RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-14
LONG-TERM CARE PHARMACY PRACTICE SITES

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1140-14-.01 APPLICABILITY.

A long-term care pharmacy practice site providing products and services to any long-term care facility shall be subject to all rules of the board dependent upon services provided.

***Authority**: T.C.A. §§ 63-10-204 and 63-10-304. **Administrative History:** New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.02 PERSONNEL.

(1) Pharmacist in charge. The practice of pharmacy and the performance of pharmacists and supportive pharmacy personnel associated with any long-term care facility shall be under the direction, supervision and responsibility of the pharmacist in charge. The pharmacist in charge shall also be responsible for the dispensing and storage of prescription and nonprescription drugs used throughout the long-term care facility. Policies and procedures defining the scope of pharmacy practice and the responsibilities of the pharmacists and supportive personnel, and the safe use and management of drugs, devices and related materials shall be established by the pharmacist in charge. The pharmacist in charge or designee shall participate in the long-term care facility's drug policy committees which serve to ensure rational drug use, patient care evaluation processes relating to drug utilization and effectiveness, drug delivery device selection and evaluation systems, and educational activities for the safe and appropriate use of drugs which will assess the quality of services and products provided and document actions taken. Policies and procedures as indicated in this chapter shall be written and shall be made available to the Board.

(2) Pharmacists. The pharmacist in charge shall be supported by a sufficient number of pharmacists to provide appropriate practice of pharmacy for the patients served by the long-term care facility.

(3) Long-term care consultant pharmacist. A long-term care facility may utilize a consultant pharmacist who may or may not be independent of the pharmacy practice site, who shall provide patient care service which includes, but is not limited to:

(a) Providing consultation on matters pertaining to efficient drug distribution systems, proper drug selection, rational and safe drug use, and drug therapy assessment;

(b) Evaluation of a patient's drug therapy to maximize outcome(s), including effective communication with prescribing practitioners and other healthcare professionals;

(Rule 1140-14-.02, continued)

(c) Service on committees or governing bodies; and

(d) Providing in service educational programs for members of the healthcare team.

(4) Supportive personnel. The pharmacist in charge shall be assisted by a sufficient number of pharmacy technicians, as defined in 1140-02-.02, pharmacy interns, and other supportive personnel as may be required to operate the pharmacy competently, safely, and adequately to meet the needs of the patients served by the long-term care facility.

(5) Supervision. All of the activities associated with the practice of pharmacy and the operations of the pharmacy at a specific long-term care pharmacy practice site shall be supervised by a sufficient number of pharmacists to ensure that all functions and activities are performed competently, safely and without risk of harm to patients.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.03 PHYSICAL REQUIREMENTS.

(1) Area. A long-term care pharmacy practice site shall have sufficient floor space allocated to it to ensure that medical and prescription orders are prepared and dispensed in sanitary, well lighted, and enclosed spaces. The long-term care pharmacy shall also have sufficient counter space or other suitable work module to ensure that medical and prescription orders are prepared and dispensed in an orderly manner.

(2) Equipment and Materials. The pharmacy practice site shall have sufficient equipment and physical facilities for the practice of pharmacy. This shall include but not be limited to:

(a) Hot and cold running water;

(b) Refrigerated storage space;

(c) Frozen storage space as appropriate; and

(d) Adequate information systems.

(3) Storage. All prescription drugs and devices and related materials shall be stored in designated areas within the pharmacy practice site which are sufficient to ensure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security.

(4) Alcohol and Flammables. Alcohol and flammables shall be stored in an area that shall, at a minimum, meet basic local building code requirements for the storage of volatiles, and such other laws, ordinances, or regulations that may apply.

(5) Security. A pharmacy practice site shall be capable of being locked to prevent access by unauthorized personnel. If a long-term care pharmacy practice site is located within a long-term care facility, a pharmacist must be accessible within that long-term care facility; and when no pharmacist is present at the long-term care facility, the pharmacy practice site must be kept closed and securely locked except as provided in 1140-14-.11.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.04 PRESCRIPTION ORDERS.

A pharmacist shall review all prescription orders before the drug is first dispensed. In the event that medications available in the long-term care facility are ordered and administered before the pharmacist's review, the order shall be reviewed by a pharmacist in a timely manner. The pharmacist shall have access to the patient's medical record. The prescription order must be maintained in a readily retrievable manner according to the pharmacy practice site policy.

If a patient residing in a long-term care facility has an existing prescription order for a controlled substance, and a valid prescription is needed from the prescriber to continue that order, a fax or electronic communication containing the required information listed in 1140-03-.03 (4)(a) may be generated by a pharmacist, or pharmacy technician working under the direct supervision of a pharmacist, and communicated to the prescriber. Upon receipt of the communication, the prescriber may complete the prescription order by indicating the name of the patient, name and signature of the prescriber, drug, quantity, and date. The completed prescription order may then be faxed or electronically communicated to the long-term care pharmacy practice site. When received by the long-term care pharmacy practice site, this signed fax or electronic communication shall be considered a valid prescription order.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.05 DISTRIBUTION AND CONTROL OF DRUGS.

The pharmacist in charge shall be responsible for approving policies for the distribution and control of drugs within the long-term care facility. The process shall be established to provide for the safe and efficient distribution of drugs and for the provision of pharmaceutical care, and shall include but not be limited to:

(1) A drug dispensed from the pharmacy for subsequent administration to a patient shall be appropriately identified with the name and location of the patient and the name and strength of the drug.

(2) The pharmacist in charge is responsible for the development and maintenance of an audit trail on drugs dispensed and delivered.

(3) The prescription order shall be recorded on a patient medication profile that will be maintained during the patient's treatment. This profile shall include the date of the prescription order, the name and dosage form of the drug and the dose and administration frequency.

(4) The long-term care facility distribution system may be based on a combination of processes that will ensure compliance with federal and state guidelines such as, but not limited to, emergency kits/crash carts, automated dispensing devices, and/or after-hours procedures for pharmacy site access.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.06 CONTROLLED DRUGS.

(1) As permitted by state and federal rules and regulations, controlled substances (and those drugs deemed by the pharmacist in charge to have a potential for abuse) which are issued as floorstock shall be accounted for by providing documentation of:

(a) The drug name, strength, and dosage form;

(Rule 1140-14-.06, continued)

(b) The date and time of administration;

(c) The quantity/dose administered;

(d) Identification of the patient;

(e) Identification of the prescriber; and

(f) Identification of the authorized personnel administering the controlled substance.

(2) As permitted by state and federal rules and regulations, record of the destruction of controlled substances previously dispensed to or for patients and returned to the dispensing pharmacy for destruction shall be maintained so as to be readily retrievable, and such records shall include:

(a) The identification of the patient;

(b) Drug name, strength, dosage form, and quantity;

(c) The date and method of destruction; and

(d) The identification of authorized personnel witnessing the destruction and its record.

(3) Schedule II controlled substances which are kept within a pharmacy practice site shall be stored in a secured, substantially constructed cabinet, safe, or other structure.

(4) Nothing in this rule shall be interpreted to authorize the destruction of controlled substance floorstock or pharmacy stock. Such drugs shall upon request, be destroyed by a board approved agent or vendor.

Authority: *T.C.A. § 63-10-304*. ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.07 EMERGENCY AND HOME CARE KITS.

Drugs and devices and related materials may be provided by emergency kits as defined by policies and procedures provided that such kits meet the following requirements:

(1) Emergency Kits.

(a) Drugs and devices and related materials may be provided by emergency kits as defined by pharmacy policies and procedures, provided that such kits meet the following requirements:

1. Emergency kit drugs are those drugs which may be required to meet the therapeutic needs of patients and which are not available from any other authorized source in sufficient time to prevent risk of harm to patients.

2. The policies and procedures to implement the requirements of this subsection and to approve the contents of the emergency kit will be determined by the pharmacist in charge or his/her designee.

3. The emergency kit shall be sealed or electronically secured by authorized personnel in accordance with established policies. The expiration date of the kit shall be clearly marked on the exterior of the kit or kept electronically to

represent the earliest expiration date of any drug, device, or related materials contained in the kits.

4. Emergency kits shall be stored in a secured area at the long-term care facility or patient care site to prevent unauthorized access. To ensure a proper environment for preservation of the drugs contained therein, appropriate policies and procedures shall be written to include storage at the site of patient care.

5. Only authorized individuals may obtain drugs, devices or related materials from the emergency kit in accordance with established policies and state and federal laws and regulations.

6. A list of the emergency kit contents shall be readily accessible and it shall include the drugs, devices, and related materials contained therein and include the name (trade and/or generic), strength, and quantity of the products contained therein.

7. Drugs contained within the emergency kit shall be properly labeled according to the United States Food and Drug Administration (FDA) labeling requirements for the drug or device and with additional information that may be required by the staff to prevent misunderstanding or risk of harm to the patients.

8. Removal of any drug, device, or related material from the emergency kit shall be pursuant to a valid medical or prescription order and must be documented by established policy which may include patient's identification, name of the drug, strength, amount, date, time, and identification of the authorized individual removing the drug.

9. When an emergency kit is opened for any reason, the pharmacy practice site shall be notified, and the kit shall be restocked and resealed within a reasonable time so as to prevent risk of harm to patients.

10. A pharmacy technician, holding an active registration with the Tennessee Board of Pharmacy and employed by the pharmacy, may restock and reseal the emergency kit with items prepared and checked by a pharmacist at the pharmacy.

(2) Home Care Kits.

(a) A home care kit is a kit containing certain drugs, as determined by the board, to be kept in the home of the patient for use by a healthcare professional engaged in home healthcare of a patient as necessary to meet the therapeutic needs of patients and which are not available from any other source in sufficient time to prevent risk of harm to patients.

1. A home care kit may contain:

(i) Sodium Chloride for Injection 0.9% Bacteriostatic

(ii) Sterile Water for injection Bacteriostatic or Preservative Free

(iii) Epinephrine injection 1mg/ml

(iv) Diphenhydramine

(v) Heparin Flush <or = 100units/ml

(Rule 1140-14-.07, continued)

(vi) Naloxone

(vii) Sodium Chloride for Irrigation

(viii) Sterile Water for Irrigation

(ix) Dextrose 50%

(x) Urokinase 5000units

(xi) Any other legend drug as approved by the board.

(b) Drugs contained in home care kits are to be used for emergencies only. Maintenance of a central venous catheter is considered an emergency if confirmed with the patient's physician or his/her designee.

(c) Policies and procedures for the dispensing, use, storage at the patient care site, security and expiration date review, and reconciliation of drug contents shall be determined as in section (1)(a)2 of this rule. Additional policies or protocols for treating anaphylactic reaction, maintaining patency of intravenous or central venous catheters, or flushing of intravenous devices shall be established, in the same manner.

(d) Removal of any drug from the Home Care Kit shall be pursuant to a valid medical or prescription order and/or protocol and must be documented in the patient's medical record.

(e) When a home care kit is opened for any reason, the pharmacy practice site shall be notified and the kit shall be restocked and resealed within a reasonable time so as to prevent risk of harm to patients.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.08 UNUSED DRUGS, DEVICES AND RELATED MATERIALS.

Discontinued, outdated, defective, or deteriorated drugs, devices, or related materials and containers with worn, illegible, or missing labels shall be returned to the pharmacy practice site for proper disposition. All such drugs, devices or related materials returned to the pharmacy practice site must be destroyed unless in unit dose packaging, unopened commercially prepackaged containers and in the professional judgment of the pharmacist in charge or designee, the medications or related materials meet all federal and state board standards for product integrity.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.09 TAKE-HOME AND LEAVE OF ABSENCE DRUGS, DEVICES AND RELATED MATERIALS.

(1) All prescription drugs prescribed for and released to patients who are on leave of absence from the long-term care facility must be released in accordance with the long-term care facility's policies and procedures.

(2) All prescription drugs prescribed for and dispensed to patients who are being discharged from the long-term care facility must be dispensed with labeling in accordance with 1140-03-.06.

(Rule 1140-14-.09, continued)

(3) The pharmacist in charge in coordination with the medical and nursing staff of the facility shall establish policies and procedures to assure that this process meets state and federal guidelines appropriate for the facility.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.10 RECALLS.

The recall procedure shall be readily activated to ensure that all prescription drugs and devices and related materials included on the recall are returned to the pharmacy practice site for proper disposition. The pharmacist in charge shall develop and implement policies and procedures for recalls.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.11 ABSENCE OF PHARMACIST.

(1) Long-term care pharmacy practice site.

(a) General. During such times as a long-term care pharmacy practice site is closed, facility policy as approved by the pharmacist in charge shall provide a process for authorized personnel to obtain drugs necessary for the provision of patient care. This function may also be accomplished as outlined in the After Hours Drug Provision of this section. A pharmacist must be “on call” twenty four (24) hours per day, seven (7) days per week.

(b) After Hours Drug Provision. When a long-term care pharmacy practice site is closed, access to prescription drugs shall be by locked cabinet(s), automated dispensing machines or other enclosure(s) constructed and located within the long-term care facility, to which only personnel authorized by the pharmacist in charge, in coordination with the medical and nursing staff, may obtain access. Access should be sufficiently secured to deny entry to unauthorized persons by force or otherwise. Those practice sites utilizing automated dispensing devices for after hours drug provision shall meet the requirements of rule 1140-14-.12.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.12 AUTOMATED DISPENSING SYSTEMS IN LONG-TERM CARE PRACTICE SITES.

No prescription drug or device or related material shall be distributed or issued by the use of any automated dispensing device unless the method of operation has been approved and each device licensed by the board to ensure the purity, potency, and integrity of the prescription drug or device or related material, and to protect the prescription drug or device or related material from diversion.

(1) Each pharmacy holding an active license with the Tennessee Board of Pharmacy and using automated dispensing systems shall register each automated dispensing system with the Tennessee Board of Pharmacy. Each pharmacy maintain a list of the physical locations of all automated dispensing machines in its systems, whether such systems are located in the same facility as the licensed pharmacy, or not, and shall be responsible to pay a registration fee, as defined in 1140-01-.10, for each automated dispensing system, which the licensed pharmacy is responsible for and which is located in a long-term care facility.

(2) The pharmacist in charge of the long-term care pharmacy practice site shall be designated to be accountable for this automated dispensing system.

(Rule 1140-14-.12, continued)

(a) The filling/stocking of all medications in the automated dispensing system shall be completed by a pharmacist or pharmacy technician under the direct supervision of a pharmacist, except as provided below:

1. If the automated dispensing system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager.

2. The prepackaged cartridges, unit dose packages or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(i) A pharmacist verifies the cartridge or container has been properly filled and labeled;

(ii) The individual cartridges, unit dose packages or containers are transported to the remote site in a secure, tamper-evident container; and

(iii) The automated dispensing system uses bar-coding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated dispensing system.

(iv) All drugs to be stocked in the automated dispensing system shall be delivered to the remote site by the provider pharmacy.

(b) A record of medications filled/stocked into an automated dispensing system shall be maintained and shall include identification of the persons filling/stocking and checking for accuracy.

(c) All containers of medications stored in the automated dispensing system shall be packaged and labeled in accordance with federal and state laws and regulations.

(d) All aspects of handling controlled substances shall meet the requirements of all state and federal laws and regulations.

(e) The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the automated dispensing system, all in accordance with existing state and federal law.

(f) The automated dispensing system shall provide a mechanism for securing and accounting for wasted medications or discarded medications in accordance with existing state and federal law.

(g) The pharmacist in charge will work collaboratively with healthcare professionals to ensure that appropriate controls and monitors are utilized to provide information that drugs dispensed were for the correct patient and that pilferage is identified and resolved.

(3) All persons authorized to have access to these automated systems shall have documentation that they have successfully completed a training program that teaches them to perform the functions they perform with the automated device.

(4) Automated dispensing systems shall be used only for the furnishing of drugs and devices and related materials or other products related to the care of patients of that long-term care facility; and

(Rule 1140-14-.12, continued)

(5) At the time of removal of any drug or device or related material from the system, it shall automatically make a record, to be retained by the pharmacy for a minimum of two (2) years, indicating:

(a) The date and time of removal of the drug or device or related material;

(b) The name, strength, dosage form, and quantity of drugs or devices or related material removed;

(c) The identification of the patient for whom the drug or device or related material was ordered; and

(d) The identification of the person authorized to remove the drug or device or related material from the device.

(6) The pharmacist in charge or designee is responsible for determining how access codes or other methods of access to automated devices are assigned.

(7) The facility shall have policies and procedures approved by the pharmacist in charge in coordination with members of the nursing and medical staff for the points outlined in this section for automated dispensing devices.

(8) Nothing in this section shall be interpreted to authorize the stocking of controlled substances in automated dispensing systems, except when done in a manner consistent with federal controlled substance rules and regulations.

(9) The registration fee for each automated dispensing system shall be determined by the Tennessee Board of Pharmacy and listed in 1140-01-.10. The Board shall maintain a list of registered automated dispensing systems, including physical address and number of systems located at each physical address. Registrations for automated dispensing systems must be renewed every two (2) years.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.13 INVESTIGATIONAL DRUGS.

The pharmacist in charge in coordination with the long-term care facility, medical and nursing staff and, if appropriate, the pharmaceutical manufacturer, shall develop policies and procedures for the approval, management, distribution and control of investigational drug studies. The process shall ensure that such studies contain safeguards for the patient, for the long-term care facility and for the scientific integrity of the study. Each patient or the patient's legal guardian must freely consent, in writing, to treatment with the drugs, unless otherwise not required by federal law. The pharmacist is responsible to the long-term care facility and to the principal investigator for seeing that procedures for the control of investigational drugs are developed and implemented when needed.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*

1140-14-.14 INSPECTIONS.

The pharmacist in charge shall be responsible (personally or by qualified designee) for documented inspections, at minimum quarterly, of all drugs, devices and related materials dispensed by the long-term care pharmacy practice site and delivered to the long-term care facility. Records of such inspections shall be dated, signed and maintained so as to be readily retrievable at the pharmacy practice site for at least

(Rule 1140-14-.14, continued)
two (2) years. These inspections must assure the following:

(1) Thermolabile drugs are stored at the proper temperature;

(2) Drugs, devices and related materials requiring special storage conditions to ensure their stability are properly stored;

(3) There are no outdated or deteriorated drugs, devices or related materials;

(4) All drugs, devices and related materials are properly labeled;

(5) Emergency drugs, devices and related materials are properly stored; and

(6) Medicine cabinets, carts and storage areas are accessible to authorized personnel only.

Authority: *T.C.A. § 63-10-304.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017.*