

Department of State**Division of Publications**

312 Rosa L. Parks Ave., 8th Floor, Snodgrass/TN Tower

Nashville, TN 37243

Phone: 615-741-2650

Email: publications.information@tn.gov**For Department of State Use Only**

Sequence Number: 12-11-23

Rule ID(s): 9978-9980

File Date: 12/15/2023

Effective Date: 3/14/2024

Rulemaking Hearing Rule(s) Filing Form

Rulemaking Hearing Rules are rules filed after and as a result of a rulemaking hearing (Tenn. Code Ann. § 4-5-205).

Pursuant to Tenn. Code Ann. § 4-5-229, any new fee or fee increase promulgated by state agency rule shall take effect on July 1, following the expiration of the ninety (90) day period as provided in § 4-5-207. This section shall not apply to rules that implement new fees or fee increases that are promulgated as emergency rules pursuant to § 4-5-208(a) and to subsequent rules that make permanent such emergency rules, as amended during the rulemaking process. In addition, this section shall not apply to state agencies that did not, during the preceding two (2) fiscal years, collect fees in an amount sufficient to pay the cost of operating the board, commission or entity in accordance with § 4-29-121(b).

Agency/Board/Commission: Board of Pharmacy**Division:****Contact Person:** Matthew Gibbs, Deputy General Counsel**Address:** 665 Mainstream Drive, Nashville, TN**Zip:** 37243**Phone:** (615) 741-1611**Email:** Matthew.Gibbs@tn.gov**Revision Type (check all that apply):**☒ Amendment☒ New☐ Repeal☐ Content based on previous emergency rule filed on _____☐ Content is identical to the emergency rule

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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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	Attire
1140-07-.09	Quality Assurance
1140-07-.10	Reserved

Chapter Number	Chapter Title
1140-07	Compounding
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
1140-07-.10	Reserved

Place substance of rules and other info here. Please be sure to include a detailed explanation of the changes being made to the listed rule(s). Statutory authority must be given for each rule change. For information on formatting rules go to <https://sos.tn.gov/products/division-publications/rulemaking-guidelines>.

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.
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, 53-14-107, 63-10-203, 63-10-204, 63-10-210, 63-10-216, 63-10-301, 63-10-308, 63-10-310, and 63-10-312.

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, 63-10-204, 63-10-210, 63-10-216, 63-10-308, 63-10-310, and 63-10-312.

Chapter 1140-02 Professional Conduct and Responsibilities

Amendments

Rule 1140-02-.02 Pharmacy Technicians is amended by deleting subparagraph (7)(a) in its entirety, but not its parts, 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, 63-10-308, 63-10-310, and 63-10-312.

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 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:

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 drugs products.

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

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/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) 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.

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

Rule 1140-07-.02 Standards is amended by deleting paragraphs (4) and (6) in their entirety and renumbering the remaining paragraphs accordingly, and is further amended by deleting newly renumbered paragraph (4) and its 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), 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 following information for any drug product compounded, dispensed, traded, sold, or otherwise distributed within the past two (2) 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 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");
 - (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.

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

Rule 1140-07-.03 Personnel is amended by deleting paragraphs (1) and (2) in their entirety, including their subparagraphs and parts, and substituting instead the following language, so that as amended, the new paragraphs, subparagraphs, and parts shall read:

- (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;
 - (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.

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

Rule 1140-07-.03 Personnel is amended by deleting paragraphs (3) and (6) in their entirety, including their subparagraphs if any, 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, 63-10-308, and 63-10-310.

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 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.

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

Rule 1140-07-.05 Policy and Procedure Manual is amended by deleting paragraph (1) but not its subparagraphs except for subparagraphs (1)(i), (1)(n), and (1)(q) and substituting instead the following language, and is further amended by deleting paragraph (2) in its 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/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
- (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, 63-10-308, and 63-10-310.

Rule 1140-07-.06 Labeling is amended by deleting the rule in its entirety, but not the rule title, so that as amended, the new rule 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;
 - (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;
 - (e) Name and amount of drug added. Additional labels or other written/taped 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.

Rule 1140-07-.07 Hazardous Products is amended by deleting subparagraph (1)(a) 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 adding new subparagraph (1)(c), so that as amended, the new 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.
- (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.

Authority: T.C.A. §§ 63-10-216, 63-10-308, and 63-10-310.

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

- (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.

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/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.

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 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.

* If a roll-call vote was necessary, the vote by the Agency on these rulemaking hearing rules was as follows:

1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-01-.09 Renewal of Licenses

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-02-.02 Pharmacy Technicians

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane		X			
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.01 Applicability

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.02 Standards

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				

Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.03 Personnel

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.04 Physical Requirements

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.05 Policy and Procedure Manual

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.06 Labeling

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.07 Hazardous Products

Board Member	Aye	No	Abstain	Absent	Signature (if required)
--------------	-----	----	---------	--------	-------------------------

Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.08 Quality Assurance

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger	X				
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				

1140-07-.09 Nonsterile Simple Compounding Preparations

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Dr. Melissa McCall				X	
Dr. Marlin Blane	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Robert Harshbarger		X			
Dr. Richard Breeden			X		
Dr. Adam Rodgers	X				


I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Pharmacy on 05/08/2023, and is in compliance with the provisions of T.C.A. § 4-5-222.

I further certify the following:

Notice of Rulemaking Hearing filed with the Department of State on: 03/01/2023

Rulemaking Hearing(s) Conducted on: (add more dates). 05/08/2023

Date: November 15, 2023

Signature: 

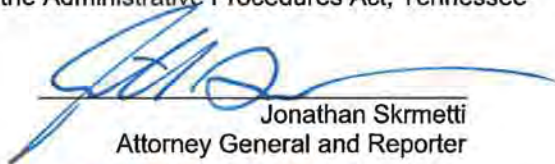
Name of Officer: Matthew Gibbs

Title of Officer: Deputy General Counsel, Department of Health

Agency/Board/Commission: Board of Pharmacy

Rule Chapter Number(s): 1140-01, 1140-02, and 1140-07.

All rulemaking hearing rules provided for herein have been examined by the Attorney General and Reporter of the State of Tennessee and are approved as to legality pursuant to the provisions of the Administrative Procedures Act, Tennessee Code Annotated, Title 4, Chapter 5.


Jonathan Skrmetti
Attorney General and Reporter
Nov. 29, 2023
Date

Department of State Use Only

Filed with the Department of State on: 12/15/2023

Effective on: 3/14/2024


Tre Hargett
Secretary of State

RECEIVED

Dec 15 2023, 3:13 pm

Secretary of State
Division of Publications

Public Hearing Comments

One copy of a document that satisfies T.C.A. § 4-5-222 must accompany the filing.

Oral Comments:

Mark Binkley, Health & Wellness Compounding Pharmacy

Compounding - Dr. Binkley asked if a United States Food and Drug Administration inspection would be acceptable for both an outsourcing pharmacy and a patient-specific sterile compounding pharmacy. The Board noted all inspections shall be evaluated for appropriateness.

Compounding - Dr. Binkley requested removal of the requirement to maintain, in a record, the name of the practitioner or health care entity who received the compounded drug product. The Board rejected this request and stated with the removal of the language specific to "compounding record" the rule as amended allows for information to be kept across a variety of records and pieced together for purposes of inspection.

Compounding - Dr. Binkley suggested the deletion of all language pertaining to simple compounding preparations. By majority vote, the Board rejected this comment and decided to allow flexibility with sterile compounding preparations to accommodate patient access through relief of physical United States Pharmacopeia ("USP") requirements.

Lindsay Adams / Nicole Wynne, Vanderbilt University Medical Center

Compounding – The proposed rule language regarding a final product label required recordation of the assigned lot and batch number. Dr. Adams requested a change in the proposed rule language to "internal identification number." The Board accepted this change.

Sheena Illarramendi, Vanderbilt University Medical Center

Pharmacy technician ratio – Ms. Illarramendi opposed to removal of a cap on the ratio of pharmacy technicians to pharmacist when all technicians beyond the 6:1 ratio are certified. The Board acknowledge the concern but decided, by majority vote, the pharmacist in charge shall be responsible for the ratio number.

Randy Davis, Designer Drugs

Compounding – Dr. Davis expressed concerns regarding nonsterile simple compounding preparations and the element of manipulation. Specifically, Dr. Davis sought clarification regarding when manipulation occurs. The Board pointed to the description of manipulation in the proposed rule language and did not make any further amendments.

Out-of-state compounding pharmacy inspections – Dr. Davis raised concerns about language which appeared to require an inspection every twelve months for out-of-state compounding pharmacies. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Dr. Scott Denaburg, investigator – Tennessee Board of Pharmacy

Compounding – Dr. Denaburg asked for clarification regarding the types of quality assurance issues and events which require reporting. The Board voted to add clarity to the proposed rule by indicating events in addition to a corrective action preventative action event shall be reported.

Compounding – Dr. Denaburg urged the Board to adopt language which allows more than one designated person to perform a compounding task. The Board adopted this suggestion by making "person" plural inside the proposed rule language.

Written Comments:

Tennessee Pharmacists Association ("TPA")

Fees – TPA supports the Board's intent to lower the cost for pharmacy technicians to register with the Board. The Board noted the comment because, as the Board observed, there were no specific changes requested or a request to describe the principal reasons for action.

Accessible prescription labels – TPA supports the Board's proposed rules pertaining to accessible prescription labels. The Board noted the comment because, as the Board observed, there were no specific changes requested or a request to describe the principal reasons for action.

Pharmacy Technicians ratio – TPA opposes the proposed rule language as currently written which does not provide a cap on the number of technicians that a single pharmacist can supervise at one time. TPA suggested a maximum limit of six pharmacy technicians for each pharmacist on duty while preserving the authority of a pharmacist in charge to request a waiver from the 6:1 cap. The Board rejected TPA's suggestions after a lengthy discussion. The Board observed other states which do not have a ratio as the basis for keeping the proposal of an unlimited number of technicians beyond 6:1 if the technicians beyond 6:1 are certified. The Board, in discussion, deferred to the pharmacy's pharmacist in charge to make the best determination for the ratio. The Board kept waiver language in the existing rule.

Compounding - TPA sought clarification from the Board regarding which rule chapter of the USP is applicable – does the rule pertain to officially adopted standards or draft standards. The Board clarified the current compendially applicable standards are the standards of USP which apply. TPA supports removal of quarterly reporting requirements. The Board noted this comment because, as the Board observed, there were no specific changes requested or a request to describe the principal reasons for action. TPA asked the Board to remove the requirement, in proposed rule language, to identify each person on the dispensing label who participated in the compounding process. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label) but added a requirement for the dispensing label to contain an internal identification number which allows tracking of a final compounded drug product through the product's lot and batch number. TPA supports a rule change which allows a waiver from the facility requirements of nonsterile simple compounded preparations. The Board noted this comment because, as the Board observed, there were no specific changes requested or a request to describe the principal reasons for action.

Jay Phipps, president and chief executive officer, Phipps Pharmacy

Technician ratio – Dr. Phipps suggested increasing the pharmacy technician ratio to 10:1. The Board rejected this suggestion and noted there is flexibility allowed in the proposed rule for a ratio of greater than 6:1 if the additional technicians are certified. Moreover, the proposed rule language preserved the waiver authority for any pharmacist who seeks such waiver.

Compounding – Dr. Phipps sought clarification regarding training under the proposed rules as training pertains to compounded drug products. The Board stated training must occur in accordance with USP concepts. During this discussion, the Board deemed the proposed rule language too strict regarding a designated pharmacist as the only person who may accomplish various compounding tasks. The Board adopted a change which allows either a pharmacist or other designated person (which may or may not be a pharmacist) to serve various functions in the compounding pharmacy. Dr. Phipps asked the Board to remove the requirement, in proposed rule language, to identify each person on the dispensing label who participated in the compounding process. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label) but added a requirement for the dispensing label to contain an internal identification number which allows tracking of a final compounded drug product through the product's lot and batch number. Dr. Phipps suggested removal of the pharmacist who performed final verification from the dispensing label. The Board rejected this suggestion and determined the pharmacist who performed final verification is required information for a dispensing label.

Scott Brunner, chief executive officer, Alliance for Pharmacy Compounding

Compounding – Mr. Brunner broached concerns about the impetus for listing all personnel who participated in the compounding process on the dispensing label. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label) but added a requirement for the dispensing label to contain an internal identification number which allows tracking of a final compounded drug product through the product's lot and batch number.

Out-of-state compounding pharmacy inspections – Mr. Brunner asked the Board to provide a basis for requiring an inspection every twelve months. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Omar B. Hamid, pharmacist in charge, O'Brien Pharmacy

Compounding – Dr. Hamid asked the Board to strike proposed rule language which required all personnel who participated in the compounding process to be listed on the dispensing label. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label) but added a requirement for the dispensing label to contain an internal identification number which allows tracking of a final compounded drug product through the product's lot and batch number.

Out-of-state compounding pharmacy inspections – Dr. Hamid stated an inspection every twelve months is unduly burdensome on a pharmacy and asked the Board to reject this proposed rule language. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Robert P. Nickell, pharmacist and chief executive officer, Pharmco, Inc.

Compounding – Dr. Nickell urged the Board to reject the proposed rule language which required all personnel who participated in compounding the anticipatory drug product to be listed on the dispensing label. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label).

Out-of-state compounding pharmacy inspections – Dr. Nickell asked the Board to strike proposed rule language which requires an inspection within twelve months of renewal or, in the alternative, to allow risk-based inspections. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Brad McCloskey, pharmacist and president/chief executive officer, University Compounding Pharmacy

Compounding – Dr. McCloskey asked the Board to strike the proposed rule requirement to include all personnel who participated in compounding the anticipatory drug product to be listed on the dispensing label. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label).

Out-of-state compounding pharmacy inspections – Dr. McCloskey asked the Board to strike proposed rule language which requires an inspection within twelve months of renewal. The Board clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Wayne Sartorio Sr, pharmacist and pharmacy director, Boothwyn Pharmacy

Compounding – Dr. Sartorio noted the proposed rule language which required all personnel who participated in the compounding process to be listed on the dispensing label creates a cluttered label with unnecessary information. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label) but added a requirement for the dispensing label to contain an internal identification number which allows tracking of a final compounded drug product through the product's lot and batch number.

Rodney Tubbs, pharmacist

Compounding – Dr. Tubbs ask the Board to consider only the dispensing pharmacist to be listed on the dispensing label. The Board accepted this comment by deleting the requirement for all personnel to be identified (on the dispensing label) but added a requirement for the dispensing label to contain an internal identification number which allows tracking of a final compounded drug product through the product's lot and batch number.

Dan Lynch, pharmacist and director of regulatory services, Synchrony Pharmacy

Out-of-state compounding pharmacy inspections – Dr. Lynch asked the Board to consider inspections by affidavit, or, in the alternative, allowing inspections to occur every twenty-four months. The Board rejected the comment and clarified the inspections shall happen within twelve months of renewal. Given that the renewal cycle is two years in length, the inspection may occur every two years.

Dr. Scott Denaburg, investigator – Tennessee Board of Pharmacy

Compounding – Dr. Denaburg suggested the addition of clarifying terms to the proposed rule language to note only the applicable chapters of USP to a given pharmacy's practice are required for compliance. In other words, if one or more USP chapters do not apply to the pharmacy practice site, the pharmacy practice site shall not be responsible for compliance with inapplicable chapters. The Board added "and/or" and "pursuant to the compounding pharmacy's site practice" to the proposed rule language in various places to provide clarification that training and policies and procedures of the compounding pharmacy shall only pertain to the specific chapter of USP which applies to the compounding pharmacy.

Compounding – Dr. Denaburg indicated the proposed rule language required record retention for three years. At the time of drafting, the proposed language mirrored other USP requirements of retention for three years. Subsequently, USP changed its recommendations from three years to two years. The Board adopted this change in the proposed rule language.

Compounding – Dr. Denaburg asked the Board to add clarifying language regarding the monitoring of pressure differentials. The Board voted to add "[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" to the proposed rule language to clarify the use of a pressure-monitoring device.

Lindsay Ford, pharmacist, Vanderbilt University Medical Center

Compounding – Dr. Ford asked the Board to remove "the compounding record which shall contain the" from the proposed rules. As proposed, the rule language confused a term of art as defined in USP, the compounding record, with records required by the Board to ensure protection of the health, safety, and welfare of the citizens. While the Board still requires specific records to be kept, the Board deleted proposed rule language which referred to the records specifically as a "compounding record."

Compounding – Dr. Ford retracted comments related to beyond use date because of changes made by the Board to the language of beyond use date. As originally proposed, the rule required a compounding pharmacy to create both a date and time from which a compounded drug product cannot be used or stored. The amendment removes the mandate to record a time and rewords the definition to allow for the recording of time as necessary.

Compounding – Dr. Ford requested the Board to make exception from the training requirement for certain personnel who have non-critical roles in the compounding process. The Board rejected this request and noted the proposed rules are consistent with effective rules regarding training. The Board desired to leave the training requirements unchanged.

Compounding – Dr. Ford sought clarification for reporting adverse events. The Board added "in addition to an event that resulted in a Corrective Action Preventative Action" to the language in proposed rules to make clear events which result in the halting of compounding, in addition to an event which causes a Corrective Action Preventative Action, shall be reported.

Compounding – Dr. Ford ask the Board to clarify if both safety events and environmental events shall be reported. The clarified environmental events are not reported.

Cindy Brasher, pharmacist, St. Jude Children's Research Hospital

Compounding – Dr. Brasher sought clarification of "designated person." While the comment was accepted previously in the rulemaking hearing, the Board deemed the original proposed language too strict as only a pharmacist, and not other compounding personnel, could be designated for tasks. The Board adopted a change which allows either a pharmacist or other designated person (which may or may not be a pharmacist) to serve various functions in the compounding pharmacy.

Compounding – Dr. Brasher inquired about the training requirement for the person(s) designated by the pharmacist in charge. The Board stated previous rule amendments regarding a designated person clarified the training requirements.

Compounding – Dr. Brasher asked if hazardous drug documents and the Gap analysis were no longer required. The Board confirmed neither the requirements for hazardous drug documents nor the Gap analysis were retained in the proposed rule language.

Compounding – Dr. Brasher asked for examples of nonsterile simple compounding. The Board stated Magic Mouthwash is a nonsterile simple compounding preparation.

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process, all agencies shall conduct a review of whether a proposed rule or rule affects small business.

(1) The extent to which the rule or rules may overlap, duplicate, or conflict with other federal, state, and local governmental rules.

These amended rules do not overlap, duplicate, or conflict with other federal, state, and local government rules.

(2) Clarity, conciseness, and lack of ambiguity in the rule or rules.

The proposed rules are established with clarity, conciseness, and lack of ambiguity.

(3) The establishment of flexible compliance and/or reporting requirements for small businesses.

Current implementing regulations of the Board allow the Board to permit exceptions in the application process. To the extent a pharmacy needs an exception, the waiver authority is not impacted by this packet. The rule packet allows the Board to waive selected portions of the compounding standards upon request by the licensee. Lastly, the rule packet authorizes an unlimited technician ratio if each technician beyond the sixth person is certified.

The Board attempts to provide some regulatory flexibility by adopting the non-sterile simple compounding rule to enable an exception to the facility portion of USP 795 standards.

(4) The establishment of friendly schedules or deadlines for compliance and/or reporting requirements for small businesses.

The rules are drafted with the intent to allow at least one year before their implantation to permit those impacted an opportunity to acclimate with the new requirements.

(5) The consolidation or simplification of compliance or reporting requirements for small businesses.

The requirements for the proposed rules cannot be consolidated or simplified. There is no other reasonable alternative than the proposed rules to ensure all pharmacies engaged in the compounding of prescription drug products are inspected for minimum competency (including safety concerns) by their home-state oversight body or an equivalent 3rd party during the initial licensure and renewal process. Moreover, setting minimum standards in the compounding of prescription drug products helps to provide patients compounded drug products that are safe and effective in their use.

The increase in ratio of technicians to pharmacists allows delivery of pharmaceutical care to achieve maximum efficiency by using more employees in the process. Moreover, with more employees engaged in the delivery of care, pharmacists are freed to focus on complex tasks which has a strong bearing on patient health, safety, and welfare.

(6) The establishment of performance standards for small businesses as opposed to design or operational standards required in the proposed rule.

These new rules do not establish performance standards for small businesses as opposed to design or operational standards required for the proposed rule.

(7) The unnecessary creation of entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

The rules contain a waiver provision on a case-by-case basis which serves to eliminate a barrier to entry. The rules expressly except nonsterile simple compounding from the requirements for facilities engaged in generalized nonsterile compounding. This exception helps eliminate costs of compliance as a barrier for entry for nonsterile simple compounding.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228, "On any rule and regulation proposed to be promulgated, the proposing agency shall state in a simple declarative sentence, without additional comments on the merits or the policy of the rule or regulation, whether the rule or regulation may have a projected financial impact on local governments. The statement shall describe the financial impact in terms of increase in expenditures or decrease in revenues."

The proposed rule amendments should not have a financial impact on local governments.

Additional Information Required by Joint Government Operations Committee

All agencies, upon filing a rule, must also submit the following pursuant to T.C.A. § 4-5-226(i)(1).

A brief summary of the rule and a description of all relevant changes in previous regulations effectuated by such rule;

This rule packet: (1) implements provisions of a recent statutory change by allowing out-of-state pharmacies engaged in the compounding of prescription drug products to submit additional types of acceptable inspections in the initial licensure and renewal process; (2) modernizes minimum standards, that are enforceable by the Board, for the compounding of (and the dispensing of compounded) prescription drug products; and (3) enacts an increased technician-to-pharmacist ratio of 6:1. The current allowable ratio, without further Board intervention or further credentialing, is 2:1.

A citation to and brief description of any federal law or regulation or any state law or regulation mandating promulgation of such rule or establishing guidelines relevant thereto;

T.C.A. § 63-10-308(c) provides the Board the authority to promulgate rules to establish minimum standards for the practice of pharmacy.

In April of 2021, the General Assembly amended the Practice Act via 2021 Tenn. Pub. Acts 149, codified at T.C.A. § 63-10-216, to allow the Board to accept multiple forms of inspections from out-of-state pharmacies desiring licensure by the Board and to allow expansion of compounding standards from one specific area – sterile compounding – to all forms of compounding (e.g. non-sterile, hazardous, and radiopharmaceutical).

T.C.A. § 63-10-204(38) gives the Board authority to define the scope of practice for pharmacy technicians.

Identification of persons, organizations, corporations or governmental entities most directly affected by this rule, and whether those persons, organizations, corporations or governmental entities urge adoption or rejection of this rule;

The rule packet allows multiple types of acceptable inspections for out-of-state compounding pharmacies as part of the Board's initial licensure and renewal process. Any compounding pharmacy physically located in another state is impacted. Any pharmacy licensed by the Board who is engaged in the compounding of drug products is subject to the updated, comprehensive compounding standards. Any pharmacy that employs a ratio of technicians to pharmacists is impacted by the increased number of technicians authorized in the ratio. The increased number of technicians allows the pharmacy to employ more persons to deliver pharmaceutical care while freeing the pharmacist to perform the tasks commensurate with the pharmacist's training and education.

Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule or the necessity to promulgate the rule;

None.

An estimate of the probable increase or decrease in state and local government revenues and expenditures, if any, resulting from the promulgation of this rule, and assumptions and reasoning upon which the estimate is based. An agency shall not state that the fiscal impact is minimal if the fiscal impact is more than two percent (2%) of the agency's annual budget or five hundred thousand dollars (\$500,000), whichever is less;

These rules should not impact revenues or expenditures.

Identification of the appropriate agency representative or representatives, possessing substantial knowledge and understanding of the rule;

Matthew Gibbs, Deputy General Counsel, Department of Health

Identification of the appropriate agency representative or representatives who will explain the rule at scheduled meeting of the committees;

Matthew Gibbs, Deputy General Counsel, Department of Health

Office address, telephone number, and email address of the agency representative or representatives who will explain the rule at a scheduled meeting of the committees; and

Department of Health, Office of General Counsel, 665 Mainstream Drive, 2nd Floor, Nashville, TN 37243, 615-741-1611, Matthew.Gibbs@tn.gov

Any additional information relevant to the rule proposed for continuation that the committee requests;

None.

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER, OUTSOURCING FACILITY, OXYGEN SUPPLIER AND WHOLESALE/DISTRIBUTOR LICENSES

- (1) Application for a license to operate as a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor within the state of Tennessee shall be submitted to the office of the board at least thirty (30) days prior to the scheduled opening date. No pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor may open within the state of Tennessee until a license has been obtained; and such license will not be issued until an inspection by an authorized representative of the board has been made.
- (2) An application for an existing pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor changes name, location or ownership.
 - (a) Transactions constituting a change of ownership include, but are not limited to, the following:
 1. A sole proprietor becomes a member of a partnership or corporation, which succeeds him as the new operator;
 2. A partnership dissolves;
 3. One partnership is replaced by another through the removal, addition or substitution of a partner;
 4. Two (2) or more corporations merge and the originally-licensed corporation does not survive; and
 5. Transfers between levels of government.
 - (b) Transactions which do not constitute a change of ownership include, but are not limited to, the following:
 1. Changes in the membership of a corporate board of directors or board of trustees;
 2. Two (2) or more corporations merge and the originally-licensed corporation survives; and
 3. Corporate stock transfers or sales, even when a controlling interest.
- (3) No out-of-state pharmacy practice site, manufacturer outsourcing facility, oxygen supplier or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor physically located out-of-state the following standards must be met.
 - (a) Pharmacy practice site.
 1. Submit an application for a license, which shall include the address of the pharmacy practice site, name of owner if a sole proprietorship, names of partners

if a partnership or names and titles of all officers if a corporation and names of all pharmacists who practice at the site, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license, including names of pharmacists practicing at the site.

2. Comply with all statutorily authorized directions and requests for information from the board.
3. Maintain at all times a current permit, license or registration to conduct the pharmacy practice site in compliance with the laws of the state in which the site is physically located.
4. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Thereafter, the pharmacy practice site shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the site is physically located.
 - (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.
6. All records of prescription orders prepared and dispensed to persons residing in Tennessee shall be readily retrievable from other records.
7. During regular hours of operation, but not less than six (6) days per week nor for a minimum of forty (40) hours per week provide access to a pharmacist by a toll-free telephone service. A toll-free number shall be placed on the label affixed to the dispensing container for each prescription dispensed to a person residing in Tennessee.
8. Designate a pharmacist in charge who shall be responsible for compliance with the provisions in this section, and who shall hold a current Tennessee pharmacist license.
9. All out-of-state pharmacy practice sites shall comply with the requirements for patient counseling, patient profiling, drug regimen review and pharmaceutical care as set forth at 1140-03-.01.
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.

- (b) Manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor.
1. Submit an application for a license, which shall include the address of the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor, name of owner if a sole proprietorship, names of partners if a partnership or names and titles of all officers if a corporation, together with the appropriate application fee. The director shall be notified in writing within thirty (30) days of any change in the information contained on the original application for a license.
 2. Submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located, or by the Food & Drug Administration. Thereafter, the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor shall submit to the director a copy of any subsequent inspection report conducted by the regulatory or licensing agency of the state in which the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor is physically located, or by the FDA.
 3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.
- (4) Representatives of a manufacturer, outsourcing facility or wholesaler/distributor conducting business in the state of Tennessee and who possesses and distributes controlled substances shall obtain a controlled substance registration from the Board of Pharmacy.
- (5) Any entity licensed as or applying for licensure as manufacturer or outsourcing facility conducting business in the state of Tennessee and who manufactures, prepares, propagates, repackages, or processes sterile drug products or biological products using aseptic processing must register and possess a modifier as a sterile manufacturer with the Board of Pharmacy in accordance with this chapter. This section shall not apply to wholesalers/distributors of sterile products.
- (6) It shall be unlawful for any person to procure or attempt to procure a license or certificate of registration for such person or for any other person by making any false representations.
- (7) In determining whether to grant a license under this rule, the board shall require from the applicant proof satisfactory to the board that the:
- (a) Applicant is of good moral character, or, if the applicant is a partnership or corporation, that the managing officers are of good moral character; and
 - (b) That the applicant is equipped as to land, buildings and equipment necessary to conduct the business for which the application has been submitted.
- (8) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 53-14-104, ~~53-14-106~~, 53-14-107, ~~56-1-302(b)(1)(2)~~, ~~63-10-101~~, ~~63-10-102(a)~~, 63-10-203, 63-10-204, 63-10-210, 63-10-216, 63-10-301, ~~63-10-304~~, ~~63-10-306~~, ~~63-10-308~~, ~~63-10-404(18)~~, ~~(28)~~, and ~~(37)~~, ~~63-10-504(b)(1)~~, ~~63-10-504(b)(2)~~, and ~~63-10-508~~ 63-10-308, 63-10-310, and 63-10-312.

1140-01-.09 RENEWAL OF LICENSES

- (1) All licenses and certificates of registration granted by the board shall be for a two (2) year period beginning on the date the license is initially granted. All licenses and certificates of registration shall be renewed on or before the last day of the two (2) year license cycle.
- (2) A pharmacist or pharmacy technician serving in the uniformed services of the United States shall not be required to pay license or registration renewal fees during the period of active duty and the pharmacist shall not be required to complete continuing pharmacy education requirements during the period of active duty.
- (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.
- ~~(4)(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. §§ 53-11-301, 53-11-302, ~~56-1-302(b)(1)(2), 63-10-102(a), 63-10-204, 63-10-210, 63-10-216, 63-10-304, 63-10-308, 63-10-404(17), 63-10-504(1) and (2), 63-10-304(b)(1), and 63-10-508~~ 63-10-310, and 63-10-312.

1140-02-.02 PHARMACY TECHNICIANS

- (1) Any person acting as a pharmacy technician shall register with the Board by submitting a complete application on a form prescribed by the Board accompanied by the following:
 - (a) An affidavit signed by both the applicant and employer attesting that the applicant has read and understands the laws and rules relative to pharmacy technicians and the practice of pharmacy in Tennessee. (A copy of this affidavit shall be retained at the applicant's place of employment);
 - (b) Registration fee established in rule 1140-01-.10; and
 - (c) The result of a criminal background check, which the applicant shall pay for and cause to be submitted to the Board's administrative office directly from the vendor identified in the Board's registration application materials.
 - (d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for registration will be returned to the applicant with written notification of the information that is lacking or the reason(s) the application does not meet the requirements for registration and will be held in "pending" status until satisfactorily completed within a reasonable period of time, not to exceed sixty (60) days from date of written notification.
- (2) The following individuals are exempt from registration as a pharmacy technician:

- (a) Any individual performing tasks that may be performed by a pharmacy technician who is classified by the employer as a probationary employee. The exemption shall not exceed ninety (90) days from the date of employment.
 - (b) A student enrolled in a formal pharmacy technician training program while performing experiential rotations as a part of the academic curriculum. The student shall wear a school-issued identification badge.
- (3) The pharmacist in charge at each pharmacy practice site is responsible for compliance with the provisions of this chapter by pharmacy technicians at that pharmacy practice site.
- (4) A registered pharmacy technician may, under the supervision of a pharmacist, perform those tasks associated with the preparation and dispensing process except those tasks identified in Rule 1140-02-.01(13) that must be personally performed by a pharmacist or pharmacy intern under the personal supervision and in the presence of a pharmacist.
- (5) Certified pharmacy technicians may also:
 - (a) Receive new or transferred oral medical and prescription orders;
 - (b) Receive and transfer copies of oral medical and prescription orders between pharmacy practice sites; and
 - (c) Verify the contents of unit dose carts/automated dispensing systems prepared by other registered technicians when an additional verification by use of bar code technology or a licensed health care professional is performed prior to administration to the patient.
- (6) No prescription drugs and devices and related materials may be released to a patient without verification by a pharmacist of the functions performed by a pharmacy technician.
- (7) Pharmacy Technician to Pharmacist Ratio
 - (a) The pharmacy technician to pharmacist ratio shall not exceed ~~6~~2:1; however the ratio may be removed if ~~increased up to a maximum of 4:1 by the pharmacist in charge based upon public safety considerations but only 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:
 - 1. The pharmacy technician's experience, skill, knowledge and training; and
 - 2. The workload at the practice site; and
 - 3. Detailed information regarding the numbers of pharmacy technicians and the specific duties and responsibilities of each of the pharmacy technicians; and
 - 4. Justification that patient safety and quality of pharmacy services and care can be maintained at the pharmacy.
 - (b) Requested modifications of the established ratios may not be implemented until the written request is considered and approved by the Board.

- (8) Pharmacy technicians must wear appropriate identification showing name and appropriate title (e.g. pharmacy technician, certified pharmacy technician).
- (9) All pharmacy technician functions shall be performed under the supervision of a pharmacist, who shall direct and verify the accuracy of all pharmacy technician functions.
- (10) A registered technician shall maintain his or her registration certificate at the pharmacy practice site; additionally, all certified technicians shall display in like manner evidence of certification. Pharmacy technicians shall possess at all times, while on duty, proof of registration and proof of certification, if applicable.
- (11) All registered technicians shall immediately notify the board in writing of any change of address or employer.
- (12) For purposes of this rule, a pharmacy intern is not considered to be a pharmacy technician.
- (13) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: T.C.A. §§ 63-1-116, 63-10-204, 63-10-304, ~~63-10-304(b)(1), (e), and (j), 63-10-306, 63-10-308, 63-10-404(30), 63-10-504(b)(1), 63-10-504(b)(1)(C), 63-10-506, and 63-10-508~~ 63-10-310, and 63-10-312.

RULES OF THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-07 ~~STERILE PRODUCT PREPARATION IN PHARMACY PRACTICE~~ COMPOUNDING

TABLE OF CONTENTS

1140-07-.01	Applicability	1140-07-.06	Labeling
1140-07-.02	Standards	1140-07-.07	Hazardous Products
1140-07-.03	Personnel	1140-07-.08	Attire <u>Quality Assurance</u>
1140-07-.04	Physical Requirements	1140-07-.09	Quality Assurance <u>Nonsterile Simple Compounding Preparations</u>
1140-07-.05	Policy and Procedure Manual	1140-07-.10	Reserved

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 drugsterile products.

Authority: T.C.A. §§ ~~63-10-404(4), (11), (26), (28), (29), (30) and 63-10-504(b)(1), (2)~~; 63-10-216, 63-10-308, and 63-10-310.

1140-07-.02 STANDARDS

- (1) ~~All sterile products shall be prepared in compliance with applicable USP standards for pharmaceutical compounding.~~ 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 sterile products, except hospital pharmacies compounding for inpatients of a hospital, shall submit to the Board of Pharmacy, on a quarterly basis, a report listing the quantity of high risk or batch sterile products, as defined by USP standards, compounded and dispensed during the previous quarterly period and any other information as required by USP standards.~~
 - ~~(a) Quarterly reports submitted pursuant to this paragraph shall be submitted by the 15th day of the month following the end of each calendar quarter.~~
 - ~~(b) In any calendar year where any one of the above dates fall on a weekend or official state holiday, all quarterly reports due on that date shall be submitted on the following business day.~~
 - ~~(c) The format for reports submitted pursuant to this paragraph shall be determined by the Board of Pharmacy through policy and made available to the public on the Board of Pharmacy's website.~~

~~(4)~~(5) Any licensed pharmacy which compounds and dispenses ~~sterile~~ drug products shall provide at a minimum upon request of the Board of Pharmacy the following information for any ~~sterile~~ drug product compounded, dispensed, traded, sold, or otherwise distributed within the past two (2) years:

- (a) Name, strength, and dosage form;
- (b) Quantity compounded, dispensed, traded, sold, or otherwise distributed during the preceding ~~quarterly~~ period;
- (c) ~~All components~~The source, lot number, expiration date and an accurate statement of the weight or measure of each component;
- (d) ~~The beyond-use date~~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~~beyond-use date~~ 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.

~~(6) Any licensed pharmacy which compounds and dispenses sterile products must ensure that the following information is on file at the practice site and readily accessible for sterile products:~~

- ~~(a) Documentation of the name and strength of all drug products compounded over the past two (2) years;~~
- ~~(b) The sources and lot numbers of the components used in those drug products;~~
- ~~(c) The total number of dosage units compounded over the past two (2) years;~~
- ~~(d) The name of the person who prepared the drug product;~~
- ~~(e) The name of the pharmacist who approved the drug product;~~
- ~~(f) The name of the practitioner or the name of the patient or healthcare entity who received the compounded drug product;~~

~~(g) — The results of any sampling, testing or other quantitative evaluation conducted for the purposes of quality control for any sterile compounded products, as defined by chapter 1140-01, compounded over the past two (2) years.~~

~~(5)(7)~~ 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~~, 63-10-216, ~~63-10-301~~, ~~63-10-304~~, and ~~63-10-306~~ 63-10-308, and 63-10-310.

1140-07-.03 PERSONNEL

- (1) The pharmacist in charge or the person(s) designated by the pharmacist in charge ~~designee~~ shall be responsible for, at a minimum, the following:
 - (a) Procurement, storage, compounding, labeling, repackaging, dispensing, and distribution of all ~~prescription~~ drugs and devices and related materials necessary in compounding and dispensing compounded drug ~~sterile~~ products;
 - (b) Establishment of policies and procedures for the compounding and dispensing of compounded drug ~~sterile~~ products;
 - (c) Documentation of competency in proper~~aseptic~~ techniques of all pharmacists, pharmacy interns and pharmacy technicians. The proper~~aseptic~~ technique of each person compounding and dispensing compounded drug ~~sterile~~ products shall be observed and evaluated as satisfactory during orientation and training ~~and at least on an annual basis~~ 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;
 - (d) Establishment of a quality assurance program;
 - ~~(e) — Reviewing and updating annually all policies and procedures; and~~
 - ~~(f) — Provision of sterile products on a twenty four (24) hour a day basis.~~
- (2) All pharmacists, pharmacy interns and pharmacy technicians as defined in 1140-02-.02 responsible for compounding or dispensing compounded drug ~~sterile~~ products shall:
 - (a) Obtain practical and/or academic training in the compounding and dispensing of compounded drug ~~sterile~~ products;
 - (b) Complete ~~annual continuing~~ education ~~related~~ 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~~to sterile product compounding and dispensing and utilization;~~ 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:~~continuing education.~~

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 ~~aseptic~~ technique in all sterile 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) A pharmacist shall be available to respond to patients' and other health care practitioners' information needs on a twenty four (24) hour a day basis.~~

(3)~~(4)~~ The pharmacist in charge shall be assisted by such additional pharmacists, pharmacy interns, pharmacy technicians as defined by 1140-2-.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)~~(5)~~ 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 ~~sterile~~compounded drug products.

~~(6) A written record of initial and subsequent training and competency evaluations shall be maintained in the pharmacy practice site and contain the following information:~~

- ~~(a) Name of the person receiving the training or evaluation;~~
- ~~(b) Date(s) of the training or evaluation;~~
- ~~(c) General description of the topics covered; and~~
- ~~(d) Signature of the person receiving the training or evaluation and the pharmacist in charge or pharmacist designee of the pharmacist in charge.~~

~~(5)(7)~~ 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, 63-10-204, 63-10-304, 63-10-404(4), (5), (8), (11), (14), (16), (26), (27), (29), and (30), and 63-10-504(b)(1),(2),~~ 63-10-308, and 63-10-310.

1140-07-.04 PHYSICAL REQUIREMENTS

- (1) Any facility that compounds ~~sterile~~drug products shall comply with ~~applicable USP~~ 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. §§ ~~63-10-204, 63-10-216, 63-10-301, 63-10-304, and 63-10-306~~ 63-10-308, and 63-10-310.

1140-07-.05 POLICY AND PROCEDURE MANUAL

- (1) A policy and procedure manual related to ~~drug~~sterile product compounding shall be available for inspection at the pharmacy practice site. The manual shall include policies and procedures for ~~sterile~~ 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~~sterile~~ products;
 - (j) Record keeping;
 - (k) Quality assurance;

- (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 ~~sterile~~ 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 ~~all applicable USP standards~~ the standards established by 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 ~~sterile~~ 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. §§ ~~63-10-204, 63-10-216, 63-10-301, 63-10-304, 63-10-306, 63-10-404 (4), (8), (14), (26), (29), (30), and 63-10-504(b)(1),(2)~~ 63-10-308, and 63-10-310.

1140-07-.06 LABELING

- (1) At the time of ~~dispensing of labeling~~ the final sterile-compounded drug product, the dispensing container must bear a label which contains the following information:
- (a) Patient's name ~~(if for outpatient use)~~ 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 who compounded the sterile product;~~

- ~~(d)(e)~~ When applicable, identification of the pharmacy intern or pharmacy technician who assisted in the compounding of the sterile product. Identification of the pharmacist performing the final product verification;
- ~~(e)(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;
- ~~(f)(g)~~ Expiration date and, when applicable, expiration time, Beyond Use Dating (BUD) 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)(h)~~ Date of compounding;
- ~~(h)~~ Date of dispensing;
- (i) Appropriate auxiliary label(s); ~~and~~
- ~~(j)~~ Assigned internal identification number; and
- ~~(k)(l)~~ 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)(2)~~ Original medical or prescription orders for sterile products shall comply with applicable state and federal laws and regulations.

Authority: T.C.A. §§ ~~63-10-204, 63-10-216, 63-10-301, 63-10-304, 63-10-306, 63-10-404 (11), (14), (19), (26), (28), (29), (30), (32), (34), and 63-10-504(b)(1),(2)~~ 63-10-308, and 63-10-312.

1140-07-.07 HAZARDOUS PRODUCTS

(1) Physical Requirements.

- (a) If the pharmacy practice site is engaged in the compounding of hazardous ~~sterile~~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.

~~(1) A dedicated Class II, Type A contained vertical flow biohazard cabinet is the minimally acceptable compounding site for the routine compounding of hazardous sterile products.~~

~~(2) Hazardous sterile products shall be segregated within the pharmacy practice site and storage areas so identified.~~

(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) ~~Dispensing~~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.

~~(a) Prepared doses of hazardous sterile products for patients shall be placed in an appropriate outer wrap to minimize the risk exposure in case of accidental rupture of the primary container.~~

~~(b) Reasonable effort shall be made to assure that all hazardous sterile product primary containers and waste are removed from the site of use and disposed of as hazardous waste in accordance with applicable state and federal laws.~~

~~(3) Training.~~

~~(a) As part of the training for all pharmacists, pharmacy interns and pharmacy technicians involved in compounding of hazardous sterile products, an annual certification must be made by each pharmacist, pharmacy intern and pharmacy technician and the pharmacist in charge that each has read and understands the latest editions of:~~

~~1. Work Practice Guidelines for Personnel Dealing with Cytotoxic (Antineoplastic) Drugs (Occupational); and~~

~~2. The American Society of Health-System Pharmacists (ASHP) technical assistance bulletin on handling cytotoxic and hazardous substances.~~

~~(4) Hazardous sterile products dispensed shall bear a distinctive warning label with an appropriate caution statement thereon.~~

- ~~(5) — Gloving and gowning shall be required in the compounding of hazardous sterile products. Gloves should be rinsed frequently with a sanitizing agent (e.g., seventy percent (70%) isopropyl alcohol) and shall be changed when the integrity of the gloves is compromised.~~
- ~~(6) — In the compounding of hazardous sterile products, a protective disposable gown made of lint-free low permeability fabric with a closed front, long sleeves and elastic or knit closed cuffs with cuffs tucked under the gloves shall be worn. Gowns and gloves used in the compounding of hazardous sterile products shall not be worn outside the sterile product compounding area.~~

Authority: T.C.A. §§ ~~63-10-404(4), (11), (26), (27), (28), (29), (30) and 63-10-504(b)(1), (2).~~ 63-10-216, 63-10-308, and 63-10-310.

~~1140-07-.08 ATTIRE~~

- ~~(1) — All pharmacists, pharmacy interns and pharmacy technicians shall wear applicable outer garments and shall use applicable respiratory precautions as set out in USP 797.~~

~~Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304, and 63-10-306. 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 filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. Rule was previously numbered 1140-07-.07, but was renumbered to 1140-07-.08 with the addition of a new 1140-07-.02. Rule filed July 11, 2014; effective October 9, 2014.~~

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.

~~1140-07-.09 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 sterile products.~~
- ~~(3) All quality assurance programs shall follow applicable USP standards.~~
- ~~(4) As part of its quality assurance program, any licensed facility which engages in sterile compounding shall perform a gap analysis pursuant to guidelines adopted by the Board of Pharmacy. Any exceptions or serious deficiencies noted in this analysis shall be reported to the Board of Pharmacy.~~
- ~~(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. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304, 63-10-306, 63-10-404(26), (28), (29), and (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 filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. 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.~~

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.