RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-12
CHARITABLE CLINIC PHARMACIES

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1140-12-.01 PURPOSE.

The rules in this chapter implement the Nina Norman Prescription Drug Donation Act of 2006, T.C.A. § 63-10-501, et seq., which has been enacted into law to develop a prescription drug redispensing program that authorizes charitable clinic pharmacies to redispense medicines to indigent patients that would otherwise be destroyed.

Authority: *Chapter 919 of the Public Acts of 2006, §1 and T.C.A. §§63-10-501 through 63-10-505.* ***Administrative History:*** *Public necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.02 DEFINITIONS. In addition to the definitions contained in T.C.A. § 63-10-503, the following definitions are applicable to this chapter:

(1) "Board" means the Tennessee Board of Pharmacy;

(2) "Dispense" shall have the same meaning as set forth in T.C.A. § 63-10-204(11);

(3) "Distribute" shall have the same meaning as set forth in T.C.A. § 63-10-204 (12);

(4) "Manifest" means a list of drugs being transferred or destroyed and shall include at a minimum, the drug name, strength, quantity, and expiration date;

(5) "Person" means any individual, partnership, association, or corporation;

(6) "Pharmacist" shall have the same meaning as set forth in T.C.A. § 63-10-204(26);

(7) "Pharmacy" means a charitable clinic pharmacy as set forth in T.C.A. § 63-10-503(2);

(8) "Pharmacy practice site" shall have the same meaning as set forth in Tenn. Comp. R. & Regs. Rule 1140-1-.01(23);

(9) "Pharmacist in charge" shall have the same meaning as set forth in T.C.A. § 63-10-204(27);

(10) "Program" means the drug donation program established by the Nina Norman Prescription Drug Donation Act of 2006 established in T.C.A. § 63-10-501, et seq.;

(11) "Single Unit Dose" means sealed, tamper-evident packaging of medication from a manufacturer, repackager licensed by the Food and Drug Administration, or from a pharmacy when packaged in individual dosage units in United States Pharmacopeia Class B packaging and labeled with the appropriate product information including full product name, dosage form, strength, lot number, and expiration date.

(Rule 1140-12-.02, continued)
Authority: *Chapter 919 of the Public Acts of 2006, §1 and T.C.A. §63-10-505(g).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.03 APPLICATION AND RENEWAL REQUIREMENTS.

(1) Any person who desires to obtain a charitable clinic pharmacy license shall submit an application to the board, along with the required license fee, and comply with the pharmacy practice site licensure requirements established in Rule 1140-1-.08(3)(a).

(2) Applications for licensure are available upon request from the board.

(3) All charitable clinic pharmacy licenses shall be renewed on a biennial basis from the date that the license was initially granted. All licenses shall be renewed on or before the last day of the two (2) year license cycle.

(4) An applicant may renew the charitable clinic pharmacy license within six (6) months from the license expiration date with payment of the renewal fee and late renewal penalty fee.

Authority: *Chapter 919 of the Public Acts of 2006, §1 and T.C.A. §§63-10-502(2) and 63-10-505(g)(4)(A).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.04 FEES.

(1) Initial license fee……$168.00

(2) Renewal fee……$168.00

(3) The late renewal penalty fee is ten dollars ($10.00) per month for each month or fraction of a month that renewal is late.

Authority: *Chapter 919 of the Public Acts of 2006, §1 T.C.A. §§63-10-502(2) and 63-10-505(g)(4)(A).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.05 PHARMACIST RESPONSIBILITIES.

(1) Medication Transfers.

(a) Any pharmacist working at a charitable clinic pharmacy shall ensure that the following criteria are satisfied upon receiving medications from the institutional facility:

1. the only drugs that are accepted by the pharmacy to be dispensed are those drugs that are in their dispensed, sealed and tamper-evident packaging which includes, but is not limited to, single-unit doses or blister packs with the outside packaging opened if the single unit dose packaging remains intact;

2. the donor patient or donor patient's representative executed a drug donation form for the drugs transferred from the institutional facility to the pharmacy. In the event that the pharmacist does not receive a copy of the donor form with the transferred drugs, then the pharmacist shall not dispense the drugs;

3. the donor patient's name, prescription number, and any other identifying marks have been removed or redacted from the package by the institutional facility. In the event that the identifying patient information is not removed when received by the charitable clinic

(Rule 1140-12-.05, continued)

pharmacist from the institutional facility, then the pharmacist shall remove or redact this information;

4. the drug name, strength, lot number, and expiration date is on the drug package or label. In the event that the identifying drug information is not on the package or label when received from the institutional facility, the pharmacist shall not dispense these drugs and shall destroy them;

5. drug(s) that are being transferred are accompanied by a manifest from the institutional facility;

6. drugs that are expired, misbranded, recalled, deteriorated or not kept under the proper conditions shall not be dispensed from the pharmacy if they are transferred from the institutional facility. In the event that the pharmacist receives drugs that are expired, misbranded, recalled, deteriorated or not kept under the proper conditions from the institutional facility, the pharmacist shall not dispense these drugs and shall destroy them after creating the documentation required in Rule 1140-12-.05(3)(a);

7. controlled substances are not accepted or dispensed from the pharmacy if they are transferred. In the event that institutional facility transfers controlled substances, the pharmacist shall send the controlled substances back to the institutional facility;

8. the donated drugs may be transferred from one (1) pharmacy to another by an individual designated by the pharmacist in charge or through any other means by which the donated drugs may be tracked and delivery confirmed; and

9. the donated drugs are physically transferred from the institutional facility to the pharmacy by an individual designated by the pharmacist in charge of the pharmacy or through any other means by which the donated drugs may be tracked and delivery confirmed.

(2) Prohibited Activities.

(a) Any pharmacist working at a charitable clinic pharmacy shall not purchase, possess, trade, distribute or dispense any controlled substances from the charitable clinic pharmacy.

(3) Recordkeeping.

(a) Any pharmacist working at a charitable clinic pharmacy shall create and maintain a manifest of the prescription drugs transferred from the institutional facility to the pharmacy that were not dispensed because the drugs were expired, adulterated, misbranded, recalled, deteriorated, not kept under proper conditions, or did not have the identifying drug information on them as provided in Rule 1140-12-.05(4). Pharmacists shall maintain this manifest at the pharmacy for two (2) years from the date of destruction.

(b) The pharmacists working at the charitable clinic pharmacy shall maintain a manifest of all prescription drugs transferred from the institutional facility to the pharmacy and dispensed from the pharmacy for two (2) years from the date of receipt.

(c) The pharmacists working at the pharmacy shall maintain a manifest of all prescription drugs transferred from one (1) pharmacy to another for two (2) years from the date of transfer.

(4) Labeling.

(a) Any pharmacist working at a charitable clinic pharmacy shall ensure that the donor patient's identifying information is redacted from the donated drugs prior to redispensing.

(Rule 1140-12-.05, continued)

(b) Any pharmacist working at a charitable clinic pharmacy shall redispense the donated drugs to an indigent patient and place a label on the drugs with the indigent patient's identifying information, dosage instructions, auxiliary labels, and drug expiration date.

(5) All pharmacists working at a charitable clinic pharmacy shall comply with all other applicable Board rules.

Authority: *Chapter 919 of the Public Acts of 2006, §1 and T.C.A. §63-10-505 (c)(1) and (g)(4)(A).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.06 PHARMACIST-IN-CHARGE RESPONSIBILITIES.

(1) The pharmacist in charge at the charitable clinic pharmacy shall ensure that the following occurs at the pharmacy:

(a) donated drugs dispensed from pharmacy are properly labeled;

(b) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions are not redispensed to indigent patients;

(c) donated drugs are inspected prior to redispensing to determine that the donated drugs meet all federal and state requirements for product integrity;

(d) donated drugs that are expired, adulterated, misbranded, recalled, deteriorated, or not kept under proper conditions are destroyed;

(e) manifests for donated drugs that are dispensed or destroyed are created or maintained at the pharmacy in accordance with Rule 1140-12-.05;

(f) that the institutional facility transferring the drugs has a contract with the pharmacy about the transfer of drugs that is approved by the Board of Pharmacy in cooperation with the Department of Health in accordance with T.C.A. § 63-10-505; and

(g) that the contract between the institutional facility and the pharmacy will contain a description of the drugs that will be included in the contract. The pharmacist in charge is responsible for determining the description of the drugs.

Authority: *Chapter 919 of the Public Acts of 2006, §1, T.C.A. §§63-10-505(g)(4)(A) and 63-10-505(b)(3).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.07 DONOR PATIENT FORM.

(1) The donor patient form shall include, at a minimum, the following:

(a) name of the patient to whom the medication was originally dispensed;

(b) name of the institutional facility authorized to deliver the unused prescription medication;

(c) name of drug, quantity, prescription number, date of prescription and name of pharmacy where it was originally dispensed;

(d) name of the charitable clinic pharmacy;

(e) date the drug was donated;

(Rule 1140-12-.07, continued)

(f) authorization to donate the drug voluntarily for use in the program;

(g) a signature line for the donor patient or for the donor patient's representative in the event that patient is deceased or not competent; and

(h) a statement that the donor patient's participation in the pilot program shall not be used as an independent basis for a civil, criminal, or disciplinary action against the donor patient's, donor patient's estate, health care provider, charitable clinic, department of health, board, or the charitable clinic pharmacy, pharmacists and pharmacy technicians as long as they abide by board rules.

Authority: *Chapter 919 of the Public Acts of 2006, §1 and T.C.A. §§63-10-505(g)(2) and 63-10-505(c)(5)(A).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.08 WAIVER FORM.

(1) The waiver form shall include, at a minimum, the following:

(a) name of indigent patient;

(b) name of drug, quantity, prescription number, date of prescription, name of charitable clinic pharmacy dispensing the drug;

(c) a signature line for the indigent patient; and

(d) waiver releasing the institutional facility, donor patient, and donor patient' estate from liability.

Authority: *Chapter 919 of the Public Acts of 2006, §1 and T.C.A. §§63-10-505(g)(3) and 63-10-505(f).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*

1140-12-.09 CIVIL PENALTIES.

(1) The board may, in a lawful proceeding respecting licensing (as defined in the Uniform Administrative Procedures Act), in addition to or in lieu of any other lawful disciplinary action, assess civil penalties for violations of statutes, rules or orders enforceable by the board in accordance with the following schedule:

Violation	Penalty
T.C.A. Section 63-10-505(b)(B)(3)	$0-$1,000
T.C.A. Section 63-10-505(c)(2)	$0-$1,000
T.C.A. Section 63-10-505(c)(3)	$0-$1,000
Rule 1140-12-.03	$0-$1,000
Rule 1140-12-.05	$0-$1,000
Rule 1140-12-.06	$0-$1,000

(2) Each day of continued violation may constitute a separate violation.

(3) In determining the amount of any penalty to be assessed pursuant to this rule, the board may consider such factors as the following:

(a) Willingness of the violation;

(b) Repetitions of the violation; and

(Rule 1140-12-.09, continued)

(c) Magnitude of the risk of harm cased by the violation.

(4) Each violation of any statute, rule or order enforceable by the board shall constitute a separate and distinct offense and render the person committing the offense subject to a separate civil penalty for each violation.

Authority: *Chapter 919 of the Public Acts of 2006, §1 and T.C.A. §§56-1-308, 63-10-505(g)(4)(A).* ***Administrative History:*** *Public Necessity rule filed February 16, 2007; effective through July 31, 2007. Original rule filed June 19, 2007; effective September 2, 2007.*