RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-03
STANDARDS OF PRACTICE

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1140-03-.01 RESPONSIBILITIES FOR PHARMACEUTICAL CARE.

(1) Patient counseling

(a) Upon the receipt of a medical or prescription order and following a review of the patient's record, a pharmacist shall personally counsel the patient or caregiver "face-to-face" if the patient or caregiver is present. If the patient or caregiver is not present, a pharmacist shall make a reasonable effort to counsel through alternative means.

(b) Alternative forms of patient information may be used to supplement, but not replace, face-to-face patient counseling.

(c) Patient counseling, as described herein, shall also be required for outpatients of hospitals or other institutional facilities dispensing medical and prescription orders and for patients when medications are dispensed on discharge from the hospital or other institutional facility.

(d) Patient counseling as described in this rule shall not be required for inpatients of an institutional facility.

(e) Patient counseling shall cover matters, which in the exercise of the pharmacist's professional judgement, the pharmacist deems significant including:

1. the name and description of the medication;

2. the dosage form, dose, route of administration, and duration of drug therapy;

3. special directions and precautions for preparation, administration, and use by the patient;

4. common side effects or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

5. techniques for self-monitoring drug therapy;

6. proper storage;

7. prescription refill information; and

8. action to be taken in the event of a missed dose.

(f) Upon the receipt of a request for a refill of a medical or prescription order, a pharmacist or a person designated by the pharmacist shall offer for the pharmacist to personally counsel the patient or caregiver. Counseling as described in (e) above is not required unless requested by the patient or deemed necessary in the professional judgment of the pharmacist.

(g) A pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such counseling.

(2) Patient Profiling.

(a) A patient's record system shall be maintained by all pharmacy practice sites for patients for whom medical and prescription orders are dispensed. The patient's record system shall provide for the immediate retrieval of information necessary for the pharmacist to identify previously dispensed medical and prescription orders at the time a medical or prescription order is presented.

(b) In order to effectively counsel patients, the pharmacist or a person designated by the pharmacist shall, through communication with the patient, caregiver, or agent make a reasonable effort to obtain, record, and maintain the following information for each patient of the individual pharmacy practice site.

1. Name, address, telephone number.

2. Date of birth (age), gender.

3. An individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

4. Pharmacist's comments as deemed relevant. This may be done manually or by computer.

(3) Drug Regimen Review.

(a) A pharmacist shall be responsible for a reasonable review of a patient's record prior to dispensing each medical or prescription order. The review shall include evaluating the medical and prescription order for:

1. over-utilization or under-utilization;

2. therapeutic duplication;

3. drug-disease contraindication;

4. drug-drug interactions;

5. incorrect drug dosage or duration of drug treatment;

6. drug-allergy interactions;

(Rule 1140-03-.01, continued)

7. clinical abuse/misuse.

(b) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the problem.

(4) Implementation of Pharmaceutical Care.

(a) As a necessary health care provider, pharmacists shall carry out, in addition to the responsibilities in paragraphs (1) through (3) of this rule, those professional acts, professional decisions and professional services necessary to maintain a patient's pharmacy-related care and to implement and accomplish the medical and prescription orders of licensed practitioners, including but not limited to:

1. Developing relationships with licensed practitioners to enable the pharmacist to accomplish comprehensive management of a patient's pharmacy related care and to enhance a patient's wellness, quality of life and optimize outcomes; and

2. Communicating to the health care provider any knowledge of unexpected or adverse response to drug therapy, or resolving unexpected or adverse response; and

3. Having a pharmacist accessible at all times to patients and healthcare providers to respond to their questions and needs.

Authority: *T.C.A. §§ 63-10-404(19),(22),(23),(26), and (34), 63-10-504(b)(1) and (2), 63-10-504(j), and 63-10-504(c).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-03-.02 LOCATION OF PRACTICE.

A pharmacist may compound and dispense prescription drugs and devices and related materials only in a pharmacy practice site which is duly licensed by the board and which operates in compliance with Tennessee and federal laws and rules governing the practice of pharmacy. The practice of the knowledge skills of pharmacy is not pharmacy practice site dependent. However, any person practicing any aspect of the art and science of pharmacy must be licensed by the board.

Authority: *T.C.A. §§ 63-10-404(4),(8),(11),(14),(26), and (28), 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.*

1140-03-.03 MEDICAL AND PRESCRIPTION ORDERS.

(1) To the extent that a medical order contains an order for the compounding, dispensing or administration of a prescription drug or device or related material, the medical order shall be treated as a prescription order. Written medical and prescription orders must be signed by the prescriber. Verbal medical and prescription orders must be immediately reduced to writing (by hand or other means), dated, and initialed by the authorized individual accepting the medical and prescription orders.

(2) Each medical and prescription order when dispensed shall be serially numbered, filed numerically and maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date the medical and prescription order was last dispensed. Institutional pharmacies shall not be required to serially number medical and prescription orders dispensed for administration to inpatients of that institution.

(Rule 1140-03-.03, continued)

(3) A pharmacist upon initial dispensing of a medical or prescription order shall record on that medical or prescription order: the date such medical or prescription order was dispensed, the pharmacist's initials, and the amount of any product dispensed. If the pharmacist merely initials and dates a medical or prescription order the pharmacist shall be deemed to have dispensed the full face amount of the medical or prescription order.

(4) A pharmacist upon refilling a medical or prescription order shall enter on the back of that medical or prescription order: the date such medical or prescription order was refilled, the pharmacist's initials, and the amount of any product dispensed on such refill. If the pharmacist merely initials and dates the back of the medical or prescription order the pharmacist shall be deemed to have dispensed a refill for the full face amount of the medical or prescription order. As an alternative to recording refill information on the back of medical and prescription orders, an automated data processing system may be used for the storage and retrieval of refill information for medical and prescription orders, subject to the following conditions:

(a) Any such computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of the original medical or prescription order information and the complete refill history of all medical and prescription orders which are currently authorized for refilling. This shall include all the information contained in and required to be entered on each such medical or prescription order. This data must include at least the medical or prescription order serial number; date of issuance of the medical or prescription order; patient's name (and address on controlled substance medical and prescription orders); prescriber's name (and address and DEA registration number on controlled substance medical and prescription orders); product name, strength, dosage form, and quantity prescribed; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and identity (name, initials, or identification code) of the dispensing pharmacist for the original dispensing and each refill.

(b) Each individual pharmacist using a computerized system in the refilling of a medical or prescription order shall certify that the information entered into the computer for such a refill is correct by verifying, dating, and signing a hard-copy printout of each day's medical or prescription order refill data, or in lieu of such a printout, by signing a statement in a book or file each day attesting that the refill information entered that day has been reviewed by the pharmacist and is correct as shown. Such documentation shall be separately maintained at the pharmacy practice site for at least two (2) years from the date of the last dispensing.

(c) Any such computerized system shall have the capability of producing a hard-copy printout of any medical or prescription order refill data which the pharmacy practice site is responsible for maintaining under the laws and/or regulations of this state and/or the federal government. (This would, for example, furnish a medical or prescription order-by-medical or prescription order, refill-by-refill audit trail for any specified strength and dosage form of any prescription drug and device, by either brand or generic name or both.) Such a printout must include: the medical or prescription order serial number; patient's name (and address on controlled substance medical and prescription orders); name of prescriber; name, strength, and dosage form of the product; and the date of each refill, quantity dispensed on each refill, and the name or identification code of the dispensing pharmacist. Controlled substance data contained on such a printout must be separated, asterisked, or in some other manner visually identifiable apart from other items appearing on the printout. Any computerized system employed by a pharmacy practice site must, upon the request of an authorized representative of the board, send or provide such a printout to the pharmacy practice site within forty eight (48) hours excluding weekends (Saturdays and Sundays) and legal holidays.

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(d) In the event that a pharmacy practice site which utilizes such a computerized system experiences system down-time, the pharmacy practice site must have a written or readily retrievable auxiliary policy and procedure which will be used for documentation of refills of all medical and prescription orders. This auxiliary procedure must ensure that each refill is authorized, and that all appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(e) Each pharmacy practice site and pharmacist using such a computerized system must comply with the provisions of paragraphs one (1) and two (2) of this rule. In addition, the requirements of paragraph three (3) of this rule shall apply, unless this initial dispensing data is included on the printout required by subparagraph four (4)(b) of this rule, and is identified as pertaining to the initial dispensing.

(5) A pharmacist may dispense an appropriately authorized refill of a medical or prescription order by referral to a patient profile (medication record) instead of the original medical or prescription order on file at that pharmacy practice site, subject to the following conditions:

(a) The patient profile must contain all the information contained in and required to be entered on the original medical or prescription order, including the complete refill history of that medical or prescription order. This data includes the medical or prescription order serial number; date of issuance of the medical or prescription order; name of patient; name of the prescriber; product name; strength; dosage form, and quantity prescribed; directions for use, and labeling instructions; refill instructions; and the date of dispensing, quantity dispensed, and initials of the dispensing pharmacist for the original dispensing and each refill. Dispensing data must be identified as to whether it pertains to the original dispensing or to a refill.

(b) Controlled substance data contained on the patient profile must be asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the profile.

(c) The patient profile system must contain a complete and accurate record of the refill history of all medical and prescription orders dispensed at the pharmacy practice site. (This record will constitute compliance with the provisions of paragraph four (4) of this rule.)

(d) Each such profile must be maintained so as to be readily retrievable at the pharmacy practice site for at least two (2) years from the date of the last dispensing recorded on the profile.

(e) A pharmacist dispensing a medical or prescription order by referral to a patient profile in so doing certifies as to the accuracy and validity of the information contained on the patient profile.

(f) Each pharmacy practice site and pharmacist using such a patient profile system must comply with the provisions of paragraphs one (1) and two (2) of this rule. In addition, the requirements of paragraph three (3) of this rule shall obtain, unless the patient profile system contains a record of this initial dispensing information for all medical and prescription orders dispensed at the pharmacy practice site.

(6) No pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, shall compound or dispense any medical or prescription order except upon the following conditions:

(a) All medical and prescription orders shall be compounded and dispensed in strict conformity with any directions of the prescriber. Nothing in this rule shall prohibit a

(Rule 1140-03-.03, continued)

pharmacist from substituting a therapeutically equivalent prescription drug or device or related material containing the same active ingredient or ingredients, dosage form and strength;

(b) No medical or prescription order shall be refilled if it contains a statement over the signature of the prescriber that it is not to be refilled, and a medical or prescription order shall not be refilled unless so authorized by the prescriber;

(c) If any medical or prescription order contains a statement that it may be refilled a specified number of times within or during any particular period, such order shall be refilled in strict conformity with such statement; and

(d) If a prescription contains a statement that during any particular time it may be refilled at will, the order shall be refilled in strict conformity to dosage directions, with the exception that it may not be refilled after the expiration of the time specified or one (1) year from the date the order was originally issued or dispensed, whichever comes first.

(e) At a rate, based on the actual number of medical and prescription orders compounded and dispensed per hour or per day, that does not pose a danger to the public health, safety or welfare.

(7) Copies of Medical and Prescription Orders.

(a) Copies of medical and prescription orders issued directly to the patient by the pharmacy practice site where the order was originally compounded and dispensed pursuant to the receipt of the order shall bear on the face thereof, in letters red in color and equal in size to those describing the prescription drug or device or related material, the statement: “Copy for Information Only.” Presentation of an informational written copy or label of a dispensing container shall be for information purposes only and have no legal status as a valid medical or prescription order. The recipient pharmacist of such copy or label shall contact the prescriber or transferor pharmacy practice site and obtain all information required by this rule, which is the same as obtaining an original medical or prescription order;

(b) Medical and prescription orders shall be transferred between pharmacy practice sites for the purpose of compounding and dispensing provided that the transferee, upon receiving such order directly from the transferor, records the following:

1. The name, address and original medical or prescription order serial number at the pharmacy practice site from which the order was transferred;

2. The name of the transferor; and

3. All information constituting a medical or prescription order including the following:

(i) Date of original dispensing;

(ii) Original number of refills authorized on the original order;

(iii) Date of last dispensing; and

(iv) Number of valid refills remaining.

(c) The transferee informs the patient that the original medical or prescription order has been canceled at the pharmacy practice site from which it was obtained.

(Rule 1140-03-.03, continued)

(d) Computerized systems must satisfy all information requirements.

(e) The transfer of schedule III, IV, V, controlled substances are subject to the conditions set forth in C.F.R. 1306.26.

(8) It is permissible for any pharmacy practice site, pharmacist, or pharmacy intern or pharmacy technician under the supervision of a pharmacist, or any other place of business engaged in compounding and dispensing prescription drugs and devices and related materials for human consumption to receive from any patient or other person the return of any portion of an order that has been taken from the premises of the pharmacy practice site or other place of business, only if authorized:

(a) Pursuant to Tennessee Board of Pharmacy rule 1140-04-.10; or

(b) For the purpose of collection for disposal or destruction of any prescription drug; provided that participation in the program shall be voluntary, and such collection and destruction shall be conducted in accordance with the provisions of 21 CFR § 1317.

(9) Medical and prescription orders cannot be accepted, solicited, collected or advertised at a location other than a pharmacy practice site for which a license has been issued by the board, and such pharmacy practice site shall be actively engaged in compounding and dispensing medical and prescription orders.

(10) Medical and prescription orders typed or printed must be signed by the prescriber. Oral medical and prescription orders shall be initialed by the authorized individual accepting the order.

Authority: *T.C.A. §§ 63-10-404(4),(11),(14),(19),(26),(29),(30), and (34), 63-10-504(b)(1), 63-10-504(j), 63-10-504(b)(1) and (2), 63-10-204, 63-10-304, and 2015 Acts, Pub. Chap. 40.* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed September 15, 2015; effective December 14, 2015.*

1140-03-.04 FACSIMILE AND ELECTRONIC MEDICAL AND PRESCRIPTION ORDERS.

(1) Facsimile Orders

(a) The transmission of a facsimile medical or prescription order shall be to a pharmacy practice site of the patient's choice and shall occur only at the option of the patient.

(b) Medical and prescription orders may be transmitted to a pharmacy practice site by a facsimile device. Medical and prescription orders for controlled substances may be transmitted by facsimile devices in compliance with 21 C.F.R. 21306.11, 1306.21 and 1306.31.

(c) A pharmacist may dispense medical and prescription orders transmitted by facsimile devices only when transmitted by an authorized prescriber or the prescriber's designated agent.

(d) A facsimile medical or prescription order which meets the requirements of this rule shall be deemed the original medical or prescription order for purposes of filing. The facsimile medical or prescription order must either be photocopied or the original medical or prescription order should be of such quality to not fade within the legal requirements of medical or prescription order record keeping.

(Rule 1140-03-.04, continued)

(e) Wholesalers, manufacturers, pharmacists and pharmacy practice sites are prohibited from supplying facsimile devices or supplies to any authorized prescriber under any conditions.

(f) An original medical or prescription order that indicates that it has been faxed to a pharmacy practice site, consistent with the provisions of this rule, may only be dispensed as an original medical or prescription order by the pharmacy practice site to which it was faxed, consistent with the notation on the medical or prescription order to be made in accordance with the requirements contained in this rule.

(2) Electronic Orders.

(a) Prescription or medical orders transmitted electronically shall meet the following criteria:

1. All prescription or medical orders shall be transmitted directly from an authorized prescriber or prescriber's agent to a licensed pharmacist or to an area in a licensed pharmacy of the patient's choice that is under the direct supervision of a licensed pharmacist, with no intervening person or entity having access to the order for purposes other than transmission of the order. Subject to the provisions of this rule, a prescriber or prescriber's agent may electronically transmit medical or prescription orders to a pharmacist within an institutional facility for inpatients and/or outpatients currently under treatment at that facility. Nothing in this subsection shall apply to distributors of medical gases.

2. The transmission shall include:

(i) The telephone number of the authorized prescriber to allow verbal confirmation of the validity and accuracy of the order;

(ii) The correct time and date of the transmission;

(iii) The name of the pharmacy to which the order is being transmitted; and

(iv) The prescribing practitioner's electronic signature or other secure method of validation. "Electronic Signature" is defined as the process that secures the user authentication (proof of claimed identify, such as by biometrics, fingerprints, retinal scans, hand written signature verification, etc.) at the time the signature is generated and creates the logical manifestation of a signature.

(v) If the transmission is delegated by the prescriber to an agent of the prescriber, the identity of the agent shall be included in the transmission.

(b) A hard copy or exact image of the transmitted order shall be maintained in the pharmacy and shall be deemed the original prescription or medical order meeting all requirements of rule 1140-03-.03 of the rules of the board.

(c) The Pharmacist receiving any transmitted order shall not knowingly participate in any system that restricts the patient's choice of pharmacy.

(d) The pharmacist may not provide financial or other remuneration to the prescriber for any prescription transmitted to the dispensing pharmacy. No person or entity, including but not limited to wholesalers, distributors, manufacturers, pharmacists, and pharmacies, shall supply electronic equipment, software, devices, or modems to any prescriber in exchange for transmitting orders.

(Rule 1140-03-.04, continued)

(e) The pharmacist shall not use the electronic transmission of orders to circumvent or violate any provision of state or federal drug laws, or the Tennessee Pharmacy Practice Act, or the regulations of the board.

(f) This rule shall not apply to medical or prescription orders electronically transmitted between pharmacies or medical or prescription orders transmitted by facsimile.

Authority: *T.C.A. §§ 63-10-404(19),(26),(29),(30), and (34), 63-10-504, 63-10-504(b)(1) and (2), and 63-10-504(j).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002.*

1140-03-.05 AREAS OF RECEIPT AND DISPENSING.

All medical and prescription orders shall be received or accepted and compounded and dispensed from a pharmacy practice site which is in a building permanently located and non-mobile in nature. In case of emergency, the board may waive this rule upon request.

Authority: *T.C.A. §§ 63-10-404(4),(11),(19),(28), and (34), and 63-10-504(b)(1) and (2)(j).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-03-.06 LABELING REQUIREMENTS.

The dispensing label for a medical or prescription order shall bear at least the following information: name and address and telephone number of pharmacy practice site; the medical or prescription order serial number, name of prescriber; name of patient; directions for use; date medical or prescription order originally dispensed, and/or refill date; “poison”, “shake”, “caution”, or other appropriate advisory label; name of product (unless otherwise required by the prescriber); and expiration date of the product (if applicable). This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy for administration to inpatients of that institution.

Authority: *T.C.A. §§ 63-10-404(11),(15), and (19), and 63-10-504(b)(1) and (2)(j).* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed October 30, 1991; effective December 14, 19991. Amendment filed November 16, 1992; effective January 8, 1993. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-03-.07 TEMPORARY ABSENCE OF PHARMACIST.

A pharmacist is permitted one (1) temporary absence for a period not exceeding one (1) hour per day. During the absence of a pharmacist from the pharmacy practice site, a sign containing the words “pharmacist not on duty” must be conspicuously displayed in the pharmacy practice site. It shall be unlawful to fail or refuse to display the required sign in a conspicuous place when a pharmacist is absent. No medical or prescription order may be compounded or dispensed during the absence of a pharmacist. Additionally, during the absence of the pharmacist the prescription department shall be closed off by physical barrier from floor to ceiling.

Authority: *T.C.A. §§ 63-10-404(4),(11),(19),(26),(28), and (34), 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.*

1140-03-.08 REPACKAGING.

(1) Any repackaging of prescription drugs and devices and related materials must be supervised and controlled by a pharmacist with in-process and end-process verification and documentation.

(2) Prescription drugs and devices and related materials which are repackaged by an institutional pharmacy practice site for subsequent dispensing and use within the institution shall be labeled to include:

(a) the name, strength, and quantity of prescription drug or device or related material, if larger than one (1), in the container;

(b) the manufacturer's name, and lot or control number;

(c) the expiration date of the prescription drug or device or related material being repackaged; and

(d) cautionary notations (e.g., refrigerate, shake well, not for injection), if applicable.

(3) A batch number assigned by the pharmacy practice site may be placed on the label in lieu of the manufacturer's name and lot number, provided that the pharmacy practice site maintains a readily retrievable record which identifies, by batch number, the manufacturer and lot number of the prescription drug or device or related material.

(4) The pharmacy practice site shall have proper facilities, qualified personnel, effectual operational practices, suitable packaging material, and adequate control procedures to assure that the purity, integrity, safety, and effectiveness of the prescription drug or device or related material are not affected by such repackaging. All repackaging must be performed by a pharmacist or by a pharmacy intern or pharmacy technician under the supervision of a pharmacist.

Authority: *T.C.A. §§ 63-10-404(8),(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.*

1140-03-.09 LOSS OF PRESCRIPTION DRUGS, DEVICES AND RELATED MATERIALS.

The pharmacist in charge shall immediately report to the board any robbery, embezzlement, theft, burglary, or fire or disaster resulting in a loss of prescription drugs, or controlled substances or medical devices or related materials. The report shall include a list, including amounts, of such prescription drugs or controlled substances or medical devices or related materials lost or damaged.

Authority: *T.C.A. §§ 63-10-404(6),(8),(14), and (27), 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.*

1140-03-.10 CONDITIONS FOR DELIVERY OR SALE.

(1) No package containing any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes shall be placed in stock, offered for sale or dispensed or otherwise sold. Any repossession proceedings must be performed with the approval of the board.

(2) Under no circumstances shall any prescription drug or device or related material damaged by fire, heat, smoke, water, or other causes be delivered or handed over to any insurance

(Rule 1140-03-.10, continued)

company, adjustor, salvage company, or other person unless approved by the board prior to delivery.

Authority: *T.C.A. §§ 63-10-404(8),(11), and (14), 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.*

1140-03-.11 OUTDATED AND DETERIORATED DRUGS.

The owner or pharmacist in charge of a pharmacy practice site shall immediately return or destroy all outdated, defective, or deteriorated prescription drugs and devices and related materials; except that the destruction of controlled substances listed in any schedule shall be performed by a board approved agent or vendor.

Authority: *T.C.A. §§63-10-404(6), (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 November 25, 1985; effective February 12, 1986. Repeal and new rule filed May 11, 1998; effective July 25, 1998.*

1140-03-.12 STORAGE, SALE AND DELIVERY.

(1) All prescription drugs and controlled substances and devices and related materials shall be stored in an area not accessible to the public.

(2) A controlled substance which is not a prescription drug under the Federal Food, Drug, and Cosmetic Act may be dispensed by a pharmacist without a prescription to a patient provided the pharmacist complies with the provisions of 21 CFR §1306.32 and any other applicable law.

(3) Instruments and/or devices intended for the injection of any substance through the skin shall be stored in an area not accessible to the public, and shall be sold only on proof of medical need by a pharmacist or a pharmacy intern or pharmacy technician under the direct supervision of a pharmacist.

(4) All insulin preparations must be stored in an area not accessible to the public, and shall be sold only by a pharmacist or a pharmacy intern or pharmacy technician under the direct supervision of a pharmacist.

(5) Nothing in this section prohibits delivery of a prescription to a patient's home or business by an agent of the pharmacy practice site.

Authority: *T.C.A. §§63-10-404(6),(8),(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.*

1140-03-.13 AUTOMATED DISPENSING DEVICES FOR AMBULATORY PHARMACY PRACTICE.

The following procedures shall be observed in the use and operation of automated dispensing devices used for storing and dispensing capsules or tablets:

(1) The lot number of each drug contained therein must be listed or posted on the device.

(2) After each lot number is used, the portion of the device where the drug was contained must be thoroughly cleaned to remove all residue before refilling.

(3) Lot numbers may not be mixed.

(Rule 1140-03-.13, continued)

(4) The device may be loaded by a pharmacist; or a pharmacy intern or a pharmacy technician under the supervision of a pharmacist.

Authority: *T.C.A. § 63-10-404(8),(14),(26),(29), and (30), 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.*

1140-03-.14 PHARMACIST IN CHARGE.

(1) The board shall maintain a current record of all pharmacists who have been designated "pharmacist in charge" of a pharmacy practice site in the state of Tennessee.

(2) It shall be the responsibility of the person, partnership, firm, or corporation holding a pharmacy practice site license issued pursuant to T.C.A. § 63-10-50*6* to notify the board immediately of:

(a) the resignation, removal, or death of the pharmacist in charge named in the application for license (or successor pharmacist in charge); or

(b) the disability for a period exceeding thirty (30) days of the pharmacist in charge named in the application for license (or successor pharmacist in charge).

(3) The notice required by paragraph two (2) of this rule shall contain:

(a) the name and (except in the case of death or disability) signature of the outgoing pharmacist in charge;

(b) the effective date of the appointment (whether temporary or permanent) of the new pharmacist in charge;

(c) the name and signature of the new pharmacist in charge; and

(d) the name and address of the pharmacy practice site.

(4) Except in case of death or incapacity, the outgoing pharmacist in charge shall, prior to departure, conduct with the successor pharmacist in charge a joint inventory of all controlled substances. In case of failure of the outgoing pharmacist in charge to comply with this requirement, the successor pharmacist in charge shall conduct such inventory alone.

(5) In the event of death of a pharmacist in charge, the successor pharmacist in charge shall, immediately upon assuming the appointment as pharmacist in charge, conduct an inventory of all controlled substances.

(6) In the event of disability for a period exceeding thirty (30) days of a pharmacist in charge, the successor pharmacist in charge (temporary or permanent) shall conduct an inventory of all controlled substances. Should the disabled pharmacist in charge return, the disabled pharmacist in charge and successor pharmacist in charge shall immediately conduct a joint inventory of all controlled substances.

(7) A record of any inventory required by this rule shall be signed by the pharmacist(s) in charge conducting it and maintained at the pharmacy practice site with other controlled substance records for at least two (2) years. The inventory record shall indicate:

(a) the name and address of the pharmacy practice site;

(b) the name, strength, dosage form, and quantity of each controlled substance on hand;

(Rule 1140-03-.14, continued)

(c) the date of inventory; and

(d) whether the inventory was taken as of the opening or close of business on that date.

(8) The pharmacist in charge shall immediately notify the board in writing in the event of termination of business by the pharmacy practice site at which the pharmacist in charge practices. Such notice shall include a complete statement concerning the disposition by the pharmacy practice site of controlled substances and all prescription drugs and devices and related materials, invoices, records, and files.

(9) In a transaction involving the purchase of a pharmacy practice site or its stock of prescription drugs and devices and related materials, both the pharmacist in charge, except in case of death or incapacity, of the pharmacy practice site selling and the pharmacist in charge of the pharmacy practice site buying the stock, or the new owner of the pharmacy practice site if no pharmacist in charge has been appointed, shall jointly inventory all controlled substances and both shall sign and date that inventory and mail a copy of that inventory to the board within thirty (30) days of the completion of the sale.

(10) The pharmacist in charge shall maintain a current registry of individuals employed at the pharmacy practice site performing the functions of a pharmacy technician.

(11) This rule does not relieve other pharmacists or persons from their responsibility to comply with state laws and regulations.

(12) No pharmacist shall be designated pharmacist in charge of more than one (1) pharmacy practice site except where the board determines that such is in the best interest of the public health.

(13) The designated pharmacist in charge at a particular pharmacy practice site shall be on duty a minimum of fifty percent (50%) of the hours that the pharmacy is in operation. Except, in any event, the pharmacist in charge shall not be required to be on duty more than an average of forty (40) hours per week.

(14) The designated pharmacist in charge shall report to the board any situation in which a medical or prescription order has caused serious personal injury or death.

Authority: *T.C.A. §§63-10-404(2),(25),(26),(27), 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. Amendment filed August 19, 2002; effective November 2, 2002.*

1140-03-.15 REFERENCE BOOKS.

Each pharmacy practice site shall maintain an adequate reference library (printed or electronic) consistent with its scope of practice. The reference library shall include a current edition of the Tennessee Pharmacy Laws issued by the Tennessee Board of Pharmacy and may include current material regarding the technical, clinical, and professional components of the practice of pharmacy, with particular emphasis in the area in which the pharmacy specializes.

Authority: *T.C.A. §§63-10-304.* ***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 November 24, 2008; effective February 7, 2009.*

1140-3-.16 AUTOMATED DISPENSING DEVICES FOR PHARMACY PRACTICE.

Centralized Prescription Processing:

(Rule 1140-03-.16, continued)

(1) A pharmacy may perform or outsource centralized prescription processing services to another pharmacy, provided that the following criteria are satisfied:

(a) both pharmacies shall be licensed by the State of Tennessee;

(b) both pharmacies shall share a common electronic file or both shall have the appropriate technology to allow each other access to information that is necessary to fill or refill a prescription order; and

(c) both pharmacies shall have the same owner or in the event that the pharmacies do not have the same owner, then the pharmacies shall enter a written contract stating the services that will be provided by each pharmacy as well as the responsibilities of each pharmacy in fulfilling the terms of the contract and in complying with federal and state laws and rules.

(2) The pharmacy performing or contracting for centralized prescription processing services shall maintain a policy and procedures manual stating how prescription orders will be filled or refilled through centralized prescription processing. The pharmacies shall provide the Board with a copy of the manual and appropriate documentation of the processes for the Board's review, upon the Board's request. The pharmacies shall ensure that the manual includes, but is not limited to the following:

(a) a description of how the pharmacies will comply with federal and state law and rules;

(b) the maintenance of records to identify the responsible pharmacist(s) in the dispensing process;

(c) the maintenance of a mechanism for tracking the prescription order during each step of the dispensing process:

1. the maintenance of a mechanism to identify all of the pharmacies involved in dispensing the prescription order on the prescription label;

2. adequate security measures to protect the confidentiality and integrity of the patient information; and

3. the maintenance of a quality assurance program for pharmacy services designed to objectively and systematically monitor and evaluate the quality of patient care, the identification of problems with patient care and the resolution of any identified problems with patient care.

(d) The pharmacies that are not physically located in the State of Tennessee shall comply with Tenn. Code Ann Title 63, Chapter 10 and the rules of the State of Tennessee Board of Pharmacy.

Authority: *Chapter 966 of the Public Acts of 2008, §1, and T.C.A. §63-10-304.* ***Administrative History:*** *New rule filed November 24, 2008; effective February 7, 2009.*