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Sequence Number: 03-02-23
Notice ID(s): 3604-3606
File Date: 3/1/2023

Notice of Rulemaking Hearing

Hearings will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, T.C.A. § 4-5-204. For questions and copies of the notice, contact the person listed below.

Agency/Board/Commission:	Board of Pharmacy
Division:	
Contact Person:	Matthew Gibbs, Deputy General Counsel
Address:	665 Mainstream Drive, Nashville, TN 37243
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Any Individuals with disabilities who wish to participate in these proceedings (to review these filings) and may require aid to facilitate such participation should contact the following at least 10 days prior to the hearing:

ADA Contact:	ADA Coordinator
Address:	710 James Robertson Parkway, Andrew Johnson Building, 5th Floor, Nashville, Tennessee 37243
Phone:	(615) 741-6354
Email:	Marci.Martinez@tn.gov

Hearing Location(s) (for additional locations, copy and paste table)

Address 1:	Metro Center		
Address 2:	665 Mainstream Drive, Iris Conference Room		
City:	Nashville		
Zip:	37243		
Hearing Date:	05/08/2023		
Hearing Time:	9:30 A.M.	_X_CST/CDT ___EST/EDT	

Additional Hearing Information:

Revision Type (check all that apply):

X Amendment

X New

Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart

below. Please enter only **ONE** Rule Number/Rule Title per row)

Chapter Number	**Chapter Title**
1140-01	Introductory Rules
Rule Number	**Rule Title**
1140-01-.08	Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses
1140-01-.09	Renewal of Licenses

Chapter Number	**Chapter Title**
1140-02	Professional Conduct and Responsibilities
Rule Number	**Rule Title**
1140-02-.02	Pharmacy Technicians

Chapter Number	**Chapter Title**
1140-07	Sterile Product Preparation in Pharmacy Practice
Rule Number	**Rule Title**
1140-07-.01	Applicability
1140-07-.02	Standards
1140-07-.03	Personnel
1140-07-.04	Physical Requirements
1140-07-.05	Policy and Procedure Manual
1140-07-.06	Labeling
1140-07-.07	Hazardous Products
1140-07-.08	Quality Assurance
1140-07-.09	Nonsterile Simple Compounding Preparations

Chapter 1140-01
Introductory Rules

Amendments

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses is amended by adding new subparts (3)(a)4(i) and (3)(a)4(ii), and is further amended by adding new part (3)(a)10, so that as amended, the new subpart and part shall read:

(3) (a) 4. (i) An out-of-state pharmacy practice site engaged in compounding must provide an inspection performed within the previous twelve (12) months.

(ii) An inspection completed by the United States Food and Drug Administration, or an inspection performed by the National Association of Boards of Pharmacy in lieu of an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located is acceptable.5. Maintain records of prescription orders dispensed to and/or of medication assessments provided to persons residing in Tennessee.

10. The board may require additional information before issuing or renewing a pharmacy license to ensure compliance with applicable laws of this state and rules of the board.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 53-14-104, 53-14-106, 53-14-107, 63-10-203, 63-10-204, 63-10-210, 63-10-216, 63-10-301, 63-10-304, 63-10-306, and 63-10-308.

Rule 1140-01-.09 Renewal of Licenses is amended by adding new paragraph (3) and renumbering the remaining paragraph accordingly, so that as amended, the new paragraph shall read:

(3) Prior to renewal of its license in this state, an out-of-state pharmacy practice site engaged in compounding must provide to the board the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, an inspection performed by the United States Food and Drug Administration, or an inspection performed by the National Association of Boards of Pharmacy, that must have been within the previous twelve (12) months.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 63-10-203, 63-10-204, 63-10-210, 63-10-216, 63-10-304, 63-10-306, 63-10-308, and 63-10-304(b)(1).

Chapter 1140-02
Professional Conduct and Responsibilities

Amendments

Rule 1140-02-.02 Pharmacy Technicians is amended by deleting subparagraph (7)(a) in its entirety and substituting instead the following language, so that as amended, the new subparagraph shall read:

(7) (a) The pharmacy technician to pharmacist ratio shall not exceed 6:1; however the ratio may be removed if the additional pharmacy technicians beyond the 6:1 ratio are certified pharmacy technicians. However, the pharmacist in charge may request a modification of the ratio from the Board in writing which addresses:

Authority: T.C.A. §§ 63-1-116, 63-10-204, 63-10-304, 63-10-306, and 63-10-308.

Chapter 1140-07
Sterile Product Preparation in Pharmacy Practice

Amendments

Chapter 1140-07 Sterile Product Preparation in Pharmacy Practice is amended by deleting the chapter title in its entirety and substituting instead the the following language, so that as amended, the new chapter title shall read:

Chapter 1140-07
Compounding

Rule 1140-07-.01 Applicability is amended by deleting the rule in its entirety, but not the rule title, and substituting instead the following language, so that as amended, the new rule shall read:

(1) 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.

(2) The provisions of this chapter relative to pharmacy practice sites shall be enforceable on January 1, 2024.

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

Rule 1140-07-.02 Standards is amended by deleting paragraphs (1) and (3) in their entirety and substituting instead the following language, so that as amended, the new paragraphs shall read:

(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 825, 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) 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.

Rule 1140-07-.02 Standards is amended by deleting paragraph (4) in its entirety and renumbering the remaining paragraphs accordingly, and is further amended by deleting newly renumbered paragraph (4) and substituting instead the following language, and is further amended by deleting newly renumbered subparagraphs (4)(b), (4)(c), (4)(d), and (4)(f) in their entirety and substituting instead the following language, and is further amended by adding new subparagraphs (4)(g), (4)(h), (4)(i), and (4)(j), and is further emended by deleting paragraph (6) in its entirety, so that as amended, the new paragraphs and subparagraphs shall read:

(4) Any licensed pharmacy which compounds and dispenses drug products shall provide at a minimum upon request of the Board of Pharmacy the compounding record which shall contain the following information for any drug product compounded, dispensed, traded, sold, or otherwise distributed within the past three (3) years:

(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 hour and date beyond which the compounded drug product(s) must not be used and must be discarded (“BUD”);

(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 three (3) years.

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

Rule 1140-07-.03 Personnel is amended by deleting paragraphs (1) and (2) in their entirety and substituting instead the following language, and is further amended by deleting subparagraphs (1)(a), (1)(b), (1)(c), (2)(a), (2)(b),(2)(c), and (2)(d) in their entirety and substituting instead the following language, and is further amended by deleting subparagraphs (1)(e) and (1)(f) in their entirety, and is further amended by adding new parts (2)(c)1, (2)(c)2, (2)(c)3, and (2)(c)4, so that as amended, the new paragraphs, subparagraphs, and parts shall read:

(1) The pharmacist in charge or the pharmacist 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 825, 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;

(2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-2-.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 825, 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 three (3) 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 pharmacist 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 825, 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.

Rule 1140-07-.03 Personnel is amended by deleting paragraphs (3) and (6) in their entirety and renumbering the remaining paragraphs accordingly, and is further amended by deleting newly renumbered paragraph (4) in its entirety and substituting instead the following language, so that as amended, the new paragraph shall read:

(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.

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

Rule 1140-07-.04 Physical Requirements is amended by deleting paragraph (1) in its entirety and substituting instead the following language, so that as amended, the new paragraph shall read:

(1) Any facility that compounds drug products shall comply with applicable USP standards established by USP chapters 795, 797, 800, and 825, 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.

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

Rule 1140-07-.05 Policy and Procedure Manual is amended by deleting paragraphs (1) and (2) in their entirety and substituting instead the following language, and is further amended by deleting subparagraphs (1)(i), (1)(n), and (1)(q) in their entirety and substituting instead the following language, so that as amended, the new paragraphs and subparagraphs shall read:

(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:

(i) Dispensing of compounded drug products;

(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;

(q) Compliance with the standards established by USP chapters 795, 797, 800, and 825, 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

(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.

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

Rule 1140-07-.06 Labeling is amended by deleting paragraph (1) its entirety and substituting instead the following language, and is further amended by deleting subparagraphs (1)(a), (1)(d), (1)(e), (1)(f), and (1)(g) their entirety and substituting instead the following language, and is further amended by adding new subparagraph (1)(i) and re-lettering the remaining subparagraphs accordingly, so that as amended, the new paragraph and subparagraphs shall read:

(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;

(d) Identification of all personnel who compounded the drug product;

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

(f) 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);

(g) The hour and date beyond which the compounded drug product must not be used and must be discarded (“BUD”);

(i) Date of dispensing;

Rule 1140-07-.06 Labeling is amended by adding new paragraph (2) and renumbering the remaining paragraph accordingly, so that as amended, the new paragraph shall read:

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

(a) Identification of all personnel who compounded the product;

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

(c) Name and amount of drug added;

(d) The hour and date beyond which the compounded prescription drug product must not be used and must be discarded (“BUD”);

(e) Date of compounding;

(f) Appropriate auxiliary label(s);

(g) Assigned lot and batch; and

(h) Storage requirements, if applicable.

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

Rule 1140-07-.07 Hazardous Products is amended by deleting subparagraph (1)(a) in its entirety and substituting instead the following language, and is further amended by deleting parts (1)(b)1 and (1)(b)2 in their entirety, and is further amended by deleting paragraph (2) in its entirety and substituting instead the following language, and is further amended by deleting paragraphs (3), (4), (5), and (6) in their entirety, so that as amended, the new paragraphs and subparagraphs shall read:

(1) (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.

(2) Compounding hazardous drug products shall comply with USP 800.

Authority: T.C.A. §§ 63-10-216, 63-10-304, and 63-10-306.

Rule 1140-07-.08 Attire is amended by deleting the rule in its entirety, including the title, and substituting instead the following language, so that as amended, the new title and rule shall read:

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 825, 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, 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, 63-10-304, and 63-10-306.

Rule 1140-07-.09 Quality Assurance is amended by deleting the rule in its entirety, including the title, and substituting instead the following language, so that as amended, the new title and rule shall read:

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 the following conditions are met:

   (a) 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 currently 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.

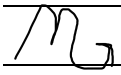
(2) Solely adding flavoring to medications is not considered compounding.

(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, 63-10-304, and 63-10-306

I certify that the information included in this filing is an accurate and complete representation of the intent and scope of rulemaking proposed by the agency.

Date: March 1, 2023

Signature: 

Name of Officer: Matthew Gibbs

Title of Officer: Deputy General Counsel, Department of Health

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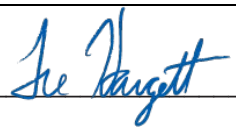
Filed with the Department of State on: 3/1/2023



Tre Hargett
Secretary of State

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