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 or long-term care 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 a working and collaborative relationship 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.

4. Where formally defined, providing patient care services consistent with a collaborative pharmacy practice agreement.

Authority: *T.C.A. §§ 63-10-204, 63-10-217, 63-10-304, 63-10-404(19), (22), (23), (26), and (34), 63-10-504(b)(1) and (2), 63-10-504(c), and 63-10-504(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.*

1140-03-.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. 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(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. Amendments filed November 22, 2016; effective February 20, 2017.*

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.

(Rule 1140-03-.03, continued)

(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.

(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

(Rule 1140-03-.03, continued)

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.

(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.

(Rule 1140-03-.03, continued)

(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 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 the order was originally issued and dispensed;

(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.

(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 21 C.F.R. 1306.25.

(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 any 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. An entity or other non-licensed site which does not dispense drugs directly to patients may accept, solicit, and collect prescriptions for the purpose of medication therapy management or other consultative services related to drug therapy and patient care.

(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. §§ 63-10-204, 63-10-304, 63-10-404(4), (11), (14), (19), (26), (29), (30), and (34), 63-10-504(b)(1) and (2), 63-10-504(j), 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. Amendments filed November 22, 2016; effective February 20, 2017.*

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.

(Rule 1140-03-.04, continued)

(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.

(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.

(Rule 1140-03-.04, continued)

(b) Electronic data related to 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.

(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.

(g) 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(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. Amendments filed November 22, 2016; effective February 20, 2017.*

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), 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.*

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). All reasonable accommodations for individuals who are blind, visually impaired, or otherwise print-disabled shall be made. This rule shall not apply to medical and prescription orders dispensed by an institutional pharmacy or long-term care pharmacy for administration to inpatients of that institutional facility or long-term care facility, except when medications are dispensed to patients residing in assisted-care living facilities. 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 1140-03-.06, continued)
Authority: *T.C.A. § 63-10-308.* ***Administrative History:*** *Original rule filed February 7, 1983; effective March 9, 1983. Amendment filed October 30, 1991; effective December 14, 1991. Amendment 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. Amendments filed December 15, 2023; effective March 14, 2024.*

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), 63-10-504(b)(1) and (2), and 63-10-504(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.

(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.

(Rule 1140-03-.08, continued)
Authority: *T.C.A. §§ 63-10-204, 63-10-304, 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. Amendments filed November 22, 2016; effective February 20, 2017.*

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

(3) Medications may be returned to, and received by, the pharmacy/pharmacist if received expressly for the purpose of destruction of the returned medication, provided the pharmacy is equipped for doing so with a policy for complete and timely destruction of medications and in strict accordance with 1140-03-.03(8).

(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(8), (11), and (14), 63-10-504(b)(1) and (2), 63-10-703, and 63-10-706.* ***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.*

1140-03-.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. 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(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. Amendments filed November 22, 2016; effective February 20, 2017.*

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.

(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. § 63-10-306 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;

(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.

(Rule 1140-03-.14, continued)

(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.

(15) 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(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. Amendments filed November 22, 2016; effective February 20, 2017.*

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. 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.* ***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. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-03-.16 CENTRALIZED PRESCRIPTION PROCESSING.

Centralized Prescription Processing:

(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

(Rule 1140-03-.16, continued)

(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: *T.C.A. § 63-10-304 and Chapter 966 of the Public Acts of 2008, § 1.* ***Administrative History:*** *New rule filed November 24, 2008; effective February 7, 2009. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-03-.17 COLLABORATIVE PHARMACY PRACTICE.

(1) Definitions—In addition to the definitions contained in Tenn. Code Ann. Title 63, Chapter 10, Part 2, the following definitions are applicable to collaborative pharmacy practice:

(a) "Active practice", for purposes of the qualifications of a pharmacist under (4)(b) of this rule, means engagement in paid, unpaid, or volunteer activity which requires a pharmacist's license under Tennessee law, for at least 2,000 hours within the 24-month period immediately preceding the date of the agreement. "Active practice" is not limited to direct patient care and includes supervisory, educational or consultative activities or responsibilities for the delivery of such services.

(b) "Agreement" means the collaborative pharmacy practice agreement.

(c) "Authorizing physician" means a medical doctor or osteopathic physician with an unencumbered Tennessee license who has a direct provider/patient relationship with

(Rule 1140-03-.17, continued)

the patients served under a collaborative pharmacy practice agreement or who is the supervising physician of an advanced practice nurse or physician assistant who has such direct relationship or who, in the case of a multi-specialty practice, is the representative or chief responsible for particular specialty care within that multi-specialty practice recognized and certified by the American Board of Medical Specialties (hereinafter "ABMS") or the American Osteopathic Association Bureau of Osteopathic Specialists (hereinafter "AOABOS").

(d) "Collaborating prescriber" means the physician, advanced practice nurse or physician assistant who is a party to a collaborative pharmacy practice agreement, who has a direct provider/patient relationship with the patient served by the agreement and who has prepared the patient specific, drug specific, disease or condition specific plan of care based on a physical examination of the patient where required under these rules.

(e) "Hospice patient" means an individual who has been diagnosed as terminally ill, has been certified in writing by a physician to have an anticipated life expectancy of six (6) months or less and who has voluntarily requested admission to, and been accepted by, a licensed hospice as defined in T.C.A. § 68-11-201.

(f) "Institutional-based pharmacy setting" means any institutional facility or long-term care facility, as defined in 1140-01-.01, or an academic health care institution, and where the pharmacist is responsible for the care of patients within that facility, including prescriptive practices, under the terms of a collaborative agreement.

(g) "Patient care services" means services rendered by physicians and members of the healthcare profession under their supervision, including advanced practice nurses, physician assistants and pharmacists for the benefit of the patient and which must be within the professional training and experience of the healthcare practitioner and be covered by the collaborative pharmacy practice agreement.

(h) "Routine scope of practice and services" means any patient care service provided by the authorizing physician and their practice in compliance with the respective applicable licensing board's laws, rules, policies and procedures. In addition, the services to be provided by the pharmacist shall be services that the authorizing physician generally provides to his or her patients in the normal course of his or her clinical medical practice. The pharmacist should only provide services to the patients whom the authorizing physician or collaborating prescriber routinely treats in the course of his or her clinical medical practice.

(i) "Unencumbered", for the purpose of this rule, means an active license that is not revoked, suspended or on probation at the time and is not subject to any conditions, restrictions, or limitations imposed by the applicable licensing board, which relate directly to the delivery of health care services. A condition, restriction or limitation directly relates to the delivery of health care services when it prevents a provider from treating certain types of patients or certain types of ailments or injuries, or otherwise limits a provider from fully engaging in the practice which would otherwise be authorized pursuant to his or her license.

(2) Physicians, advanced practice nurses and physician assistants may only engage in collaborative pharmacy practice agreements with pharmacists when an appropriately executed collaborative pharmacy practice agreement has been executed and a written attestation has been filed with the licensing boards for all practitioners participating in the agreement notifying those boards of the existence of such agreement; and when the patient or the patient's authorized representative has signed a general consent that the patient is to receive services from a healthcare team, including a pharmacist. However, no such general consent shall be required in an institutional based pharmacy setting where consent to

(Rule 1140-03-.17, continued)

treatment has already been given. All consent given related to treatment at an institutional facility or to treatment under a collaborative pharmacy practice agreement is to be made part of the patient record.

(a) Any pharmacist who is a participant in a collaborative pharmacy practice agreement must be provided a copy of said agreement by the director of pharmacy, pharmacist in charge, or designated pharmacist in a group.

(b) The written attestation shall include the names of all signatories and practitioners participating in the collaborative pharmacy practice agreement, the date of the Agreement and a description of the scope of the services covered by the Agreement.

(c) In the event that an advanced practice nurse or physician assistant is a party to a collaborative pharmacy practice agreement, the physician with responsibility for supervision and control of that advanced practice nurse or physician assistant must approve and sign the Agreement.

(d) In addition, for those Agreements not involving the institutional-based pharmacy setting, the written attestation shall include a formulary of the categories of drugs and services authorized by the Agreement.

(e) The written attestation must be provided to the appropriate licensing boards of the signatories no later than thirty (30) days following the effective date of the Agreement.

(3) No physician, advanced practice nurse, physician assistant or pharmacist may engage in a collaborative pharmacy practice agreement unless each collaborating provider holds an active, unencumbered license in Tennessee and possesses at least one million dollars ($1,000,000) in professional liability insurance coverage per occurrence.

(4) In addition to the other requirements of these rules, a pharmacist must meet one of the following qualifications in order to engage in a collaborative pharmacy practice agreement:

(a) Has been awarded a doctor of pharmacy degree from a program accredited by the Accreditation Council for Pharmacy Education; or

(b) Has been awarded a bachelor of science in pharmacy and been in the active practice of pharmacy.

(5) Each collaborative pharmacy practice agreement (“Agreement”) shall contain the following elements, at a minimum:

(a) Names and Titles of Collaborating Providers. The agreement must contain identification of all pharmacists and all physicians and other prescribers (collectively, “collaborating providers”) who are parties to the Agreement. The Agreement shall state the procedure to be followed to indicate changes in the members of the group(s) participating in the Agreement. Unless expressly stated in the Agreement, changes to the list of collaborating providers bound by the Agreement shall not automatically void the Agreement. When the Agreement involves a group or groups of practitioners, the chief medical officer or medical director, where applicable, and the director of pharmacy or pharmacist in charge shall sign the Agreement, and the Agreement shall identify all collaborating providers in one or more addendums. In the case of a healthcare institution with an organized medical staff or a multi-specialty group with more than one ABMS or AOABOS recognized physician specialty, the signature of the authorizing physician representing or responsible for that specialty unit will suffice. Nevertheless, each collaborating provider must affirm understanding and acceptance of the terms of the Agreement by signing an addendum to the Agreement within thirty

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(30) days of the effective date of the agreement (or within thirty days of employment or association with such multi-specialty group) and all members of the medical staff or group must be provided a copy of the collaborative agreement within fifteen (15) days of execution, with a copy also made available via online access. Signatures may be handwritten, electronic, or any other method authorized by the Board of Pharmacy and the respective licensing board of the signatory.

(b) Authorized Care and Services. The Agreement must contain a provision defining the nature and scope of patient care services and activities, including screening, prevention, assessment, management, and care, authorized or restricted to be provided by the pharmacist(s) under the collaborative pharmacy practice agreement. All care and services authorized to be provided shall be within the routine scope of practice and services delivered by the authorizing physician and the advanced practice nurse or physician assistant, where applicable. All care and services provided, except immunizations, opioid antagonists, ivermectin, and preventive care, must be pursuant to a diagnosis appropriately made and documented by the physician, advanced practice nurse or physician assistant. An Agreement which grants the collaborating pharmacist prescriptive authority, including authority for initiation and discontinuance of drug therapy, must be specifically authorized in the authorized care and services portion of the Agreement and must contain a listing of the drugs or categories of drugs that may be prescribed by the collaborating pharmacist under the terms of the Agreement.

(c) Documentation and Communication. Any patient care services provided by a pharmacist or pharmacists pursuant to a collaborative pharmacy practice agreement shall be documented in a patient record accessible by the pharmacist(s) and the collaborating prescriber(s) or communicated in writing to the collaborating prescriber or prescribers within three (3) business days of the service. The Agreement shall describe the methods for maintenance and access to the records by the pharmacist(s) and the prescriber(s), for documentation of services performed pursuant to the Agreement and for communication and feedback between the pharmacist(s) and the collaborating prescriber(s). All such records shall be maintained by the collaborating prescriber(s) and pharmacist(s) for a period of not less than ten (10) years from the date of the last patient contact.

(d) Override Clause. A provision must be included in the Agreement allowing the collaborating prescriber to override the actions taken by the collaborating pharmacist specific to services provided under the Agreement if he or she determines that the override is essential to the optimal health outcomes of the patient, and stating how such overrides shall be documented and communicated to the collaborating pharmacist and the patient in a timely manner, as defined in the agreement.

(e) Expiration, Modification and Termination. The effective date of the Agreement shall be stated in the Agreement. Each agreement must contain a term or expiration date, upon which the agreement will expire if not renewed; however, in any event, all Agreements must be reviewed and updated at least every two (2) years as evidenced by signatures of the parties. Every Agreement must contain a provision stating the process for modification or termination of the agreement by either party. This process shall include written notification to all affected parties when modification or termination is sought. An Agreement may be amended upon mutual approval by the collaborating prescriber, authorizing physician (where applicable) and pharmacist who have been duly authorized to execute, modify, or change the Agreement. Such amendments shall include, at a minimum, a description of the desired change and the effective date of the change. Additional prescriber(s) and additional pharmacist(s) may be added to an existing participating group through an addendum without affecting the effective date of the agreement. Any amendment executed shall not automatically void the terms and

(Rule 1140-03-.17, continued)

conditions of the existing Agreement unless expressly stated. Amendments to the authorized care and services not involving an institutional-based pharmacy setting which institute substantive additions or reductions to the scope of patient care services provided under the agreement including new therapeutic classes of drugs to the authorized formulary must be provided to the appropriate licensing boards no later than thirty (30) days from the effective date of the amendment.

(f) Automatic Exclusions. A provision must be included in the Agreement which identifies any terms under which a provider will be automatically excluded from participation in the Agreement, which may include but need not be limited to death, suspension, surrender, revocation, or retirement of license; loss or restriction of prescriptive authority; the suspension or revocation of a Drug Enforcement Administration registration; exclusion from any federally funded health programs, or the formal termination of the supervising relationship between an advanced nurse practitioner or physician assistant and his or her supervising physician. Any Agreement involving an advanced practice nurse or physician assistant participating in a collaborative pharmacy practice agreement shall contain a procedure for immediate notification to the collaborating pharmacist(s) if that supervisory relationship is terminated for any reason.

(g) Quality Assessment. The authorizing physician(s) and pharmacist(s) shall create written measurable and objective performance goals for evaluating the quality of care provided for the patients treated pursuant to the Agreement. The Agreement must provide for such goals and data as identified by the collaborating providers, to be aggregated and reviewed by the participants to the Agreement at least quarterly. Such quarterly review shall include consideration of any changes necessary to the Agreement, authorized formulary, and patient orders, in addition to strategies regarding patient education and medication adherence, increased or improved monitoring of side effects and the need for further screening/testing. The Agreement shall also provide at a minimum for monthly patient record review by the authorizing physician(s) of at least five percent (5%) of the patients treated pursuant to the Agreement. The quality assessment review shall be properly documented, retained by the participating parties of the Agreement, and available for review by representatives of the various licensing boards for at least ten (10) years.

(6) The scope of a collaborative pharmacy practice agreement shall NOT include:

(a) Any patient of the collaborating prescriber for whom such collaborating prescriber has not prepared a patient-specific, drug-specific, disease- or condition-specific plan of care based on a physical examination of the patient by the collaborating prescriber, with the exception of immunizations, dispensing of ivermectin, and screening/testing which do not require such patient-specific plans, as well as the dispensing of opioid antagonists as defined in T.C.A. § 63-1-152, which require neither a physical examination nor a patient-specific plan;

(b) The prescribing of controlled substances, except by a pharmacist practicing within an institutional-based pharmacy setting or for hospice patients.

(7) A copy of the Agreement, including any addendum, modification or termination shall be accessible at each practice site and shall be made available to the applicable regulatory board for review upon request.

(8) Pharmacists engaging in the collaborative pharmacy practice must utilize an area for in-person, telephonic or other approved consultations with patients that ensures the confidentiality of the communication.

(Rule 1140-03-.17, continued)

(9) Physicians, advanced practice nurses and physician assistants engaged in a collaborative pharmacy practice agreement shall:

(a) Retain professional responsibility to his/her patients for the management of their drug therapy;

(b) Establish and maintain a physician-patient relationship with each patient subject to the collaborative pharmacy practice agreement;

(c) Be available at all times through direct telecommunication for consultation, assistance and direction, or shall make arrangements for a substitute physician to be available.

(10) Any pharmacist issuing a prescription order, as defined in T.C.A. § 63-10-204, or medical order, as defined in T.C.A. § 63-10-204, pursuant to an Agreement shall issue the prescription order or medical order in accordance with the requirements set forth in Tenn. Comp. Rules and Regs. 1140-03-.03 and within the terms set forth in the collaborative pharmacy practice agreement.

(11) All collaborative pharmacy practice agreements authorizing pharmacists to provide services and activities shall include language that ensures compliance with all applicable by-laws, policies, and procedures of that facility.

(12) For patient care services performed by a pharmacist and authorized only pursuant to a collaborative pharmacy practice agreement, the Board of Pharmacy expressly adopts the guidelines, rules, and standards of practice of the Board of Medical Examiners, Board of Osteopathic Examiners, or other Tennessee Health Related Boards, as applicable.

(13) Pharmacists engaged in the collaborative pharmacy practice are strongly encouraged to complete ten (10) hours of the biennially required thirty (30) hours of continuing education in topics related to the clinical practice of pharmacy.

(14) All signatories and other parties engaging in a collaborative pharmacy practice shall be subject to disciplinary action by their licensing boards if the licensee violates the terms of these rules or the terms of the collaborative pharmacy practice agreement. Each board with jurisdiction over any of the signatories to the agreement shall report to the other appropriate board any conduct which it believes to be in violation of any such agreement.

(15) Pharmacists who hold a current federal drug enforcement administration (“DEA”) license must complete a minimum of two (2) hours biennially of continuing education related to controlled substance prescribing, which must include instruction in the Department’s treatment guidelines on opioids and chronic pain and may include such other topics as medicine addiction, risk management tools, and other topics as approved by the Board of Pharmacy. Such continuing education hours shall be counted toward the pharmacist’s mandatory continuing education requirement.

Authority: *T.C.A. §§ 63-10-217, 63-10-224, and 63-10-308.* ***Administrative History:*** *New rule filed November 22, 2016; effective February 20, 2017. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-03-.18 PROVISION OF IVERMECTIN.

(1) A pharmacist may provide ivermectin under this rule to eligible individuals as identified in T.C.A. § 63-10-224 through a valid collaborative pharmacy practice agreement containing a non-patient-specific prescriptive order and standardized procedures developed and executed by one (1) or more authorized prescriber(s).

(Rule 1140-03-.18, continued)

(a) The pharmacist shall maintain the collaborative pharmacy practice agreement in accordance with § 63-10-217 and shall comply with all requirements of Tenn. Comp. R. & Regs. 1140-03-.17 except for patient-specificity.

(b) Within 30 days from the effective date of a collaborative pharmacy practice agreement, the prescribing pharmacist shall submit written attestation to the Board for the purpose of notifying the Board of the collaborative agreement.

(2) A pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall provide the patient with and review a screening risk assessment tool that screens for the following elements:

(a) Comorbidities;

(b) Contraindications; and

(c) Pregnancy.

(3) A pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall provide the patient with a standardized factsheet that includes at minimum the following elements:

(a) The statement “Off-label use is not prohibited by state or federal law. The FDA has not authorized or approved ivermectin for the treatment or prevention of COVID-19 in people or animals. Ivermectin has not gone through the new drug application process with the FDA for COVID-19.”

(b) FDA factsheet or at least the following elements:

1. Approved indications, dosage and administration as listed in the FDA factsheet;

2. Contraindications, warnings, and precautions as listed in the FDA factsheet; and

3. Adverse reactions as listed in the FDA factsheet.

(4) A pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall counsel the patient on matters contained in Tenn. Comp. R. & Regs. 1140-03-.01(1)(e)1. through 1140-03-.01(1)(e)8. at the time ivermectin is prescribed and dispensed.

(5) A pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall advise the patient to consult with the patient’s primary care practitioner if their symptoms seem to be worsening.

(6) A pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin shall document, at a minimum, the completed self-screening risk assessment and the medication and dosage prescribed to the patient by the pharmacist. While not required by this rule, the pharmacist is authorized to include additional information related to the patient encounter. These records shall be maintained by the pharmacy practice site for a period of ten (10) years. Records regarding the dispensed ivermectin shall be maintained in accordance with Tenn. Comp. R. & Regs. 1140-03-.03.

(7) If the pharmacist who is participating in a collaborative pharmacy practice agreement for the provision of ivermectin determines that the patient is eligible to receive ivermectin, then, as soon as it is practicable, the collaborating pharmacist shall dispense ivermectin to the patient or refer the patient to another pharmacy that may dispense ivermectin.

(Rule 1140-03-.18, continued)

Authority: *T.C.A. §§ 63-10-217, 63-10-224, and 63-10-308.* ***Administrative History:*** *New rule filed December 15, 2023; effective March 14, 2024.*