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May 3, 2022

Senator Stephen West, Co-Chair
Representative David Hale, Co-Chair
c/o Emily Caudill, Regulation Compiler
Administrative Regulation Review Subcommittee
Legislative Research Commission
029, Capitol Annex
Frankfort KY 40601

Re: 201 KAR 2:440

Dear Co-Chairs West and Hale:

After discussions with Administrative Regulation Review Subcommittee staff of the issues raised by 201 KAR 2:440, the Board of Pharmacy proposes the attached amendment to 201 KAR 2:440.

Sincerely,

Christopher P. Harlow
Executive Director

REVISED:
5/3/2022 8:44 AM

SUGGESTED SUBSTITUTE

BOARDS AND COMMISSIONS
Board of Pharmacy
(Amended After Comments)

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

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the **Kentucky Board of Pharmacy**~~[board]~~ 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**~~[requires]~~ 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the board to participate in the legend drug repository program pursuant to Section 2 and whose authorization has not been revoked by the board pursuant to Section 3.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**~~[has the same meaning as]~~ defined **by**~~[in]~~ KRS 218A.010.

(4) "Dispense" **is**~~[has the same meaning as]~~ defined **by**~~[in]~~ KRS 315.010.

(5) "Distribute" **is**~~[has the same meaning as]~~ defined **by**~~[in]~~ KRS 315.400.

(6) "Donor" **means: (a)**~~[shall mean]~~ Any entity legally authorized and permitted to possess drugs, **such as**~~[including but not limited to]~~ 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)~~[. Donor shall also mean]~~ Government agencies and entities that are federally authorized to possess drugs, **such as: 1.**~~[including but not limited to]~~ 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[Federal FD&C Section 801, 804,]** or similar provisions[~~-, and prisons~~].

(7) "Drug" ~~is[has the same meaning as]~~ defined ~~by[in]~~ KRS 315.010.

(8) "Eligible patient" means: **(a)** An individual who is indigent, uninsured, or underinsured; **and**

(b)[;] Other patients,~~[shall be considered eligible]~~ if a need for the donated drugs is not identified among indigent, uninsured, and underinsured individuals.

(9) "Health care provider" ~~is defined by[has the same meaning as in]~~ KRS 304.17A-005**(23)**.

(10) "~~Health[Heath]~~ facility" ~~is defined by[has the same meaning as in]~~ KRS 216B.015**(13)**.

(11) "Original packaging" ~~means[shall mean]~~ the packaging in which the drug was donated by the donor.

(12) "Pharmacist" ~~is[has the same meaning as]~~ defined ~~by[in]~~ 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[has the same meaning as defined in 201 KAR 2:320]**.

(15) "Repackager" ~~is[has the same meaning as]~~ defined ~~by[in]~~ KRS 315.400**(16)**.

(16) "Returns processor": **(a) Is defined by[shall have the same meaning as in]** 21 U.S.C. Section 360eee(18); and

(b) Includes[shall include but is not limited to] a reverse distributor **or similar entity**.

(17) "Unopened tamper-evident packaging" ~~is defined by the [shall have the same meaning as]~~ United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements, **and includes[including but not limited to]** 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[must]~~ 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.

(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 [Such]** 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) ~~**[Nothing in this chapter shall require]**~~ 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[may]** 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)[4.4]**~~;
 - (b) If in a single unit dose, ~~**have[the]**~~ packaging ~~**that is[of that dose must be]**~~ 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) ~~**[Have packaging that lists the lot number of the drug;**~~
 - ~~**(h)]**~~ Are not considered to be medical supplies;
 - ~~**(h)[(i)]**~~ 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) ~~(j)~~ 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** ~~**3.1 must**~~ 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 ~~**as**~~ described **in paragraph (a) of this subsection;** ~~**above;**~~

2. The date of the disposal; ~~**;**~~ and

3. The name, strength, and quantity of each drug disposed.

(c) ~~**No**~~ Other **records** ~~**record**~~ 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** ~~**accepting**~~ 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.** ~~**the**~~ 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) ~~**No**~~ Other **records** ~~**record**~~ of donation shall **not** be required.

(5) An authorized recipient shall store and maintain donated drugs **in a manner that distinguishes them** ~~**physically separated**~~ 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** ~~**standards**~~.

Section 4. Safe Distribution and Dispensing of Drugs. (1) ~~**Notwithstanding any other law or rule,**~~ 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)** ~~**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** ~~**may**~~ only administer or dispense drugs that:

(a) Meet the requirements of Section **3(1) and are not** ~~**3.1, including not being**~~ 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[may]*** dispense or administer drugs to an eligible patient ***if permitted by KRS Chapter 315 and 201 KAR Chapter 2[only if otherwise permitted by law]***. Prescription drugs ***shall: (a)[may]*** Only be dispensed or administered to patients pursuant to a valid prescription drug order; and

(b)[shall] 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.[shall be] 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[this]*** program, and in the case of a pharmacy, may dispense donated drugs to residents of ***Kentucky[this state]***. This entity ***shall be[is]*** required to comply with all ***Kentucky statutes[laws]*** and ***administrative regulations [rules in this state]***.

(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[No]*** legend drug or supply needed to administer a legend drug that ***is[are]*** donated for use under this program ***shall not[may]*** be resold.

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

(10) ***A[No]*** 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[and/or]** 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[such]** 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[which]** chooses to participate in the program shall make all records available to audit by the board within forty-eight (48) hours.

(3) **If[When]** 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[under federal law].**

(4) A donation, or other transfer of possession or control, shall not be construed as a change of ownership unless **[it is-]**specified **[as such-]**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)[-shall]** Include all prior donations; **[-]** and **(c)[-]** If the drugs were previously dispensed,**[shall]** only include drug information required to be on the patient label in accordance with KRS Chapter 315 and 201 KAR Chapter 2.

Section 6. **[Authority. This chapter shall have sole authority over the program and**

~~**shall supersede any inconsistent law or rule.**~~

—~~**Section 7.]**~~ Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) "USP 659 Packaging and Storage Requirements," 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).

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