**RULES**
**OF**
**THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-17**
**DRUG DONATION REPOSITORY PROGRAM**

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## 1140-17-.01 DEFINITIONS.

In addition to the definitions contained in T.C.A. § 63-10-501, the following definitions are applicable to this chapter:

(1) "Cancer Drug" means a prescription drug that is used to treat any of the following:

(a) Cancer or the side effects of cancer; or

(b) The side effects of any prescription drug that is used to treat cancer or the side effects of cancer.

(2) "Controlled Substance" means the same as defined in T.C.A. § 39-17-402.

(3) "Department" means the Tennessee Department of Health.

(4) "Donor" means a person, pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the Tennessee Board of Pharmacy, who donates prescription drugs to a repository program approved pursuant to these rules.

(5) "Eligible individual" means an indigent person or an uninsured person who meets all other criteria established by these rules.

(6) "Indigent" means a person with an income that is below 200 percent (200%) 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.

(7) "Medical facility" means any of the following:

(a) A physician's office;

(b) A hospital;

(c) A health clinic;

(Rule 1140-17-.01, continued)

(d) A nonprofit health clinic, including a federally qualified health center as defined in 42 U.S.C. § 1396d(l)(2)(B); a rural health clinic as defined in 42 U.S.C. § 1396d(l)(1); and a nonprofit health clinic that provides medical care to patients who are indigent, uninsured, or underinsured;

(e) A free clinic as defined in T.C.A. § 63-6-703;

(f) A charitable organization as defined in T.C.A. § 48-101-501; or

(g) A nursing home as defined in T.C.A. § 68-11-201.

(8) "Legend Drug" means the same as defined in T.C.A. § 53-10-101.

(9) "NDC #" means the unique national drug code number that identifies a specific approved drug, its manufacturer and its package presentation.

(10) "Nurse practitioner" means an advanced practice nurse as defined in T.C.A. § 63-7-126.

(11) "Pharmacist" means a pharmacist as defined in T.C.A. § 63-10-204.

(12) "Pharmacy" means a pharmacy as defined in T.C.A. § 63-10-204.

(13) "Physician" means an individual licensed under T.C.A. § 63-6-201 or § 63-9-104.

(14) "Physician's Assistant" means an individual licensed under T.C.A. § 63-19-105.

(15) "Prescription drug" means the same as defined in T.C.A. § 63-10-204 except the drug is only tablet or capsule form, and includes cancer drugs and anti-rejection drugs, but does not include controlled substances and drugs covered by the risk evaluation and mitigation strategy program of the federal food and drug administration

(16) "Repository" means a pharmacy or medical facility that meets the eligibility requirements of Rule 1140-17-.03.

(17) "Reverse Distributor" means an establishment that dispositions or otherwise processes saleable or nonsaleable legend drugs and controlled substances received from a pharmacy such that the legend drugs and controlled substances may be processed for credit to the purchaser, Manufacturer, or seller and disposed of for no further distribution.

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

(19) "USP" means United States Pharmacopoeia.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.02 PURPOSE.** The overall purpose of this chapter is to establish administrative rules in accordance with Tenn. Code Ann. §§ 63-10-501 et seq. relative to the following:

(1) Requirements for medical facilities and pharmacies to accept and dispense donated prescription drugs and supplies;

(2) Additional eligibility criteria for indigent or uninsured persons;

(Rule 1140-17-.02, continued)

(3) Necessary forms for administration of the prescription drug donation repository program, including forms for use by individuals who donate, accept, distribute, or dispense the prescription drugs or supplies under the program;

(4) A means by which an individual who is eligible to receive donated prescription drugs and supplies may indicate eligibility;

(5) The maximum handling fee that a medical facility or pharmacy may charge for accepting, distributing, or dispensing donated prescription drugs and supplies under the program; and

(6) A list of prescription drugs that the prescription drug donation repository program will accept.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.03 ELIGIBILITY CRITERIA FOR PROGRAM PARTICIPATION AS A REPOSITORY BY MEDICAL FACILITIES AND PHARMACIES.**

(1) To be eligible for participation in the prescription drug donation repository program, a medical 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, unencumbered, state-issued licenses or registrations in good standing. In the case of a physician's office, the physician(s) and other medical staff shall be duly licensed.

(2) A medical facility or pharmacy which intends to operate as a repository within the prescription drug donation repository program shall receive a determination of exemption from the United States internal revenue service pursuant to 26 U.S.C. § 501(c)(3) prior to making application to the Board to act as a repository. The medical facility or pharmacy shall present the exemption along with the form prescribed by the department and available on the program's web page as outlined in Tenn. Comp. R. & Regs 1140-17-.03(4).

(3) Participation in the prescription drug donation repository program is voluntary.

(4) A pharmacy or medical facility may elect to participate in the prescription drug donation repository program by providing, on a form prescribed by the department and available on the program's web page, written notification to the department of all of the following:

(a) The name, street address, and telephone number of the pharmacy or medical facility, and any state-issued license or registration number issued to the pharmacy or medical facility, including the name of the issuing agency;

(b) The name and telephone number of the responsible pharmacist, physician, physician's assistant or nurse practitioner who is employed by or under contract with the pharmacy or medical facility; and

(c) A statement, signed and dated by the responsible pharmacist, physician, physician's assistant or nurse practitioner, indicating that the pharmacy or medical facility meets the eligibility requirements under this rule and shall comply with the requirements of this chapter.

(5) Withdrawal from participation. A pharmacy or medical facility may withdraw from participation in the prescription drug donation repository program at any time by providing written notice to the department on a form prescribed by the department and available on the program's web page.

(Rule 1140-17-.03, continued)
***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.04 STANDARDS AND PROCEDURES FOR ACCEPTING DONATED PRESCRIPTION DRUGS AND SUPPLIES.**

(1) A person, pharmacy, or medical facility as well as any drug manufacturer or wholesaler licensed by the Tennessee Board of Pharmacy may donate drugs or supplies to the repository program. Any individual may donate legally obtained prescription drugs or supplies to a repository if the drugs or supplies meet the requirements of this rule, as determined by a pharmacist who is employed by or under contract with a repository.

(2) No drugs that require storage temperatures other than normal room temperature as specified by the manufacturer or USP 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) A 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, which includes unit dose packaging created by a licensed pharmacy. However, a prescription 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;

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

(c) The packaging contains the expiration date of the drug.

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

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

(f) All drugs shall be inventoried at the repository. The inventory shall include the name of the drug, strength of the drug, NDC number, quantity of the drug, expiration date 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 prescription drug donation repository program that is signed by the person making the donation or that person's authorized representative.

For purposes of this subparagraph a health care professional is any person licensed in accordance with the provisions of Title 63 by any health related board of the Tennessee Department of Health to perform any profession of the healing arts.

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

(Rule 1140-17-.04, continued)

(a) The supplies are in their original, unopened, sealed packaging or unit dose packaging created by a licensed pharmacy;

(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, expiration date of the supplies, and the date of donation. Such inventory shall be recorded on a form provided by the department.

(6) Drugs and supplies may be donated on the premises of a repository to a person designated by the repository. Donations of prescription drugs and supplies may be made by mail, which includes the use of any common carrier. A drop box may not be used to deliver or accept donations.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.05 STANDARDS AND PROCEDURES FOR INSPECTING AND STORING DONATED PRESCRIPTION DRUGS AND SUPPLIES.**

(1) A licensed pharmacist employed by or under contract with a repository shall inspect donated prescription drugs and supplies, prior to dispensing, 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) A 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, returned, or destroyed.

(3) Repositories shall return or destroy donated non-controlled substances that are not suitable for dispensing and make a record of such return or destruction which shall include, at a minimum, the drug name, strength, quantity, method of destruction, and date of destruction. A reverse distributor may be used for destruction.

(4) Controlled substances shall not be accepted for donation. Controlled substances submitted for donation shall be disposed of pursuant to DEA regulations. Destruction shall be accomplished by either the use of a reverse distributor or by following current DEA regulations regarding destruction of controlled substances.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.06 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, physician, physician's assistant or nurse practitioner. A Tennessee licensed pharmacist shall inspect the prescription drugs and supplies to determine the prescription drugs and supplies are not adulterated or misbranded prior to dispensing.

(Rule 1140-17-.06, continued)

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

(a) First, to an indigent individual; and

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

(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. A medical facility or pharmacy may not dispense a prescription drug after the expiration date of the drug.

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

(5) If a donor receives official notice of a recall of a prescription drug donated pursuant to these rules, the donor shall make every effort to notify the repository to whom the drugs were donated of the recall.

(6) If an organization who is administering a drug repository program receives official notice of a recall of a prescription drug donated pursuant to these rules, the organization shall make every effort to notify the pharmacy, medical facility, or patient, if known, to whom such donated drugs were dispensed, of the recall. Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number which would exclude the drug from a recall.

(7) Any donor or drug repository program who receives notice of a recall shall dispose of all recalled prescription drugs pursuant to the Tennessee Board of Pharmacy rules. Drugs specified in a recall notice shall be considered recalled unless the drug has an affixed lot number which would exclude the drug from a recall.

(8) Prescription drugs or supplies donated under this program shall not be resold.

(9) Repositories may distribute drugs and supplies donated under this program to other repositories for use pursuant to the program. The repository distributing the drugs or supplies shall complete a transfer form containing the inventory information on file in accordance with Rule 1140-17-.04(4)(f).

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.07 ELIGIBILITY CRITERIA FOR INDIVIDUALS TO RECEIVE DONATED PRESCRIPTION DRUGS AND SUPPLIES.**

(1) An individual who requests drugs from the prescription drug donation repository program shall certify to the repository that the individual is a resident of Tennessee and meets one or both of the following criteria:

(a) Is indigent.

(b) Has no active third-party prescription drug reimbursement coverage for the drug prescribed.

(Rule 1140-17-.07, continued)

(2) A repository shall collect from each individual recipient a signed intake collection form provided by the department.

(a) The intake collection form shall attest that:

1. The individual is a resident of the state of Tennessee;

2. The individual's income is below 200 percent of the FPL;

3. The individual is uninsured and has no prescription coverage for the prescribed drugs;

4. The individual acknowledges that the drugs may have been donated; and

5. The individual consents to a waiver of the requirement for child resistant packaging of the Poison Prevention Packaging Act (16 C.F.R. §§ 1700-1702).

(b) The intake collection form will include an identification card to be given to the recipient for continued use for one year.

(3) The identification card given to the recipient is valid for one year or until the new federal poverty guidelines have been published for all prescriptions and supplies.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.08 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 available on the program's web page:

(a) Prescription drug donation repository program notice of participation or withdrawal.

(b) Prescription drug donation repository program donation, transfer, inventory or destruction record.

(c) A record of medications dispensed.

(d) Intake collection form. A repository is authorized to make available to a recipient a blank intake collection form.

(2) The identification card shall be given to the recipient by the repository, and the completed intake collection form shall be collected from the recipient by the repository.

(3) Record-keeping requirements.

(a) All records required to be maintained as a part of the prescription drug donation repository program shall be maintained for a minimum of five (5) years by participating pharmacies and medical facilities.

(b) Other records required as part of this program shall be maintained pursuant to all current applicable practice acts.

(c) Data collected by the prescription drug donation repository program from all repositories shall be submitted quarterly or upon request to the department. The data will consist of the information collected in accordance with (1) above.

(Rule 1140-17-.08, continued)

(d) A repository shall submit reports to the department yearly and upon request of the department. Such reports shall include the following data:

1. Number of donors during the reporting year;

2. Number of donations during the reporting year;

3. List of prescription drugs and supplies donated during the reporting year;

4. Number of people who received donations of prescription drugs or supplies during the reporting year;

5. Total number of prescription drugs and supplies dispensed during the reporting year; and

6. Total cost to eligible individuals who received donations during the reporting year.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.09 HANDLING FEE.** A repository may charge the recipient of a donated prescription drug a handling fee, not to exceed a maximum of 200 percent of the applicable tiered reimbursement rate as produced by the Bureau of TennCare, to cover stocking and dispensing costs. A prescription drug dispensed through the prescription drug donation repository program shall not be eligible for reimbursement under the medical assistance program.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.10 LIST OF DRUGS AND SUPPLIES PROGRAM WILL ACCEPT.** 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 rules may be accepted for donation under the prescription drug donation repository program.

Any compounded drug which is made into tablet or capsule form, regardless of packaging, shall not be accepted by the prescription drug donation repository program

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.11 EXEMPTION FROM DISCIPLINARY ACTION, CIVIL LIABILITY AND CRIMINAL PROSECUTION.**

(1) Except for gross negligence, willful misconduct, or bad faith, a drug manufacturer is not civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property for matters related to the donation, acceptance, or dispensing of a prescription drug manufactured by the drug manufacturer that is donated under this part, including liability for failure to transfer or communicate product or consumer information or the expiration date of the donated prescription drug.

(2) Except as provided in subsection (4), a medical facility or another person who is not a drug manufacturer subject to subsection (1) is not civilly liable or subject to criminal prosecution for injury to or the death of an individual to whom a donated prescription drug is dispensed under this part except due to its own gross negligence, willful misconduct, or bad faith. The medical

(Rule 1140-17-.11, continued)

facility or other person who is not a drug manufacturer subject to subsection (1) is also exempt from disciplinary action related to the facility's or person's acts or omissions related to the donation, acceptance, distribution, or dispensing of a donated prescription drug under this part.

(3) Except for gross negligence, willful misconduct, or bad faith, the department of health or the board of pharmacy shall not be civilly liable or subject to criminal prosecution for injury, death, or loss to a person or property resulting from matters related to the donation, acceptance, distribution, or dispensing of a prescription drug donated pursuant to this part.

(4) The immunity and exemption provided in subsections (2) and (3) do not extend to the following:

(a) The donation, acceptance, distribution, or dispensing of a donated prescription drug under this part by a person if the person's acts or omissions are not performed reasonably and in good faith; or

(b) Acts or omissions outside the scope of the program.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*

**1140-17-.12 LONG-TERM CARE FACILITIES.** A long-term care facility licensed under title 68 may donate prescription drugs to the repository program.

***Authority:*** *T.C.A. §§ 63-10-501 through 63-10-510 and Chapter 392 of the Public Acts of 2017, § 1.* ***Administrative History:*** *Original rules filed May 31, 2018; effective August 29, 2018.*