315.450 Definitions for KRS 315.450 to 315.460.

For the purposes of KRS 315.450 to 315.460:

(1) "Controlled substance" has the same meaning as in KRS 218A.010;

(2) "Dispense" has the same meaning as in KRS 217.015;

(3) "Health care provider" has the same meaning as in KRS 304.17A-005;

(4) "Health facility" has the same meaning as in KRS 216B.015;

(5) "Legend drug" has the same meaning as in KRS 217.015;

(6) "Pharmacist" has the same meaning as in KRS 315.010; and

(7) "Prescription drug" has the same meaning as in KRS 315.010.

315.452 Legend Drug Repository Program to be established -- Purpose -- Permitted donations -- Voluntary participation -- Handling fee -- Distribution.

(1) The board shall establish and maintain a legend drug repository program to support the donation of a legend drug or supplies needed to administer a legend drug for use by an individual who meets the eligibility criteria specified by an administrative regulation promulgated by the board. The repository program shall not accept any controlled substance.

(2) Donations may be made on the premises of a health facility or pharmacy that elects to participate in the program and meets requirements specified by the board by an administrative regulation promulgated by the board.

(3) The health facility may charge a handling fee to an individual who received a legend drug or supplies under the program established under this section,

except that the fee shall not exceed the amount established by an administrative regulation promulgated by the board.

(4) A health facility or pharmacy that receives a donated legend drug under this section may distribute the legend drug or supplies to another eligible health facility or pharmacy for use under the program created under this section.

(5) Nothing in this section or KRS 315.454 shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established in this section.

315.454 Requirements for accepting and dispensing legend drug or administration supplies.

(1) A legend drug or supplies used to administer a legend drug may be accepted and dispensed under the program established in KRS 315.452 only if the following requirements are met:

(a) The legend drug or supplies needed to administer the legend drug is in its original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened;

(b) The legend drug is not classified as a controlled substance;

(c) The legend drug or supplies needed to administer a legend drug is not adulterated or misbranded, as determined by a pharmacist employed by, or under contract with, the health facility or pharmacy, who shall inspect the drug or supplies needed to administer a legend drug before the drug

or supplies are dispensed; and

(d) The legend drug or supplies needed to administer a legend drug are prescribed by a physician, advanced practice registered nurse, or physician assistant and dispensed by a pharmacist.

(2) No legend drug or supplies needed to administer a legend drug that are donated for use under this section may be resold.

315.456 Immunity from civil liability -- Exceptions.

(1) Unless the manufacturer of a legend drug or supply needed to administer a legend drug exercises bad faith or fails to exercise ordinary care, the manufacturer of a legend drug or supply shall not be subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the drug or supply under the legend drug repository created under KRS 315.452, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

(2) Health facilities, pharmacies, and health care providers shall be immune from civil liability for injury to or the death of an individual to whom a legend drug or supply is dispensed and shall not be subject to disciplinary action for unprofessional conduct for their acts or omissions related to donating, accepting, distributing, or dispensing a legend drug or supply under KRS 315.450 to 315.460, unless the act or omission involves reckless, wanton, or intentional misconduct or the act or omission results from failure to exercise

ordinary care.

315.458 Required administrative regulations.

The board shall promulgate administrative regulations to establish:

(1) The requirements for health facilities and pharmacies to accept and dispense donated legend drugs or supplies needed to administer legend drugs under KRS 315.452 and 315.454, including all of the following:

(a) Eligibility criteria for health facilities;

(b) Standards and procedures for accepting, safely storing, and dispensing donated legend drugs or supplies needed to administer legend drugs;

(c) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine if these are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened; and

(d) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine that these are not adulterated or misbranded;

(2) Eligibility criteria for individuals to receive donated legend drugs or supplies needed to administer legend drugs dispensed under KRS 315.452 and 315.454;

(3) Standards for prioritizing the dispensation to individuals who are uninsured or indigent, or to others if an uninsured or indigent individual is unavailable;

(4) A means by which an individual who is eligible to receive a donated legend drug or supplies needed to administer a legend drug may indicate that eligibility;

(5) Necessary forms for administration of the legend drug repository program;

(6) The maximum handling fee that a health facility may charge for accepting, distributing, or dispensing donated legend drugs or supplies needed to administer legend drugs;

(7) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program may accept for dispensing; and

(8) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program shall not accept for dispensing, including the reason why the legend drug or supply is ineligible for donation.

315.460 Restriction on acceptance or distribution of certain drugs.

Drugs that shall only be dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements shall not be accepted or distributed under the provisions of the program.

Proposed Repository Regulation

Section 1. Definitions

1. “Unopened tamper-evident packaging” shall have the same meaning as United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements including but not limited to unopened unit-dose and multiple-dose packaging.
2. “Original packaging” shall mean the packaging in which the drug was donated by the donor and shall not include drugs repackaged pursuant to this program.
3. “Drug” means both prescription and nonprescription drugs as defined by KRS 315.010 (10).
4. “Transaction date” means the date at which ownership of the drugs was transferred between two participants of the program as established by contract or other arrangement. If no such contract or arrangement exists, the transaction date shall be the date the drug was inspected and accepted by the recipient.
5. “National drug code” shall mean the labeler and product codes assigned by the FDA.
6. "Controlled substance" has the same meaning as in KRS 218A.010(8).
7. "Dispense" has the same meaning as in KRS 315.010(9).
8. “Distribute” has the same meaning as KRS 315.400(5).
9. "Pharmacist" has the same meaning as in KRS 315.010(17).
10. “Practitioner” shall mean a person who is authorized to dispense prescription drugs.
11. “Recipient” means a health facility as defined by KRS 216B.015 or a “pharmacy” as defined by KRS 315.010(19).

12. “Participant” means an eligible donor or recipient that has elected to participate in the program.
13. “Donor” means any person or entity legally authorized to possess prescription drugs with a license in good standing in the state in which it is located, including but not limited to a wholesaler or distributor, third party logistic provider, pharmacy, clinic, health center, prescriber or other health care professional, assisted living, skilled nursing, hospice, or health facility. It shall also include federally licensed entities that are authorized to possess prescription drugs including but not limited to drug manufacturers, Veteran Affairs hospitals, and pharmacies located inside federal prisons. It shall not include an individual member of the public.
14. “Cost of participation” means the cost of establishing and maintaining participation in the program including but not limited to the costs of educating prospective donors, providing technical support to established donors, shipping and handling, labor, storage, licensing, utilities, advertising, supplies, and equipment.
15. “Eligible patient” means an individual who is indigent, uninsured, underinsured, or enrolled in a public health benefits program including but not limited to Medicare and Medicaid. Other patients shall be considered eligible if an immediate need for the donated medicine is not identified in accordance with the criteria above.

Section 2. Participation

1. An eligible recipient may elect, but is not required, to participate in the program by completing a Recipient Form as described in Section 6 and submitting it to the Board of

Pharmacy. The completed form shall be kept on the recipient's premise at all times and serve as authority for the recipient to receive donated drugs for a period of one year, unless it is revoked by the Board of Pharmacy. An eligible recipient may renew its authority by sending a new Recipient Form each subsequent year.

2. Pursuant to KRS 315.458(3)&(4), a recipient must have a policy and procedure in place for identifying and prioritizing eligible patients that are indigent, uninsured, underinsured, or enrolled in a public health benefits program. This policy and procedure shall at minimum ensure that patients are categorized into priority and non-priority status based on the Patient Form described in Section 6. Prescriptions for non-priority patients shall only be filled after all priority prescriptions with immediate need have been filled.
3. An eligible donor may elect, but is not required, to participate in the program by completion of a Donor Form as described in Section 6 and submitting it to the recipient. Upon approval by the recipient, a donor can donate drugs to the recipient until such approval is revoked by the recipient or the recipient's authority is revoked by the Board of Pharmacy. Recipient approval may be conditioned upon a list of drugs that the recipient is willing or not willing to accept pursuant to KRS 315.458(7)&(8).

Section 3. Inspection of Drugs

1. A recipient may repackage, dispense or administer a drug under this program only if it has been inspected by a pharmacist pursuant to KRS 315.458(1)(c) and has been determined to meet all of the following requirements:

a. The drug is in the pharmacist's or practitioner's professional judgement safe to use, not adulterated, and not misbranded.
b. The drug is in unopened tamper-evident packaging, including but not limited to a full or partial single or multiple unit dose card, unit-of-use package; or the drug has been repackaged by a recipient as authorized by this program.
c. The drug's label contains the national drug code or manufacturer and the expiration date or beyond use date of the drug.
d. The drug will not expire within a minimum of six months from donation date.
e. The drug is not a controlled substance.
f. The drug does not require refrigeration or the recipient entity has verified and documented that the donor has appropriate safeguards in place to maintain drugs at an appropriate temperature during storage and transport.
g. The drug is not subject of a United States Food and Drug Administration managed risk evaluation and mitigation strategy pursuant to Section 355-1 of Title 21 of the United States Code that prohibits inventory transfer.

Section 4. Safe Storage of Drugs

1. To ensure the safe storage of donated drugs a recipient must ensure all of the following:
   a. All buildings in which drugs are stored shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

b. Buildings shall meet all applicable federal, state, and local standards. The facility shall have a quarantine area for storage of drugs that are to be destroyed in accordance with Section 7.

c. Drugs must be stored in a secure, temperature and humidity controlled area that ensures the integrity of drugs. Any area that stores drug must have access restricted to authorized personnel.

d. Recipient shall employ adequate personnel with the education and experience necessary to safely and lawfully participate in the program.

e. Donated inventory shall be differentiable from purchased inventory by either physical or electronic segregation and, if repackaged, shall also be differentiable by an easily discernible mark on the drug's new packaging.

f. A recipient shall establish, maintain, and adhere to written policies and procedures for all of the following:

    i. Ensuring, if applicable, the confidentiality of the information of the patient for whom the drug was originally dispensed including but not limited to the patient's name and prescription number. If the donor is a Covered Entity as defined by the Health Insurance Portability and Accountability Act and chooses not to remove or redact patient information from the drugs prior to donating, the donor must establish the recipient as Business Associate with a Business Associate Agreement.

ii. Handling of manufacturer recalls. Any drug must be destroyed as described in Section 7 based on the recall's drug name, strength, and national drug code or manufacturer unless the drug is labeled with a lot number that was not listed in the recall for that drug.

iii. Checking its entire inventory for expired drugs at least once every six (6) months and removing and destroying expired drugs as described in Section 7.

Section 5. Safe Distribution and Dispensing of Drugs

1. A recipient shall follow all applicable state and federal laws when dispensing donated drugs. Before a prescription drug is dispensed or administered, the recipient must ensure all of the following:
    a. The patient must have a valid prescription from a health professional authorized to prescribe prescription drugs.
    b. The patient is offered appropriate counseling pursuant to 201 KAR 2:210 (2), including but not limited to, any potential side effects.
    c. A prospective drug use review was conducted pursuant to 201 KAR 2:210 (4).
2. A recipient may receive or distribute donated medicine from/to another recipient entity or from/to a similar program operating in another state. The recipient receiving the distributed drugs must complete a Distribution Record as described in Section 6.
3. Donated inventory may be used to replenish purchased inventory that was previously dispensed or administered to an eligible patient. Replenishment shall be done in

accordance with federal 340B statute and the Health Resources and Services Administration (HRSA) guidance. A Dispensing Form as described in Section 6 must be kept for both the eligible patient who received the purchased inventory as well as the patient who received the donated inventory which replenished the purchased inventory. *How does 340B apply?*

4. Drugs may be repackaged as necessary for storage, dispensing, administration, or distribution under the supervision of a pharmacist. Repackaged drugs must be labeled with the drug name, strength, dosage form, national drug code or manufacturer, expiration date, lot number, and an easily discernable mark to show they are donated. An identifier, such as a barcode, may be used in place of any or all of this information if it allows for this information to be readily retrievable.

Section 6. Required Forms and Recordkeeping

1. A recipient shall complete and retain the following forms:
    a. A Recipient Form that it annually submits to the Board of Pharmacy.
    b. A Donor Form for every donor that has donated to the recipient.
    c. A Donation Form for every drug donated to the recipient.
    d. A Distribution Form for every drug distributed to the recipient.
    e. A Destruction Form for every drug destroyed by the recipient.
    f. A Dispensing Form for every drug dispensed by the recipient.
    g. A Patient Form for every patient given priority for donated drugs.

2. All forms required by this program shall be retained for three (3) years and be retrievable upon request. Forms shall be available for audit by the donor and the Board of Pharmacy during business hours.
    a. Recipient Form. To participate in the program, a recipient must complete a recipient form with the recipient's name, address, license number, and phone number and submit it to the Board of Pharmacy. If a recipient willfully violates any requirement of the program, the Board of Pharmacy may revoke that recipient's authority to receive donations by providing a written notice to the recipient which shall include the requirement(s) that were violated and the corrective actions necessary, if any, for the recipient to reinstate its authority to participate in the program with the Board of Pharmacy.
    b. Donor Form. Before receiving a donation from a donor, a recipient must ensure that the donor has a license in good standing and has completed and submitted to the recipient a Donor Form with the donor's name, address and phone number. A recipient may revoke a donor's authority to donate to them at any time by providing written notice to the donor.
    c. Donation Form. The donation record shall contain the drug name, strength, dosage form, national drug code or manufacturer, quantity of each drug, the transaction date, the donor's name, address, license number, and phone number, and the recipient's name, address, license number, and phone number.

d. Distribution Form. The distribution record shall contain drug name, strength, dosage form, national drug code or manufacturer, quantity of each drug; the transaction date; the name, address, license number, and phone number of the recipient sending the drugs; and the name, address, license number, and phone number of the recipient receiving the drugs.

e. Destruction Form. The destruction record shall contain drug name, strength, quantity of each drug; the recipient's name, address, license number, and phone number; and the name, address, license number, and phone number of the destruction company as described in Section 7.

f. Dispensing Form. The dispensing form must contain all of the information required by the Board of Pharmacy pursuant to KAR 2:210(1), including but not limited to, drug name, strength, dosage form, quantity, the dispensing date, expiration or beyond use date, and all applicable patient and dispenser information. If dispensed by a permitted pharmacy, the dispensing record may be substituted for the dispensing form.

g. Patient Form. A recipient shall create, maintain, and adhere to written policies and procedures by which a patient can indicate whether they are uninsured, underinsured, or enrolled in a public health benefits program, including but not limited to a patient or prescriber certification. Priority shall only be given to patients whose status has been properly indicated and documented.

3. Donation, distribution, and the brokering or other facilitation of donation or distribution of a drug pursuant to this program shall not be considered wholesale distribution and shall not require licensure as a wholesale distributor.
4. Forms and records may be retained in physical or electronic format, on or off the recipient's premise. A recipient may contract with the donor or a third-party to create and/or retain records on the recipient's behalf. Such an arrangement shall not relieve the recipient of the requirements of this Section.

Section 7. Destruction

1. Records of destruction shall be created and retained as described in Section 6.
2. Recipient must follow all state and federal laws for destruction of donated drugs, including the destruction of EPA hazardous waste as defined the federal Resource Conservation and Recovery Act.

Section 8. Fees

1. In accordance with all local, state, and federal laws, a donor may claim a state and/or federal tax credit for a drug donation if the recipient is registered as a 501(c)3 non-profit corporation.
2. The handling and U&C fees shall not exceed the reasonable cost of participation in the program and shall not exceed the greater of $10 per month supply and 50% of the average wholesale price for the drug.

3. If the U&C fee is to be charged directly to a patient and the patient can provide reasonable evidence that they are unable to afford the recipient's regular U&C fee, a recipient must waive or discount the fee based on the patient's ability to pay.

Modifed from Iowa law

LEGEND DRUG REPOSITORY PROGRAM

Definitions. For purposes of this chapter, the following definitions apply:

"Repository" means a distributor approved by the contractor and licensed pursuant to KRS 315.452 that accepts donated drugs, conducts a safety inspection of the drugs, and ships the donated drugs to a local repository to be dispensed in compliance with this chapter and federal and state laws, regulations and regulations.

"Contractor" means the third party approved by the department to implement and administer the prescription drug donation repository program.

"Controlled substance" means the same as defined in KRS 218A.010.

"Board" means the Kentucky Board of Pharmacy.

"Indigent" means a person with an income that is below 200 percent of the federal poverty level (FPL) as defined by the most recently revised poverty income guidelines published by the United States Department of Health and Human Services.

"Legend drug" as defined in KRS 217.015(28).

"Local repository" means a pharmacy or health facility that elects to accept and dispense donated drugs and that meets the eligibility requirements of KRS 315.454.

"Health facility" as defined in KRS 216B.015 Section 13.

"NDC #" means the unique national drug code number that identifies a specific approved drug.

"Pharmacist" means a pharmacist as defined in KRS 315.010(17).

"Pharmacy" means a pharmacy as defined in KRS 315.010(19).

"Health care provider" as defined in KRS 304.17A-005.

"Prescription drug" means the same as defined in KRS 315.010(24) but does not include controlled substances.

"Supplies" means the supplies necessary to administer the prescription drugs donated.

"USP" means United States Pharmacopoeia.

"Dispense" as defined in KRS 315.010(9).

Purpose. The overall purpose of this chapter is to establish administrative regulations in accordance with KRS 315.452 relative to the following:

1. Requirements for health facilities and pharmacies to accept and dispense donated prescription drugs and supplies.
2. Eligibility criteria for individuals to receive donated prescription drugs and supplies.

Eligibility criteria for program participation by health facilities and pharmacies.

1. To be eligible for participation in the legend drug repository program, a health facility or pharmacy shall be in compliance with all applicable federal and state laws, including laws applicable to the storage and distribution of drugs and the appropriate licensure standards, and shall hold active, unrestricted, state-issued permits, licenses or registrations in good standing.
2. Participation in the legend drug repository program is voluntary.
3. A pharmacy or health facility may elect to participate in the legend drug repository program by providing, on a form provided by the Board, written notification to the repository of all of the following:
    a) The name, street address, and telephone number of the pharmacy or health facility, and any state-issued license, permit or registration number issued to the pharmacy or health facility, including the name of the issuing agency.
    b) The name and telephone number of the responsible pharmacist or health care provider who is employed by or under contract with the pharmacy or health

facility.

c) A statement, signed and dated by the responsible pharmacist or health care provider, indicating that the pharmacy or health facility meets the eligibility requirements under this regulation and shall comply with the requirements of this section.

4. Withdrawal from participation. A pharmacy or health facility may withdraw from participation in the legend drug repository program at any time by providing written notice to the repository on a form provided by the Board.

Standards and procedures for accepting donated prescription drugs and supplies.

1. Any individual who is 18 years of age or older may donate legally obtained prescription drugs or supplies to the repository if the drugs or supplies meet the requirements of this regulation, as determined by a pharmacist who is employed by or under contract with a drug repository.
2. No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or United States Pharmacopoeia shall be donated or accepted as part of the prescription drug donation repository program. Drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP shall not be donated or accepted because of the increased potential for these drugs to become adulterated. Excluded from this restriction are drugs donated directly from a drug manufacturer.
3. Controlled substances shall not be donated or accepted. Pursuant to federal and state laws, a controlled substance cannot be returned or reused once the drug has been dispensed to a patient.
4. The repository may accept a prescription drug only if all of the following requirements

are met:

a) The drug is in its original sealed and tamper-evident packaging. However, a drug in a single-unit dose or blister pack with the outside packaging opened may be accepted if the single-unit-dose packaging is undisturbed; and

b) The drug has been stored according to manufacturer or USP storage requirements; and

c) The packaging contains the lot number and expiration date of the drug. If the lot number is not retrievable, all specified medications will be destroyed in the event of a recall; and

d) The drug has an expiration date that is more than six months after the date that the drug was donated; and

e) The drug does not have any physical signs of tampering or adulteration, and there is no reason to believe that the drug is adulterated; and

f) The packaging does not have any physical signs of tampering, misbranding, deterioration, compromised integrity or adulteration; and

g) All drugs shall be inventoried at the repository. The inventory shall include the name of the drug, strength of the drug, quantity of the drug, and the date of donation if the drug has been continually under the control of a health care professional. If the drug has not been continually under the control of a health care professional, the repository shall collect a donation form provided by the legend drug repository program that is signed by the person making the donation or that person's authorized representative.

5. A repository may accept supplies necessary to administer the prescription drugs donated only if all of the following requirements are met:

a) The supplies are in their original, unopened, sealed packaging;

b) The supplies are not adulterated or misbranded; and

c) All supplies shall be inventoried at the repository. The inventory shall include a description of the supplies and the date donated. Such inventory shall be recorded on a form provided by the legend drug repository program.

6. Drugs and supplies may be donated on the premises of a participating repository to a person designated by the repository. A drop box may not be used to deliver or accept donations.

Standards and procedures for inspecting and storing donated prescription drugs and supplies.

1. A licensed pharmacist employed by or under contract with the repository shall inspect donated prescription drugs and supplies to determine, to the extent reasonably possible in the judgment of the pharmacist, that the drugs and supplies are not adulterated or misbranded, are safe and suitable for dispensing, and are not ineligible drugs or supplies. The pharmacist who inspects the drugs shall sign an inspection record stating the above and attach it to the copy of the inventory or donor record provided with the drugs.

2. The repository shall store donated drugs and supplies in a secure storage area under environmental conditions appropriate for the drugs or supplies being stored. Donated drugs and supplies may not be stored with non-donated inventory. When donated drugs are not inspected immediately upon receipt, a repository shall quarantine the donated drugs separately from all dispensing stock until the donated drugs have been inspected and approved for dispensing under the program.

3. Repositories shall destroy donated non-controlled substances that are not

suitable for dispensing and make a record of such destruction.

4. Controlled substances shall not be accepted for donation.

5. If a repository receives a recall notification, the repository shall perform a uniform destruction of all of the recalled prescription drugs in the repository and document the destruction for all donated drugs destroyed. If a recalled drug has been dispensed, the repository shall immediately notify the recipient of the recalled drug pursuant to established drug recall procedures.

Standards and procedures for dispensing donated prescription drugs and supplies.

1. Donated drugs and supplies may be dispensed only if the drugs or supplies are prescribed by a health care practitioner for use by an eligible individual and are dispensed by a licensed pharmacist or licensed physician.

2. A repository shall prioritize dispensing to an individual requesting drugs through the program as follows:

   a. First, to an indigent individual;

   b. Second, to an individual who has no active third-party prescription drug reimbursement coverage for the drug prescribed; and

   c. Third, to any other individual if an indigent or uninsured individual is unavailable.

3. A repository shall dispense donated prescription drugs in compliance with applicable federal and state laws and regulations for dispensing prescription drugs, including all requirements relating to packaging, labeling, record keeping, drug utilization review, and patient counseling.

4. The repository shall remove the original donor's identification and the name of the dispensing pharmacy from the package prior to dispensing the drugs or supplies.

5. Prescription drugs or supplies donated under this program shall not be resold.

6. The participating repositories may distribute drugs and supplies donated under this program to other participating repositories for use pursuant to the program. The repository distributing the drugs or supplies shall document the transfer.

Eligibility criteria for individuals to receive donated prescription drugs and supplies.

1. A person must meet the following requirements to become an eligible recipient of drugs from a drug repository program:

(a) Is residing in Kentucky; and

(b) Has no reasonable financial means to pay for the drug prescribed.

Forms and record keeping.

1. The following forms developed for the administration of this program shall be utilized by participants of the program and are provided by the Kentucky Board of Pharmacy. Prescription drug donation repository program notice of participation or withdrawal.

a. Kentucky Dispensing Form

b. Kentucky Donor Participation Form

c. Kentucky Individual Donation From

2. Record-keeping requirements.

a. All records required to be maintained as a part of the legend drug repository program shall be maintained for a minimum of five years by participating pharmacies and medical facilities.

b. Records required as part of this program shall be maintained pursuant to all current applicable practice acts.

Handling fee. 1. A repository may charge the recipient of a donated drug a handling fee, not to exceed a maximum of 200 percent of the Medicaid professional dispensing fee, to cover stocking and dispensing costs.

List of drugs and supplies program will accept. 1. All prescription drugs, excluding controlled substances, that have been approved for medical use in the United States, that are listed in the USP or National Formulary (USP/NF), and that meet the criteria for donation established by these regulations may be accepted for donation under the legend drug repository program.

Kentucky Board of Pharmacy State
Office Building Annex, Ste 300 125
Holmes Street
Frankfort, KY 40601
Phone: (502) 564-7910
Fax: (502) 696-3806
www.pharmacy.ky.gov

Kentucky Drug Donation Repository Program
Notice of Participation to Dispense

Completion of this form meets the notification requirement to prescribe and/or dispense prescription medications as part of the prescription drug donation program under KRS 315.452. Complete and submit this form to the Kentucky Board of Pharmacy. Questions about completing this form may be directed to (502) 564-7910 .

Pharmacy or Medical Facility

Name — Pharmacy		**Telephone Number**
Address		
City	**State**	**Zip Code**
Permit or License Number	**Name of Agency/Board Issuing/Registration Number**	
Name— Pharmacist, Physician, Nurse Practitioner, Program Manager		**Telephone Number**

I certify the above named facility is in compliance with all state and federal laws and administrative rules and will comply with the requirements of this chapter. Further, I certify that if DDRP medications are taken off site for any purpose they will be transported in a manner that is secure and environmentally controlled.

Will DDRP medications be taken off site? YES / NO

***Drugs and biological products for which the Federal Food and Drug Administration (FDA) requires a Risk Evaluation and Mitigation Strategy (REMS) with an element to assure safe use and an implementation system, and such drugs and biological products as determined by the pharmacist in charge, shall not be accepted or distributed under the provisions of the program.**

Signature — Pharmacist, Physician, Nurse Practitioner, Program Manager	**Date**

Primary Contact Information

Name of Primary Contact for Drug Donation Program Communication	**Primary Contact Phone Number**
Primary Email Address	**Primary Contact Fax Number**

Kentucky Board of Pharmacy State
Office Building Annex, Ste 300 125
Holmes Street Frankfort, KY 40601
Phone: (502) 564-7910
Fax: (502) 696-3806
www.pharmacy.ky.gov

Kentucky Drug Donation Program
Program Donor Participation Form

Completion of this form meets the requirements to donate prescription medications as part of the Legend Drug Repository Program under 315.452. Complete and submit this form to the participating pharmacy. Questions about completing this form may be directed to (502) 564-7910 .

Pharmacy, Medical Facility, or Other Donor Site

Name of Donating Site		**Telephone Number**
Address		
City	**State**	**Zip Code**
Name—Pharmacist, Physician, Nurse Practitioner, or Manager		**Telephone Number**
License/Permit Number	**Name of Agency/Board Issuing License Number**	

"I am the pharmacist, physician, or nurse practitioner in charge of the pharmacy or medical facility listed above. The eligible facility or manufacturer is in compliance with all applicable federal and state laws including those related to the storage and distribution of drugs and holds an active non-restricted state issued license in good standing in Kentucky. I have read the attached rules related to the repository program and agree that this phar-macy or medical facility shall comply with such rules."

Signature -Pharmacist, Physician, Nurse Practitioner, or Manager	**Date**

Primary Contact Information

Name of Primary Contact for Drug Donation Program Communication	**Primary Contact Phone Number**
Primary Email Address	**Primary Contact Fax Number**

Please see attached Prescription Drug Donation Program Rules.

***Drugs and biological products for which the Federal Food and Drug Administration (FDA) requires a Risk Evaluation and Mitigation Strategy (REMS) with an element to assure safe use and an implementation system, and such drugs and biological products as determined by the pharmacist in charge, shall not be accepted or distributed under the provisions of the program.**

Kentucky Board of Pharmacy State
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Kentucky Drug Donation Program
Individual Donation Record

Medication/Medical Supply Information

1.	**Medication/Medical Supply**		**Manufacturer/NDC #**	
	Drug Strength & Dosage Form	**Expiration Date**	**Quantity**	**Lot # (if available)**
2.	**Medication/Medical Supply**		**Manufacturer/NDC #**	
	Drug Strength & Dosage Form	**Expiration Date**	**Quantity**	**Lot # (if available)**
3.	**Medication/Medical Supply**		**Manufacturer/NDC #**	
	Drug Strength & Dosage Form	**Expiration Date**	**Quantity**	**Lot # (if available)**

Additional Items Should Be Listed on the Back of This Form

Donor Information & Certification

Donor — Name (print)
Donor — Address (print)

I certify that the medications or medical supplies listed on this form were stored as recommended by the manufacturer and have not been tampered with:

Signature — Donor	**Date Donated**
Signature — Donation Program Representative	**Date**

Completion of this form meets the requirements of KRS 315.452 for donating drugs and supplies.

***Drugs and biological products for which the Federal Food and Drug Administration (FDA) requires a Risk Evaluation and Mitigation Strategy (REMS) with an element to assure safe use and an implementation system, and such drugs and biological products as determined by the pharmacist in charge, shall not be accepted or distributed under the provisions of the program.**

Draft Regulations – Faith Pharmacy version

Section 1. Definitions

1. “Drug” means legend drug, as defined by KRS 217.015, or supplies needed to administer a legend drug.
2. “Unopened tamper-evident packaging” shall have the same meaning as United States Pharmacopeia (USP) General Chapter 659, Packaging and Storage Requirements including but not limited to unopened unit-dose, multiple-dose, immediate, secondary, and tertiary packaging.
3. “Original packaging” shall mean the packaging in which the drug was donated by the donor.
4. "Controlled substance" has the same meaning as in KRS 218A.010.
5. "Dispense" has the same meaning as in KRS 217.015.
6. “Distribute” has the same meaning as KRS 315.400.
7. "Pharmacist" shall mean a natural person licensed by this state or the state in which an out-of-state authorized recipient is located to engage in the practice of the profession of pharmacy.
8. “Donor” shall mean any person, including an individual member of the public, or any entity legally authorized to possess drugs, including but not limited to a wholesaler or distributor, third party logistic providers, pharmacy, dispenser, clinic, surgical or health center, detention and rehabilitation centers, laboratory, medical or pharmacy school, prescriber or other health care professional, or healthcare facility. Donor shall also mean government agencies and entities that are federally authorized to possess drugs including but not limited to drug manufacturers, repackagers, relabelers, outsourcing facilities, Veteran Affairs hospitals, FDA authorized importers such as those under Federal FD&C Section 801, 804, or similar provisions, and prisons.
9. “Eligible patient” means an individual who is indigent or uninsured. Other patients shall be considered eligible if a need for the donated drugs is not identified among indigent or uninsured individuals.
10. "Health care provider" has the same meaning as in KRS 304.17A-005.
11. “Recipient” means a charitable pharmacy as defined by KRS 315.035, a pharmacy with a license in good standing in the state in which it is located, or an entity participating in a drug donation or repository program operated by another state.
12. “Authorized recipient” means a recipient that has not had its authorization revoked by the Board pursuant to Section 2.
13. “Returns processor” shall have the same meaning as 21 U.S.C. Section 360eee(18) and shall include but is not limited to a reverse distributor.
14. “Board” means the Kentucky Board of Pharmacy.

Section 2. Participation in the Legend Drug 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 must verify and record the following:
    a. The donor meets the definition provided in Section 1;
    b. The donor’s name, address, phone number, and license number if applicable;
    c. The donor will only make donations of drugs in accordance with Section 3;

d. If applicable, the donor will remove or redact any patient names and prescription numbers on donated drugs or otherwise maintain patient confidentiality by executing a confidentiality agreement with the authorized recipient.

2. The Board can revoke the authorization of a recipient to participate in the program by issuing a written notice to the recipient. 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.
3. Nothing in this chapter shall require a health facility, pharmacy, pharmacist, or practitioner to participate in the program established in this section.
4. A drug manufacturer, repackager, dispenser, or wholesaler other than a returns processor participating in this program shall comply with the requirements of 21 U.S.C. Sections 360eee-1 through 360eee-4 relating to drug supply chain security.

Section 3. Accepting, Inspecting and Storing Drugs

1. An authorized recipient may only accept into inventory donated drugs that:
    a. are in original, unopened, sealed, and tamper-evident packaging; or have been repackaged under this program;
    b. are not classified as a controlled substance;
    c. are not adulterated or misbranded;
    d. do not require only being dispensed to a patient registered with the drug's manufacturer in accordance with federal Food and Drug Administration requirements; and
    e. has a USP-recognized method to detect improper temperature variations if the drugs require temperature control other than "room temperature storage."
2. Donated drugs that do not meet the requirements of Section 3.1 must be disposed by returning it to the drug donor, destroying it by an incinerator, medical waste hauler, or other lawful method, or transferring it to a returns processor. A record of disposed drugs shall consist of the disposal method as described above, the date of disposal, and the name, strength, and quantity of each drug disposed. No other record of disposal shall be required.
3. All drugs received but not yet accepted into inventory shall be kept in a separate designated area. Prior to or upon accepting a donation or transfer into inventory, an authorized recipient shall maintain a written or electronic inventory of the donation, consisting of the name, strength, and quantity of each accepted drug, and the name, address and phone number of the donor. This record shall not be required if the two parties are under common ownership or common control. No other record of donation shall be required.
4. An authorized recipient must store and maintain donated drugs physically or electronically separated from other inventory and in a secure and temperature controlled environment that meets the drug manufacturers' recommendations and United States Pharmacopeial Convention (USP) 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.
    c. Replenish drugs of the same drug name and strength previously dispensed or administered to eligible patients in accordance with federal 340b statute.
2. An authorized recipient may only administer or dispense drugs that:
    a. meet the requirements of Section 3.1, including not being 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 the regulations of the Board; and
    d. have an expiration date brought forward from the donated drugs that will not expire before the use by the patient based on the prescribing practitioner's directions for use.
    e. are prescribed by a physician, advanced practice registered nurse, or physician assistant and dispensed by a pharmacist.
3. An authorized recipient may dispense or administer drugs to an eligible patient only if otherwise permitted by law. Prescription drugs may only be dispensed or administered to eligible patients pursuant to a valid prescription drug order and shall have patient-specific written or electronic records maintained in accordance with the regulations of the Board.
4. Repackaged drugs shall be labeled with the drug name, strength, and expiration date, and shall be kept in a separate designated area until inspected and initialed by a pharmacist. 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 this program, and in the case of a pharmacy, may dispense donated drugs to residents of this state. This entity is required to comply with all laws and rules in this state unless such laws or rules differ or conflict with the laws or rules of the state in which the entity is located.

Section 5. Forms and Recordkeeping

1. All records required by this Chapter shall be retained in physical or electronic format, on or off the recipient’s premise for a period of six years. A donor or authorized recipient

may contract with one another or a third-party to create 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 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 which chooses to participate in the program shall make all records available for audit by the Board within five business days.
3. 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 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 begin with the donor of the drugs, shall include all prior donations, and, if the drugs was previously dispensed, shall only include drug information required to be on the patient label in accordance with the Board rules and regulations.

Section 6. Fees

1. Drugs donated to the program shall not be resold and shall be considered nonsaleable; provided, however, that handling, dispensing, or usual and customary charges to an eligible patient, health plan, pharmacy benefit manager, pharmacy services administrative organization, government agency, or other entity shall not be considered reselling. If the authorized recipient is for-profit, these charges shall not exceed the authorized recipient's cost of providing that drugs including but not limited to the current and anticipated costs of educating eligible donors, providing technical support to participating donors, shipping and handling, labor, storage, licensing, utilities, advertising, technology, supplies and equipment. The amount of these charges shall not have any additional limitations except as described above.

Section 7. Authority and Waivers

1. This chapter shall have sole authority over the program and shall supersede any inconsistent law or rule.
2. A donor or recipient may request a waiver from the Board for any of the provisions of this Chapter related to this program other than the immunity provisions. The waiver shall be granted or denied within 30 days based on its potential effects to both drug access and safety for eligible patients.

Section 8. Immunity

1. Unless the manufacturer of a legend drug or supply needed to administer a legend drug exercises bad faith or fails to exercise ordinary care, the manufacturer of a legend drug or

supply shall not be subject to criminal or civil liability for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of the drug or supply under the legend drug repository created under KRS 315.452, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated drug or supply.

2. Donors, health facilities, pharmacies, and health care providers shall be immune from civil liability for injury to or the death of an individual to whom a legend drug or supply is dispensed and shall not be subject to disciplinary action for unprofessional conduct for their acts or omissions related to donating, accepting, distributing, or dispensing a legend drug or supply under KRS 315.450 to 315.460, unless the act or omission involves reckless, wanton, or intentional misconduct or the act or omission results from failure to exercise ordinary care.