RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-07
COMPOUNDING

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1140-07-.01 APPLICABILITY.

The provisions of this Chapter shall apply to all pharmacy practice sites and pharmacists, pharmacy interns, pharmacy technicians and supportive personnel involved in the compounding and dispensing of drug products.

***Authority**: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.* ***Administrative History:** Original rule filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.02 STANDARDS.

(1) The preparation, labeling, and dispensing of all compounded drug products shall comply with the standards established by United States Pharmacopeia ("USP") chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

(2) The Board of Pharmacy, upon a showing of good cause and in the best interest of the public health, safety and welfare, may waive the requirements of any applicable portion of USP standards.

(a) All waiver requests submitted pursuant to this part shall be submitted in writing.

(b) The Board of Pharmacy may authorize the Executive Director to exercise some, or all, of its waiver authority under this part.

(3) Noncompliance by a licensee with applicable standards and guidelines, or any other violation of the provisions of this rule shall be considered unprofessional conduct within the meaning of T.C.A. § 63-10-305 and a violation of a duly promulgated rule of the Board of Pharmacy.

(4) Any licensed pharmacy which compounds and dispenses drug products shall provide at a minimum upon request of the Board of Pharmacy the following information for any drug product compounded, dispensed, traded, sold, or otherwise distributed within the past two (2) years:

(a) Name, strength, and dosage form;

(Rule 1140-07-.02, continued)

(b) Quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding period;

(c) The source, lot number, expiration date and an accurate statement of the weight or measure of each component;

(d) The Beyond Use Date which is the date, or hour and date, after which a compounded drug product must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded ("BUD");

(e) Storage requirements;

(f) Labels and labeling with appropriate BUD and instructions for storage and use;

(g) The names of all personnel who prepared the compounded drug product;

(h) The name of the pharmacist who approved the compounded drug product;

(i) The name of the patient, practitioner or healthcare entity who received the compounded drug product; and

(j) The results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any compounded drug products, compounded over the past two (2) years.

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

Authority: *T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.* ***Administrative History:*** *Original rule filed July 11, 2014; effective October 9, 2014. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.03 PERSONNEL.

(1) The pharmacist in charge or the person(s) designated by the pharmacist in charge shall be responsible for, at a minimum, the following:

(a) Procurement, storage, compounding, labeling, repackaging, dispensing, and distribution of all drugs and devices and related materials necessary in compounding and dispensing compounded drug products;

(b) Establishment of policies and procedures for the compounding and dispensing of compounded drug products;

(c) Documentation of competency in proper techniques of all pharmacists, pharmacy interns and pharmacy technicians. The proper technique of each person compounding and dispensing compounded drug products shall be observed and evaluated as satisfactory during orientation and training pursuant to standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed or whenever unacceptable techniques are observed or detected;

(Rule 1140-07-.03, continued)

(d) Establishment of a quality assurance program.

(2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-02-.02 responsible for compounding or dispensing compounded drug products shall:

(a) Obtain practical and/or academic training in the compounding and dispensing of compounded drug products;

(b) Complete education pursuant to the standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed; and

(c) Maintain, in the pharmacy practice site, documentation of completion of the required initial and subsequent training and competency evaluations for (2) years. A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site. These records shall contain the following information:

1. Name of the person receiving the training or evaluation;

2. Date(s) of the training or evaluation;

3. General description of the topics covered; and

4. Signature of the person receiving the training or evaluation and the pharmacist in charge or the person(s) designated by the pharmacist in charge. The person receiving the training may not self-evaluate.

(d) Use proper technique in all drug product compounding as defined by the pharmacy practice site's policies and procedures and in compliance with standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

(3) The pharmacist in charge shall be assisted by such additional pharmacists, pharmacy interns, pharmacy technicians as defined by 1140-02-.02 and supportive personnel necessary to operate the pharmacy practice site competently and safely and to provide services in a timely and appropriate manner.

(4) All pharmacists, pharmacy interns and pharmacy technicians must be qualified at least annually through an appropriate combination of specific training and experience to operate or manipulate any item of equipment, apparatus, or device to which such pharmacists, interns and technicians will be assigned to use to compound and dispense compounded drug products.

(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 1140-07-.03, continued)
***Authority**: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310. **Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Rule was previously numbered 1140-07-.02, but was renumbered to 1140-07-.03 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.04 PHYSICAL REQUIREMENTS.

(1) Any facility that compounds drug products shall comply with standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

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

***Authority:** T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310. **Administrative History:** Original rule filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules expired effective July 31, 2014, and the rules reverted to their previous statuses. Rule was previously numbered 1140-07-.03, but was renumbered to 1140-07-.04 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014. Amendments filed November 22, 2016; effective February 20, 2017. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.05 POLICY AND PROCEDURE MANUAL.

(1) A policy and procedure manual related to drug product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for compounding pursuant to USP standards, and shall, at a minimum, include:

(a) Security;

(b) Equipment;

(c) Sanitation;

(d) Reference materials;

(e) Prescription drug and device and related material storage;

(f) Prescription drug and device and related material compounding and dispensing;

(g) Prescription drug and device and related material labeling and relabeling;

(h) Prescription drug and device and related material destruction and returns;

(i) Dispensing of compounded drug products;

(j) Record keeping;

(k) Quality assurance;

(Rule 1140-07-.05, continued)

(l) Quality control;

(m) Duties for pharmacist(s), pharmacy intern(s), pharmacy technician(s) and supportive personnel;

(n) Public safety relative to harmful compounded drug products, including the active notification of patients if they may be affected by a product found to have a defect or an out-of-specification result including any recall policy and procedures;

(o) Attire;

(p) Pharmacist, pharmacy intern, and pharmacy technician training;

(q) Compliance with the standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed; and

(r) Response to adverse events, outbreaks, and other public health threats associated with products compounded, dispensed, manufactured, propagated, distributed, or otherwise processed at the facility, including procedures for the rapid compilation and dissemination of records to appropriate authorities.

(2) Any licensed facility which engages in drug product compounding shall conduct an annual review of its policy and procedure manual, and shall update its policy and procedure manual as necessary.

(3) Failure by any licensee or registrant to comply with its policy and procedure manual, or any part of this rule shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority**: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.* ***Administrative History: *Original rule filed October 1, 1987; effective November 15, 1987. Amendment filed November 16, 1992; effective January 8, 1993. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules expired effective July 31, 2014, and the rules reverted to their previous statuses. Amendments filed July 11, 2014; effective October 9, 2014. Rule was previously numbered 1140-07-.04, but was renumbered to 1140-07-.05 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.06 LABELING.

(1) At the time of labeling the final compounded drug product, the dispensing container must bear a label which contains the following information:

(a) Patient's name or healthcare entity name;

(b) Prescriber(s) name (if for outpatient use);

(c) Pharmacy practice site name, address, and phone number (if for outpatient use);

(d) Identification of the pharmacist performing the final product verification;

(Rule 1140-07-.06, continued)

(e) Name and amount of drug added. Additional labels or other written/typed documentation may be given to the patient separately if there is not enough space on the label to accommodate all active ingredient(s), their amount(s), activity(ies), or concentration(s) as applicable;

(f) The date, or hour and date, after which a compounded drug product must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded ("BUD");

(g) Date of compounding;

(h) Date of dispensing;

(i) Appropriate auxiliary label(s);

(j) Assigned internal identification number; and

(k) Directions for use (if for outpatient), if applicable.

(2) At the time of labeling the anticipatory drug product, the container must bear a label which contains the following information:

(a) Identification of the pharmacist performing the final product verification;

(b) Name and amount of drug added;

(c) The date, or hour and date, after which a compounded drug product must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded. ("BUD");

(d) Date of compounding;

(e) Appropriate auxiliary label(s);

(f) Assigned lot and batch; and

(g) Storage requirements, if applicable.

(3) Original medical or prescription orders for sterile products shall comply with applicable state and federal laws and regulations.

***Authority**: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.* ***Administrative History:** Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules expired effective July 31, 2014, and the rules reverted to their previous statuses. Rule was previously numbered 1140-07-.05, but was renumbered to 1140-07-.06 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.07 HAZARDOUS PRODUCTS.

(1) Physical Requirements.

(Rule 1140-07-.07, continued)

(a) If the pharmacy practice site is engaged in the compounding of hazardous drug products, a suitable facility to prepare such products and minimize the risk associated with such products shall be provided.

(b) Such pharmacy practice site shall be designed and equipped for storage and have a procedure for disposal of materials containing hazardous residues in accordance with state and federal laws.

(c) A device must be used to continuously monitor pressure differentials in all hazardous drug compounding areas and all hazardous drug storage areas that require negative pressure. The quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring.

(2) Compounding hazardous drug products shall comply with USP Chapter 800 including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same.

Authority: *T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules expired effective July 31, 2014, and the rules reverted to their previous statuses. Rule was previously numbered 1140-07-.06, but was renumbered to 1140-07-.07 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.08 QUALITY ASSURANCE.

(1) There shall be a documented, ongoing quality assurance program that monitors process validation; pharmacist(s), pharmacy intern(s), and pharmacy technician(s) performance; equipment; and environment.

(2) The program shall be designed to assure that the pharmacy practice site is capable of consistently compounding quality compounded drug products.

(3) All quality assurance programs shall comply with the standards established by USP chapters 795, 797, 800, and/or 825, pursuant to the compounding pharmacy's site practice, including all USP chapters and standards incorporated into chapters by reference and including all subsequent amendments and editions of the same, governing both the compounded drug products and the physical and environmental conditions under which compounded drug products are prepared, labeled, and dispensed.

(4) Any recall or an event that results in the halting of compounding due to a quality assurance issue by a compounding facility, in addition to an event that resulted in a Corrective Action Preventative Action, shall be reported to the Board of Pharmacy immediately.

(5) Failure by any licensee or registrant to comply with its quality assurance program shall be considered a violation of a duly promulgated rule of the Board of Pharmacy and may be considered dishonorable, immoral, unethical or unprofessional conduct within the meaning of T.C.A. § 63-10-305(6).

Authority: *T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.* ***Administrative History:*** *Original chapter filed October 1, 1987; effective November 15, 1987. Amendment filed March 30, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules expired effective July 31, 2014, and the rules reverted to their previous statuses. Rule was previously numbered 1140-07-.07, but was renumbered to 1140-07-.08 with the*

(Rule 1140-07-.08, continued)
addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014. Amendments filed December 15, 2023; effective March 14, 2024.

1140-07-.09 NONSTERILE SIMPLE COMPOUNDING PREPARATIONS.

(1) The combining of commercially manufactured ready-to-use products shall be exempt from the 'Compounding Facilities' requirements in the USP 795 compounding standards if all of the following conditions are met:

(a) Only commercially manufactured ready-to-use products (that have not been manipulated) are used. Manipulation occurs when a change of a commercially available drug product occurs for patient-specific needs beyond United States Food and Drug Administration approved labeling. Crushing, using a surfactant, diluting or using a dosage form that exists as a granule or powder is manipulating for the purpose of this section.

(b) Compounding is not prepared in anticipation of medication orders.

(c) Beyond Use Dates are assigned in accordance with the current standards of USP 795.

(d) The label complies with the labeling requirements as set forth in Tenn. Comp. R. and Regs. 1140-07-.06.

(e) The compounding record complies with the requirements as set forth in Tenn. Comp. R. and Regs. 1140-07-.02.

(2) Solely adding flavoring to medications is not considered compounding.

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

Authority: *T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.* ***Administrative History:*** *Original chapter filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules expired effective July 31, 2014, and the rules reverted to their previous statuses. Rule was previously numbered 1140-07-.08, but was renumbered to 1140-07-.09 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014. Amendments filed December 15, 2023; effective March 14, 2024.*

1140-07-.10 RESERVED.

Authority: *T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304, 63-10-306, 63-10-404(26), (28), (29), (30), and 63-10-504(b)(1), (2).* ***Administrative History:*** *Original chapter filed March 30, 1994; effective June 13, 1994. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014; effective through July 30, 2014. Emergency rules expired effective July 31, 2014, and the rules reverted to reserved status. Rule was previously numbered 1140-07-.09, but was renumbered to 1140-07-.10 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014.*