

Public Necessity Rules
of the
Board of Pharmacy
Division of Regulatory Boards

Statement of Necessity Requiring Public Necessity Rules

Pursuant to T.C.A. §4-5-209, the Board of Pharmacy ("Board") is authorized to promulgate public necessity rules in the event that the rules are required by an enactment of the general assembly within a prescribed period of time that precludes utilization of rulemaking procedures described elsewhere in T.C.A. Title 4, Chapter 5, for the promulgation of permanent rules.

Chapter 1028 of the Public Acts of 2008 created a telepharmacy pilot program in a federally qualified health center ("FQHC") for the dispensing of medications from a satellite pharmacy where there is no pharmacist physically present, but would be present by video/audio link to communicate with the patient or patient's caregiver. The Act requires that on or after July 1, 2008, the Department of Health and the Board shall identify one (1) federally qualified health center located in the eastern grand division of the state that will voluntarily participate in the program. The Act also provides that the Board shall promulgate rules for the implementation of this pilot program and that the pilot program shall report information regarding patient satisfaction and safety to the Board and the House Health and Human Resources Committee and the Senate General Welfare Health and Human Resources Committee as well as the Board of Pharmacy by February 1, 2010. After that time, if the Board determines that the pilot project is successful, then the Board may expand the project beyond the one (1) FQHC.

Due to the length of time necessary to complete the rulemaking process, these public necessity rules are required in order for the Board to begin implementation of this program so that the pilot program can provide the health committees of the General Assembly with a report by February 1, 2010 and then, in turn, the Board can determine the success of the pilot program and whether the program should be expanded. The Board is conducting a rulemaking hearing on January 13, 2009 at 9:00AM (CST) to consider comments on the adoption of these as permanent rules.

For a copy of these public necessity rules contact: Kevin K. Eidson, Board of Pharmacy, 200 Athens Way, at (615) 741-2718

David Todd Bess,
President of the Board of Pharmacy

Public Necessity Rules
of the
Board of Pharmacy
Bureau of Health, Licensure and Regulation
Health Related Boards

Chapter 1140-13
Telepharmacy

New Rules

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1140-13-.01 Purpose.

The rules in this chapter implement a pilot program for the dispensing of prescription medications from federally qualified health centers through the use of telepharmacy pursuant to T.C.A. § 63-10-601, et seq.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008].

1140-13-.02 Definitions.

In addition to the definitions contained in T.C.A. § 63-10-601, the following definitions are applicable to this chapter:

- (1) "Board" means the Tennessee Board of Pharmacy;
- (2) "Central pharmacy" means the central pharmacy practice site licensed by the Tennessee Board of Pharmacy located within a federally qualified health center that is connected through computer link, videolink, and audiolink to one (1) or more satellite clinics;
- (3) "Dispense" shall have the same meaning as set forth in Tenn. Code Ann. § 63-10-204(12);
- (4) "Issue" means the delivery of drugs from the pharmacy technician employed by the federally qualified health center participating in this program to the patient or patient's agent;
- (5) "Person" means any individual, partnership, association, corporation, or entity;

- (6) "Pharmacist" shall have the same meaning as set forth in Tenn. Code Ann. § 63-10-204(30) and who is an employee of a federally qualified health center participating in this program;
- (7) "Pharmacist-in-charge" shall have the same meaning as set forth in Tenn. Code Ann. §63-10-204(31) and who is an employee of a federally qualified health center participating in this program;
- (8) "Pharmacy practice site" shall have the same meaning as set forth in Tenn. Comp. R. & Regs. Rule 1140-1-.01(23);
- (9) "Pharmacy technician" means an individual registered by the Board as a pharmacy technician who is an employee of a federally qualified health center participating in this program and is being supervised by a pharmacist at the central pharmacy;
- (10) "Program" means the pilot program established in T.C.A. §63-10-601 for the dispensing of medications (with the exception of controlled substances schedules I, II, III, and IV) from federally qualified health centers through the use of telepharmacy;
- (11) "Satellite clinic" means a clinic location located within federally qualified health center where any prescription dispensed at the central pharmacy shall be issued to the patient or patient's agent through telepharmacy;
- (12) "Telepharmacy" means the method of providing pharmaceutical services through a remote site connection between a central pharmacy and a satellite clinic.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008].

1140-13-.03 Licensing and Renewal.

- (1) Licensing.
 - (a) Beginning July 1, 2008, the central pharmacy that desires to participate in this pilot program shall obtain a pharmacy license for the central pharmacy to be issued by the Board by submitting an application to the Board, along with the required license fee, and shall comply with the pharmacy practice site licensure requirements established in Tenn. Comp. R. & Regs. Rule 1140-1-.08(1) and Rule 1140-1-.12.
 - (b) As a condition for licensure, the central pharmacy participating in this program shall meet all of the standards established in Tenn. Comp. R. & Regs. Rule 1140-1-.12(1), (2), and (3) and shall also meet the following minimal operating requirements:
 - 1. shall be connected to the satellite clinic through computer link, videolink, and audiolink;

2. shall have a computer system that is connected to the satellite clinic's computer system that shares common electronic files;
 3. shall have its own computer(s) that is/are not accessed by others employed by the federally qualified health center, scanner(s), printer(s), and fax machine(s); and
 4. shall have a licensed pharmacist at the central pharmacy location.
- (2) The central pharmacy license shall expire two (2) years from the date of issuance. All licenses shall be renewed on or before the last day of the two (2)-year license cycle.
 - (3) The central pharmacy may renew its license within six (6) months after the license expiration date with payment of the renewal fee and late renewal penalty fee. After the six (6) month grace period, the licensee may reapply for licensure.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008].

1140-13-.04 Fees.

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|-----|--------------------------|----------|
| (1) | Initial license fee..... | \$168.00 |
| (2) | Renewal fee..... | \$168.00 |
| (3) | Regulatory fee..... | \$10.00 |
- (4) 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 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008].

1140-13-.05 Civil Penalties.

- (1) With respect to any licensed central pharmacy, the Board may, in addition to or in lieu of any other lawful disciplinary action, assess a civil penalty for each separate violation of a statute, rule, or Board's order pertaining to drugs or the practice of pharmacy, including, but not limited to telepharmacy, in accordance with the following schedule:

Violation	Penalty
T.C.A. §63-10-305	\$0- \$1,000
T.C.A. §63-10-601	\$0- \$1,000
Rule 1140-2-.01	\$0- \$1,000
Rule 1140-2-.02	\$0- \$1,000
Rule 1140-13-.06	\$0- \$1,000
Rule 1140-13-.07	\$0- \$1,000
Rule 1140-13-.08	\$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) Whether the amount imposed will be a substantial economic deterrent to the violator;
 - (b) The circumstances leading to the violation;
 - (c) The severity of the violation and the risk of harm to the public;
 - (d) The economic benefits gained by the violator as a result of noncompliance;
 - (e) The interest of the public; and
 - (f) The willfulness of the violation.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008].

1140-13-06 Pharmacist Responsibilities.

- (1) Pharmacy Operations and Security.
 - (a) The pharmacist-in-charge shall ensure that the central pharmacy's connection with the satellite clinic through computer, videolink, and audiolink is operational at all times that the satellite clinic is open.
 - (b) In the event that the computer, videolink, or audiolink connection is not operational, the pharmacist-in-charge shall ensure that the satellite clinic shall cease to operate relative to the issuance of prescriptions supplied by the central pharmacy until the links are reconnected. Whenever an interruption of data, video, or audiolink occurs between the central pharmacy and the satellite clinic, no prescription shall be dispensed, and a sign shall be posted noting the closure with an estimated time until a resumption of services can be expected.
 - (c) The pharmacist-in-charge shall ensure that prescriptions for controlled substances schedules I, II, III, or IV are not issued from the satellite clinic.
 - (d) The pharmacist-in-charge shall ensure that only the pharmacists and pharmacy technicians employed by the federally qualified health center and working in the satellite clinic shall have keys to the satellite clinic.
 - (e) The pharmacist-in-charge shall ensure that the security at the central pharmacy shall be performed in accordance with Tenn. Comp. R. & Regs. Rule 1140-1-.12.
 - (f) The pharmacist-in-charge shall ensure the security of the storage of drugs at the central pharmacy and the satellite clinic.
 - (g) The pharmacist-in-charge shall ensure that there are no other medications stored in the pharmacy room of the satellite clinic, other than those medications supplied by the central pharmacy.

- (h) The pharmacist-in-charge shall ensure that pharmacy technicians working at the central pharmacy are supervised by a pharmacist in accordance with Rule 1140-2-.02(8).
- (i) The pharmacist-in-charge shall ensure that pharmacy technicians working at the satellite clinic shall be supervised by a pharmacist without a pharmacist being physically present.
- (j) The pharmacist-in-charge may request a waiver of Tenn. Comp. R. & Regs. Rule 1140-3-.14(12) upon a showing of good cause.

(2) Verification.

- (a) The pharmacist shall perform all in-process and end-process verification of the pharmacy technician's activities, including, but not limited to: checking the contents of the prescription bottle; checking the bottle label; checking the prescription; performing a drug utilization review in accordance with Tenn. Comp. R. & Regs. Rule 1140-3-.01(3); and performing patient counseling.

(3) Patient Counseling.

- (a) If a pharmacist is not physically present at the satellite clinic and the patient or patient's agent is being issued a new prescription, then the pharmacist shall counsel the patient or patient's caregiver by means of telepharmacy before the prescription is issued.
- (b) If a pharmacist is not physically present at the satellite clinic and the patient or patient's agent is being issued a refilled prescription, then the pharmacy technician shall offer counseling to the patient or patient's caregiver by means of telepharmacy before the prescription is issued.
- (c) Pharmacists shall counsel patients in accordance with Board of Pharmacy rules whether the medication is issued from the central pharmacy or the satellite clinic.

(4) Supervision.

- (a) The pharmacist-in-charge shall ensure that each individual operating as a pharmacy technician while employed by a federally qualified health center at a central pharmacy or satellite clinic is properly registered with the Board at all times.
- (b) The pharmacist-in-charge or a designee of the pharmacist-in-charge shall complete a weekly in-person inspection of the satellite clinics to ensure compliance with all applicable laws and rules relative to drugs and the practice of pharmacy outlined in the central pharmacy's policies and procedures.
- (c) The pharmacists working at the federally qualified health center are not required to be physically present to verify the accuracy of all pharmacy technician functions performed at the satellite clinic while participating in

this program; verification may be conducted by means of the computer link, videolink, and audiolink.

(5) Policies and Procedures.

(a) The pharmacist-in-charge shall ensure that the central pharmacy and satellite clinic have policies and procedures including, but not limited to the following:

1. when and how a pharmacy technician should contact a pharmacist to perform the issuing process;
2. how the pharmacy technician is to use the computer, videolink, and audiolink technology to communicate with the pharmacist;
3. delivery of the filled prescriptions to the satellite clinic to be issued to the patient or the patient's caregiver;
4. recordkeeping process to track the prescriptions dispensed from the central pharmacy and issued from the satellite clinic;
5. recordkeeping process to track the filled prescriptions received by the satellite clinic from the central pharmacy;
6. how to securely transport the filled prescriptions from the central pharmacy to the satellite clinic;
7. how to order prescriptions and refills for the central pharmacy;
8. how to ensure that patient counseling is performed in accordance with this chapter;
9. when and how unissued medications will be disposed of or sent back to the central pharmacy.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008].

1140-13-.07 Pharmacy Technician Responsibilities.

- (1) The pharmacy technician shall ensure that the central pharmacy's connection with the satellite clinic through computer, videolink, and audiolink is operational at all times that the satellite clinic is open.
- (2) In the event that the computer, videolink, and audiolink connection is not operational, the pharmacist-in-charge shall ensure that the satellite clinic shall cease to operate relative to the issuance of medications supplied by the central pharmacy until the links are reconnected. Whenever an interruption of data, video, or audio link occurs between the central pharmacy and the satellite clinic, no prescription shall be issued, and a sign shall be posted noting the closure of the clinic with an estimated time that a resumption of services can be expected.
- (3) While working at a satellite clinic, the pharmacy technician shall notify the pharmacist at the central pharmacy prior to any medication being issued in order to ensure that patient counseling is performed or offered.
- (4) The pharmacy technician shall only issue prescriptions dispensed by the central pharmacy.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008].

1140-13-.08 Recordkeeping and Inspections.

- (1) The pharmacist-in-charge, pharmacists, and pharmacy technicians employed by the federally qualified health center working at a central pharmacy or satellite clinic shall ensure that a record is maintained at each central pharmacy and satellite clinic containing the prescriptions dispensed or issued from each location, including but not limited to the date dispensed/issued; date dispensed from the central pharmacy; date received by the satellite clinic; the drug name; quantity, dosage; strength; and patient name.
- (2) All records of prescriptions dispensed from the central pharmacy and issued from the satellite clinic shall be retained for at least two (2) years from the date dispensed.
- (3) Board of Pharmacy investigators shall be able to inspect the central pharmacies and the satellite clinics to ensure compliance with the applicable laws and rules related to drugs and the practice of pharmacy.

Authority: Chapter 1028 of the Public Acts of 2008, § 2 and T.C.A. §§ 63-10-601 through 63-10-602. [effective July 1, 2008] and T.C.A. §63-10-307.

The public necessity rules set out herein was properly filed in the Department of State on this the 25th day of November, 2008, and will be effective from the date of filing for a period of 165 days. These public necessity rules will remain in effect through the 9th day of May, 2009. (FS 11-33-08; DBID)