS 315.1941(1)(a) and KRS 315.458.

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:
The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):
Only the Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):
None.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)

(a) Fiscal impact of this administrative regulation:

The regulation does not cost anything for regulated parties to implement nor does it have a cost to the Board to oversee.

(b) Methodology and resources used to reach this conclusion:

None.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14):

No, this administrative regulation does not have an overall negative or adverse major economic impact to regulated entities, or those entities identified in questions (2)-(4).

(b) The methodology and resources used to reach this conclusion:

Analysis of the Board’s expenditures as well as an assessment regarding cost of compliance for regulated entities.