RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-04
INSTITUTIONAL AND ALTERNATE OR ALTERNATIVE INFUSION PHARMACY PRACTICE SITES

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1140-04-.01 APPLICABILITY.

A pharmacy providing products and services to any institutional facility, and alternate or alternative infusion pharmacy practice site, shall be subject to all rules of the board dependent upon services provided.

Authority: *T.C.A. §§ 63-10-404(2), (28), 63-10-504(b)(1), and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983.*

1140-04-.02 PERSONNEL.

(1) Pharmacist in charge. The practice of pharmacy and the performance of supportive pharmacy personnel associated with any institutional 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, distribution, compounding, storage and the procurement of prescription and nonprescription drugs used throughout the institutional facility. Policies and procedures defining the scope of pharmacy practice, collaborative working relationships, 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 institution'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 institutional facility. Employment of pharmacists by the institutional facility shall be determined by the pharmacist in charge.

(3) Institutional consultant pharmacist. An institutional 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:

(Rule 1140-04-.02, continued)

(a) Development, interpretation, and communication of drug, device and related materials orders and health information;

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

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

(d) Effective counseling of a patient or a patient's attorney for healthcare or other caregiver;

(e) Service on committees or governing bodies; and

(f) 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 institution.

(5) Supervision. All of the activities associated with the practice of pharmacy and the operations of the pharmacy at a specific institutional 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. §§ 63-10-204, 63-10-304, 63-10-404(4), (8), (11), (14), (21), (26), (27), (28), and (30), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.03 PHYSICAL REQUIREMENTS.

(1) Area. An institutional or alternative infusion 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 institutional 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.

(Rule 1140-04-.03, continued)

(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. A pharmacist must be accessible within the institutional facility where an institutional pharmacy practice site is located; and when no pharmacist is present at the institution, the pharmacy practice site must be kept closed and securely locked except as provided in 1140-04-.14.

(6) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(8), (14), (28), 63-10-504(b)(1), and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 7, 1983. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.04 PRESCRIPTION ORDERS.

(1) A pharmacist shall review all prescription orders before the drug is first dispensed. In the event that medications available in the institutional 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 original order must be maintained in a readily retrievable manner according to the pharmacy practice site policy for at least two (2) years from the date of its issuance.

(2) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(1), (11), (14), (26), and (28), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.05 DISTRIBUTION AND CONTROL OF DRUGS.

The pharmacist in charge or designee, in conjunction with appropriate committees of the facility, shall be responsible for approving policies for the distribution and control of drugs within the 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.

(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.

(Rule 1140-04-.05, continued)

(4) The facility distribution system may be based on a combination of processes that will ensure compliance with federal and state guidelines such as emergency kits/crash carts, floorstock systems, automated dispensing devices, medication carts, and/or after-hours procedures for pharmacy site access.

(5) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(11), (14), and (27), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment to rule filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.06 MEDICATION CARTS.

(1) Drugs distributed from the pharmacy to other areas of the institutional facility may be stored in medicine cabinets or drug carts which shall be kept secured unless in use by the nursing staff or other authorized personnel. Access to the medication cart shall be defined by facility policies. It is recommended that drugs be dispensed in unit dose packaging and medications for each patient shall be distributed and stored in separate trays, drawers, compartments, or containers assigned to that resident and bearing the resident's name and location.

(2) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(11), (14), and (28), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.07 FLOORSTOCK DRUGS.

(1) The pharmacist in charge or designee, in conjunction with appropriate committees, shall be responsible for approving policies and procedures for floorstock at the institutional facility. The policies shall include specific drugs, quantities, prescription order review, storage requirements, and replenishment of drugs, devices, or related materials which are supplied to the institutional facility as floorstock.

(2) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(8), (14), and (27), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.08 CONTROLLED DRUGS.

(1) 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:

(Rule 1140-04-.08, continued)

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

(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) A record of the destruction of controlled substances previously dispensed to or for patients shall be maintained so as to be readily retrievable for at least two (2) years, and such records shall include:

(a) The identification of 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 which provides a double locked secured system.

(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 or returned to the pharmacy for destruction by a board approved agent or vendor.

(5) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 53-11-302, 63-10-204, 63-10-304, 63-10-404(11), (14), (27), and (28), and 63-10-504(b)(1) and (2)(j).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.09 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 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 immediate therapeutic needs of patients and which are not available from any

(Rule 1140-04-.09, continued)

other authorized source in sufficient time to prevent risk of harm to patients. Drugs in this kit are to be used only for emergency orders.

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 a committee composed of representatives of the medical and nursing staff and the pharmacist in charge or his/her designee.

3. The emergency kit shall be provided 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 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 institutional 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. A mechanism must be in place to ensure that the emergency kits are not in use after the expiration date.

8. 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.

9. 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 patients identification, name of the drug, strength, amount, date, time, and identification of the authorized individual removing the drug.

10. 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.

(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:

(Rule 1140-04-.09, continued)

(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

(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.

(3) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-304, 63-10-504, and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.10 UNUSED DRUGS, DEVICES, AND RELATED MATERIALS.

(1) 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

(Rule 1140-04-.10, continued)

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.

(2) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(8), (14), (16), (28), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983; effective March 9, 1983. Repeal and rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.11 TAKE-HOME AND LEAVE OF ABSENCE DRUGS, DEVICES, AND RELATED MATERIALS.

(1) All prescription drugs prescribed for and dispensed to patients who are on leave of absence from the institutional facility must be dispensed in accordance with the institution's policies and procedures.

(2) All prescription drugs prescribed for and dispensed to patients who are being discharged from the institutional facility must be dispensed with labeling in accordance with 1140-3-.06.

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

(4) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(11), (14), (16), and (27), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.12 DRUGS BROUGHT INTO THE FACILITY.

(1) The pharmacist in charge shall establish policies to control any drugs brought into the institutional facility.

(2) Administration of these drugs shall be pursuant to a medical or prescription order.

(3) Drugs brought into the facility shall not be administered until properly identified.

(4) Drugs which are not to be administered shall be packaged, sealed, and returned to an adult member of the patient's family for removal from the institutional facility or the drugs shall be securely stored and returned to the patient at discharge per facility policy.

(5) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(14), (19), (27), and (34), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983.*

(Rule 1140-04-.12, continued)
Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed August 30, 1991; effective November 27, 1991. Amendments filed November 22, 2016; effective February 20, 2017.

1140-04-.13 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. §§ 63-10-404(8), (14), (27), and (28) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed August 30, 1991; effective November 27, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-04-.14 ABSENCE OF PHARMACIST.

(1) Institutional pharmacy practice site.

(a) General. During such times as an institutional 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 an institutional 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 outside of the pharmacy practice site, to which only personnel authorized by the pharmacist in charge 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 1140-04-.15. The pharmacist in charge shall develop an inventory listing of those drugs to be included in such after hours storage, and shall ensure that:

1. Such prescription drugs are available therein, properly labeled;

2. Such prescription drugs are prepackaged in amounts not to exceed a seventy-two (72) hour medication period; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products);

3. All prescription drugs therein are inventoried at least once a month;

4. A record shall be made at the after hours storage location including the following elements:

(i) The date and time of removal of a drug;

(ii) The patient's name and location;

(iii) The name, strength, dosage form, and quantity of the prescription drug; and

(iv) The identification of the authorized personnel removing the drug.

(Rule 1140-04-.14, continued)

5. The prescription order shall be verified by a pharmacist or designee in a timely manner.

6. The above record shall be used by authorized pharmacy personnel to replenish the after hours storage location, and this record shall be kept at the institutional pharmacy practice site so as to be readily retrievable for at least two (2) years;

7. Policies and procedures shall be established to implement the requirements of this section.

(c) Access to the Pharmacy Practice Site within an Institutional Facility. Whenever any prescription drug is not available from floor supplies, emergency kits, or other approved distribution system for the facility, and such prescription drug or device or related material is required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such prescription drug, device or related material may be obtained from the pharmacy practice site in accordance with the requirements of this paragraph. Only authorized personnel, accompanied by a security guard or other authorized employee of the institution may have access to the pharmacy practice site and may remove the required drug, device or related material. Such person(s) shall be designated through policies of the facility and shall receive appropriate education and training in the proper methods of access and removal of prescription drugs, records and procedures required prior to such person(s) being permitted to obtain access to the pharmacy practice site. Such education and training shall be conducted by the pharmacist in charge or designee, who shall require, at a minimum, the following records and procedures;

1. Removal of any prescription drug, device or related material from the pharmacy practice site by an authorized person(s) must be recorded in a suitable form at the pharmacy practice site showing:

(i) The date and time of removal of the drug;

(ii) Patient identification and location;

(iii) The name, strength, dosage form, and quantity of the drug, device or related material removed; and

(iv) The signatures of the authorized personnel and the accompanying witness;

2. The above record shall be maintained at least two (2) years at the pharmacy practice site electronically, or in a separate file or log book;

3. The medication or prescription order shall be verified by a pharmacist or authorized personnel; and

4. The quantity of drug removed shall not exceed the amount needed plus one (1) dose until the pharmacy practice site reopens; unless available in a commercially prepared package dictating multiple dose therapy (e.g., ophthalmic products, topical products, otic products).

(2) Alternate or Alternative Infusion pharmacy practice site.

(a) During such times as an alternate or alternative infusion pharmacy practice site is closed, policies and procedures shall be established by the pharmacist in charge for

(Rule 1140-04-.14, continued)

the provision of prescription drugs, devices and related materials to patients on a twenty four (24) hours per day seven (7) days per week basis.

(b) A pharmacist must be "on call" during all absences.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(11), (14), (15), (19), (26), (27), (28), and (34) and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.15 AUTOMATED DISPENSING SYSTEMS.

No prescription drug or device or related material shall be distributed or issued by the use of any automated dispensing device unless the device and the method of operation have been found 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) A pharmacist shall be designated to be accountable for this automated dispensing system.

(a) Individuals authorized by the facility policies and the pharmacist in charge will stock this device under the supervision of a pharmacist, if a pharmacist is not stocking the device.

(b) The pharmacist 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.

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

(3) 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 institution or facility; and

(4) At the time of removal of any drug or device or related material from the device, 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.

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

(6) 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.

(Rule 1140-04-.15, continued)

(7) The facility may provide off-campus automated dispensing systems for care provided by the institution when the following conditions are met:

(a) 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 shall 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 an institutional facility.)

(b) The pharmacist in charge of the institutional pharmacy practice site shall be designated to be accountable for this automated dispensing system.

1. 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:

(i) 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.

(ii) The prepackaged cartridges, unit dose packages or containers may be sent to the off-campus 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 off-campus site in a secure, tamper-evident container;

(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 off-campus site by the institutional pharmacy.

2. 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.

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

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

5. The automated dispensing system shall provide a mechanism for securing and accounting for medications removed from and subsequently returned to the

(Rule 1140-04-.15, continued)

automated dispensing system, all in accordance with existing state and federal law.

6. 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.

(c) 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.

(d) 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 devices located at each physical address. Registrations for automated dispensing systems must be renewed every two (2) years.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(8), (11), (14), (26), and (27), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.16 EMERGENCY ROOMS.

(1) If prescription drugs, devices and related materials in an emergency room are to be dispensed (other than by pharmacy staff) rather than administered, the drugs, devices or related materials must be dispensed by the physician or an emergency room nurse or certified physician assistant at the direction of a physician. If the physician in an emergency room does not personally dispense, then prescription drugs, devices and related materials for outpatient use must be packaged in containers from the pharmacy practice site in amounts not to exceed a twelve (12) hour period or with products commercially prepared for multiple dose therapy (e.g., ophthalmic products, topical products, otic drops) in the smallest available package. These prescription drugs, devices or related materials shall be dispensed only after a medical or prescription order has been issued and recorded in the emergency room and shall be labeled with appropriate labeling.

(2) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(1), (8), (11), (15), (19), (28), and (34), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.17 INVESTIGATIONAL DRUGS.

(1) The pharmacist in charge in coordination with the institutional 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 institution 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 institution and to the principal

investigator for seeing that procedures for the control of investigational drugs are developed and implemented when needed.

(2) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(14) and (26), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-04-.18 MONTHLY INSPECTIONS.

The pharmacist in charge shall be responsible (personally or by qualified designee) for documented monthly inspections of all drugs, devices and related materials kept at nursing stations, surgery, delivery rooms, emergency rooms, clinics, and any other area of the 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 two (2) years. These inspections must assure the following:

(1) Test reagents, germicides, and disinfectants are stored separately from drugs, devices and related materials;

(2) External drugs, devices and related materials are stored separately from internal drugs, devices and related materials;

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

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

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

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

(7) Emergency drugs, devices and related materials are stored in accordance with rule 1140-04-.10;

(8) Medicine cabinets, carts and storage areas are accessible to authorized personnel only;

(9) Dispensing of controlled substances is properly and adequately documented;

(10) Telephone numbers of regional poison control centers and other emergency assistance organizations are posted;

(11) Metric-apothecaries' weight and measure conversion tables and charts are available; and

(12) Adequate pharmaceutical references for the drugs administered in that location are available.

(13) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

(Rule 1140-04-.18, continued)

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404(8), (14), and (28), and 63-10-504(b)(1) and (2).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed November 22, 2016; effective February 20, 2017.*