

THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTION 308.1(A), WITH AN EFFECTIVE DATE OF JULY 1, 2005.

**TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
SUBCHAPTER 12. UNUSED PRESCRIPTION DRUG PROGRAM FOR OKLAHOMA'S
MEDICALLY INDIGENT**

Section

- 535:12-1-1. Purpose
- 535:12-1-2. Definitions
- 535:12-1-3. Eligibility to donate unused prescription drugs
- 535:12-1-4. Consultant pharmacist requirements for eligible nursing homes or approved assisted living centers (ALC) who donate unused prescription medications
- 535:12-1-5. Eligible prescription drugs, formulary
- 535:12-1-6. Eligible recipients of unused prescription drugs
- 535:12-1-7. Protection for participants in the unused prescription drug program.
- 535:12-1-8. Pharmacies eligible to accept and dispense unused prescription medications
- 535:12-1-9. Requirements for eligible Oklahoma Licensed Charitable Pharmacies dispensing unused prescription medications
- 535:12-1-10. Responsibilities of pharmacist manager of eligible licensed pharmacies
- 535:12-1-11. Labeling
- 535:12-1-12. Violations

535:12-1-1. Purpose

(a) The rules of this Chapter describe a statewide program to take unused prescription drugs from nursing homes, assisted living centers; and donated drugs from pharmaceutical manufacturers and utilize them for dispensing to medically indigent Oklahoma residents as authorized under Title 59 O.S. Section 367.1 through 367.7, et seq., the Utilization of Unused Prescription Medication Act.

(b) The rules of this Chapter describe the eligibility to donate. They describe the eligible prescription drug formulary, the eligible recipients, and the protections for participants. They describe pharmacies eligible to accept and dispense such drugs, the requirements for eligible pharmacies, and the responsibilities for pharmacist managers.

(c) The rules of this Chapter describe safe handling of medications to protect drug integrity, tracking, sanitation, security and dispensing requirements for these unused prescription drugs. The rules of this Subchapter describe confidentiality requirements as well as violations.

535:12-1-2. Definitions

The following words or terms, when used in this Subchapter, shall have the following meaning, unless the context clearly indicates otherwise:

“**Assisted living center**” means assisted living center as defined in Title 59 O.S.

Section 367.2.

“**Cancer drugs**” means cancer drugs as defined in Title 59 O.S. Section 367.2.

“**Charitable Clinic**” means charitable clinic as defined in Title 59 O.S. Section 367.2.

“**Eligible Pharmacy**” means a pharmacy eligible to participate in the unused prescription drug program and includes those pharmacies operated by the following:

- (A) A County in Oklahoma;
- (B) A City-County Health Department in Oklahoma;
- (C) A firm under contract with a City County Health Department in Oklahoma;

(D) A Charitable Clinic; or

(E) The Oklahoma Department of Mental Health and Substance Abuse Services.

“**Health care professional**” means health care professional as defined in Title 59 O.S. Section 367.2.

“**Manifest**” means an invoice used to list drugs being transferred or destroyed.

“**Medically indigent**” means medically indigent as defined in Title 59 O.S. Section 367.2

“**Prescription drug**” means prescription drug as defined in Title 59 O.S. Section 367.2.

535:12-1-3. Eligibility to donate prescription drugs

(a) Oklahoma licensed Nursing homes, and approved Oklahoma licensed Assisted Living Centers (ALC) may donate eligible unused prescription drugs.

(1) Oklahoma Nursing Homes are eligible to participate if they are licensed and in good standing with the Oklahoma State Department of Health (OSDH) and are meeting OSDH drug handling standards:

(A) The OSDH will be consulted regarding rules for Nursing Homes’ participation in this program;

(B) The OSDH sets requirements under which nursing homes shall maintain prescription drugs. Such rules establish security, sanitation and control;

(C) Licensed healthcare personnel shall have kept control of such unused prescription drugs in sanitary and secure conditions as required under OSDH rules for Nursing Homes; and

(D) Such unused prescription drugs kept to these standards shall be eligible for donation.

(2) Approved licensed ALC eligibility requirements for participating in donation of unused prescription drugs under the provisions of this Subchapter:

(A) An application for participation shall be completed by the consultant pharmacist of the ALC and submitted to the Board.

(B) Only those ALC’s that maintain prescription drugs under the control of licensed healthcare professionals in sanitary and secure conditions in a manner similar to the OSDH rules for nursing home drug control may be approved.

(C) Such application must show adequate controls exist in ordering, storage, security, etc.

(D) Application must be reviewed and approved by OSBP with the advice of the Oklahoma State Health Department.

(b) A licensed prescription drug manufacturer may donate samples or eligible prescription drugs to eligible pharmacies in this program.

(1) Manufacturer’s patient assistance program (PAP) prescriptions that are not claimed in a reasonable length of time or abandoned by the patient may be used for another medically indigent patient.

(2) A patient specific stock bottle sent by a drug manufacturer and not claimed in a reasonable length of time or abandoned by the patient may be used for another medically indigent patient.

(c) A prescription is the property of the patient for whom it is prescribed regardless of who paid for the prescription as described in 59 O.S. Section 354. The patient or agent of the patient must authorize the donation of the unused prescription drugs, unless the:

(1) Patient has died; or,

(2) Drug has been discontinued as described in OSDH nursing home rules.

(d) Prescription medications donated under this Subchapter shall only be transferred to eligible pharmacies.

(e) Prescription medications donated under this Subchapter shall not be sold, resold, offered for sale nor traded, except the transfer as allowed in 535:12-1-9 (d) between eligible pharmacies.

(f) Violations of the unused prescription drug program are described in 535:12-1-12.

535:12-1-4. Consultant pharmacist responsibilities in eligible nursing homes or approved assisted living centers (ALC) participating in the program

(a) All donating nursing homes or approved ALC's must have a consultant pharmacist.

(b) Consultant pharmacists for the nursing home or the ALC eligible to donate unused prescription drugs shall be responsible to:

(1) Determine quality and suitability of the unused prescription drugs for reuse by assuring;

(A) Drugs have been kept under control of a health care professional

(B) Drugs have been stored properly (e.g. heat, cold, moisture),

(C) Drugs can be identified, and

(D) Drugs are not adulterated, mutilated, etc.

(2) Determine that the expiration date exceeds 45 days to allow time for re-distribution;

(3) Determine if it is cost effective to transfer such drugs to an eligible pharmacy;

(4) Assure manifest is properly filled out with the following;

(A) Names of Consultant Pharmacist and Director of Nursing (D.O.N.) or designee, the nursing home and the name of the receiving pharmacy;

(B) Name and strength of the eligible prescription drug (EPD);

(C) Expiration date of the EPD;

(D) Number of tablets or capsules or volume if liquid or injectable; and

(5) A copy of this manifest shall be provided to the pharmacy and a copy shall be maintained by the nursing home or ALC for two years;

(6) Assure controlled dangerous substances (CDS), also known as Scheduled drugs, are not transferred but handled as required under state and federal law;

(7) Assure that the selected pharmacy is eligible to receive unused prescription medications under these rules; and,

(8) Notify the eligible pharmacy when the drugs are ready to be picked up. The transportation of the unused drugs shall be the responsibility of the eligible receiving pharmacy. Such eligible pharmacy shall pick up donated drugs in an expedient manner.

(c) The consultant pharmacist and Director of Nursing [D.O.N.] (or designee) of the Nursing Home will initiate a manifest of the unused prescription drugs to be sent to the eligible pharmacy as described in (b)(4) and (5) above. They will be responsible for determining that the patient has authorized the donation of the drugs.

(d) The consultant pharmacist and the D.O.N. shall assure the name of the patient, name of the pharmacy, and directions on the label will be redacted with black ink or removed before sending to the eligible receiving pharmacy to protect confidentiality.

535:12-1-5. Eligible prescription drugs, formulary

(a) All FDA approved prescription drugs excluding any controlled dangerous substances (e.g. Prescription drugs found in Schedule I, II, III, IV, or V) subject to the following:

(1) Only eligible prescription drugs in original sealed unit dose or unused injectables;

(2) Packaging must be unopened;

(3) No expired drugs;

- (4) No lost identity or unknown drugs;
 - (5) No adulterated drugs; and,
 - (6) No drugs held outside of licensed healthcare person's control where sanitation and security can not be assured.
- (b) Compounded drugs shall not be eligible for transfer.
- (c) Cancer Drugs as approved by the Board and American Cancer Society representatives.
- (1) Such cancer drugs shall be in manufacturer's unit dose packaging.
 - (2) Receiving pharmacy must have the capacity to safely handle cancer drugs.
- (d) Licensed prescription drug manufacturers may donate eligible prescription drugs.

535:12-1-6. Eligible recipients of unused prescription drugs

- (a) Oklahoma medically indigent residents are entitled to receive dispensed unused prescription drugs as described in this subchapter.
- (b) This program is to provide medications to needy Oklahomans. OAC 535:12-1-12 discusses possible action for abuse and violations.

535:12-1-7. Protection for participants in the unused prescription drug program

Title 59 O.S. Section 367.6 describes protection for donors and participants in the unused prescription drug program under this act.

535:12-1-8. Pharmacies eligible to accept and dispense unused prescription medications

- (a) The following Oklahoma licensed pharmacies may accept unused prescription drugs as described in 535:12-1-4 for dispensing under this act, when operated by:
- (1) a County in Oklahoma;
 - (2) a City-County Health Department in Oklahoma;
 - (3) a firm under contract with a City County Health Department in Oklahoma;
 - (4) a Charitable Clinic; or
 - (5) The Oklahoma Department of Mental Health and Substance Abuse Services
- (b) All eligible pharmacies prior to beginning or terminating participation shall send written notice to the Board. A list of these eligible pharmacies will be posted on the Board web-site.
- (c) The Board will request input and consult with the Oklahoma State Health Department regarding rules for City-County Health Department pharmacies.
- (d) The Board will request input and consult with the Oklahoma Department of Mental Health and Substance Abuse Services (ODMHSAS) regarding rules for ODMHSAS pharmacies.

535:12-1-9. Requirements for Pharmacies dispensing unused prescription drugs

- (a) The following are requirements for eligible Oklahoma licensed pharmacies dispensing unused prescription drugs;
- (1) Maintain a current drug identification book, or may have a current computer program or online service for the same;
 - (2) Dispense unused prescription drugs only upon the valid prescription of an Oklahoma licensed health care practitioner;
 - (3) Properly label all dispensed unused prescription drugs;
 - (4) Comply with all federal and state law and rules regarding storage and distribution of prescription drugs;
 - (5) Inspect all prescription drugs prior to dispensing to determine that the donated drugs shall meet all federal and state requirements for product integrity;

(6) Unused prescription drugs, prescription drug manufacturer's drug samples and donated manufacturers drug stock obtained or donated under this Subchapter shall not be resold, except transfers as allowed in 535:12-1-9 (d) between licensed eligible pharmacies.

(b) If it is determined by the pharmacist's professional judgment that it would be best for the patient, the drugs can be removed from bingo cards (unit dose packaging [UDP]) and placed in a proper vial for dispensing. If the bingo card is relabeled and used the pharmacist must ensure that the patient is made aware that the medication is not in a child resistant container.

(1) See expiration dating requirements in labeling 535:12-1-11.

(2) The removal of the medication from the bingo card (UDP) may only be done by the dispensing pharmacy's licensed pharmacist or permitted pharmacy technician.

(3) Samples must remain in original package as required under federal law, and cannot be removed from original packaging for dispensing.

(c) Eligible Oklahoma licensed charitable pharmacies may establish the following policy and procedures for dispensing of unused prescription drugs to the medically indigent.

(1) May limit the number of prescriptions per patient per visit or per month, to allow a greater number of individuals access to such prescription drugs.

(2) When established, this should be a written policy that is enforced equally to prevent discrimination.

(d) Eligible Pharmacies (EP) may transfer unused prescription drugs to another pharmacy in the program when one EP has the need for a drug and another EP has it available.

(1) A manifest will be prepared by the transferring pharmacy and kept on file for two (2) years.

(2) A copy of the manifest will be sent with the transferred drugs and kept on file in the receiving pharmacy for two (2) years.

(e) The Board will request input from the Oklahoma Department of Mental Health and Substance Abuse Services regarding rules for their eligible pharmacies.

(f) The Board will request input from the Oklahoma Department of Health regarding rules for their eligible pharmacies.

535:12-1-10. Responsibilities of pharmacist manager of eligible licensed pharmacies

(a) The pharmacist manager of eligible licensed pharmacies shall be responsible for the following:

(1) Coordinate retrieval of donated unused prescription drugs from nursing homes and eligible ALC. Such retrieval shall be in an expedient manner;

(2) Check unused prescription drugs (UPD) against the manifest and resolve any discrepancy;

(3) Store and secure these UPD as required under state and federal law and rules;

(4) Check the unused prescription drugs for adulteration;

(5) Assure expired, adulterated, lost identity drugs are not dispensed;

(6) Assure such unacceptable drugs are not put in dispensing stock. Destroy such unacceptable drugs within 14 days as described in 535:12-1-10 (a) (8).

(7) Assure safety in drug recalls. If a drug is recalled and the eligible pharmacy does not have the lot number on the label to differentiate between the recall and non-recalled, all such donated recalled drug shall be destroyed.

(8) Assure destruction of expired, adulterated, and/or recalled unused prescription medications.

(A) A manifest shall be made of unused prescription drugs expired, adulterated and/or recalled to be destroyed.

(B) Following destruction such manifest shall be signed by the pharmacist manager and witness verifying such destruction.

(C) Drug destruction manifest shall be kept in the files of the pharmacy for two (2) years.

535:12-1-11. Labeling

(a) All previous patient or pharmacy labeling on an unused prescription drug will be redacted or removed by dispensing eligible pharmacy.

(b) Dispensed prescription for a medically indigent patient will clearly indicate the final dispensing pharmacy and the current patient information to assure clarity for receiving patient and shall be properly labeled.

(c) Expiration date is required on all unused prescription drugs dispensed.

(1) The expiration date is brought forward to the filled prescription if only one expiration date is used in the filling of the prescription.

(2) If multiple packages of unused prescription drugs are used to fill a single prescription with varied expiration dates, the shortest expiration date is used for the dispensed prescription.

535:12-1-12. Violations

(a) Theft or diversion of any of the unused prescription drugs is a violation of these rules. This includes any expired, lost identity drug, recalled drug, or other drug found to be unusable under the requirements of this Subchapter.

(1) Such violation by a licensed nursing home or licensed Assisted Living Center of these rules will be referred to the Oklahoma State Health Department and/or other proper authorities for possible action.

(2) Such violation by the Oklahoma Department of Mental Health and Substance Abuse Services facility of these rules will be reported to the Oklahoma Department of Mental Health and Substance Abuse Services and/or other proper authorities for possible action.

(3) Such violation by a registrant of the Board may result in action under Title 59 O.S. Section 353.26.

(b) Dispensing of expired unused prescription drugs is a violation of these rules.

(c) Sale, trade, offer for sale or trade (except transfer as allowed in 535:12-1-9 (d) between licensed eligible pharmacies) any of the drugs obtained pursuant to this Subchapter and shall include any expired, lost identity, recalled or other such drug unacceptable for dispensing that comes into the program shall be a violation of these rules.

(d) Violation of this section by a registrant may result in loss of the ability to participate in this program; and may include Board action against the registrant as described in Title 59 O.S. Section 353.26.

(e) Abuse of this program shall be reported to the legislature and may result in the loss of this program.