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Notice of Rulemaking Hearing

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

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

ADA Contact:	ADA Coordinator
Address:	710 James Robertson Parkway, Andrew Johnson Building, 5th Floor, Nashville, Tennessee 37243
Phone:	(615) 741-6350
Email:	Tina.M.Harris2@tn.gov

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

Address 1:	Metro Center		
Address 2:	665 Mainstream Drive - Iris Conference Room		
City:	Nashville, Tennessee		
Zip:	37228		
Hearing Date :	July 7, 2014		
Hearing Time:	9:00 a.m.	X CST/CDT ___EST/EDT	

Additional Hearing Information:

Revision Type (check all that apply):
X Amendment
X New
___ Repeal

Rule(s) (**ALL** chapters and rules contained in filing must be listed. If needed, copy and paste additional tables to accommodate more than one chapter. Please enter only **ONE** Rule Number/Rule Title per row.)

Chapter Number	**Chapter Title**
1140-01	Introductory Rules
Rule Number	**Rule Title**
1140-01-.01	Definitions

1140-01-.02	Violations Constitute Unprofessional Conduct
1140-01-.08	Application for Pharmacy Practice Site, Manufacturer and Wholesaler Licenses
1140-01-.10	Fees
1140-01-.11	Controlled Substance Registration
1140-01-.12	Standards for Pharmacies and Prescription Department Security
1140-01-.13	Standards for Manufacturers and Wholesalers
1140-01-.14	Prescription Drugs Dispensed by Health Departments

Chapter Number	**Chapter Title**
1140-07	Sterile Product Preparation in Pharmacy Practice
Rule Number	**Rule Title**
1140-07-.02	Personnel
1140-07-.03	Physical Requirements
1140-07-.04	Policy and Procedure Manual
1140-07-.05	Labeling
1140-07-.06	Hazardous Products
1140-07-.07	Attire
1140-07-.08	Quality Assurance

Chapter Number	**Chapter Title**
1140-09	Manufacturers and Wholesalers
Rule Number	**Rule Title**
1140-09-.01	Manufacturer and Wholesaler Licensing
1140-09-.02	Minimum Information Required
1140-09-.03	Minimum Qualifications
1140-09-.04	Personnel
1140-09-.05	Minimum Requirements for Operation
1140-09-.06	Minimum Requirements for Sterile Product Operation

(Place substance of rules and other info here. Statutory authority must be given for each rule change. For information on formatting rules go to http://state.tn.us/sos/rules/1360/1360.htm)

Department of Health
Emergency Rules
Division of Health Related Boards

Chapter 1140-01
Introductory Rules

Amendments

Rule 1140-01-.01 Definitions is amended by adding new paragraphs (8), (9), (33), (34), (38) and (39) and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraphs (8), (9), (33), (34), (38), and (39) shall read:

(8) "Commercially available" means any marketed FDA-approved drug or biologic product not currently listed on any official shortage list recognized by the Board of Pharmacy.

(9) "Component" means any active ingredient, or any added substance, inactive ingredient, excipient or pharmaceutic ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.

(33) "Sterile product" means any dosage form, drug product, or biological product devoid from all living microorganisms, including but not limited to bacteria and fungus.

(34) "Sterile manufacturing" means the production, propagation, processing, pooling, or repackaging of sterile products for wholesale or any other form of distribution, not pursuant to a prescription or medical order.

(38) "USP" means the United States Pharmacopeia.

(39) "USP standards" means any applicable standard or standards published in the most current version of United States Pharmacopeia National Formulary guidelines, to the extent that such guidelines do not conflict with state law, rules, or Board Policy Statements and as those guidelines may, from time to time, be amended.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301 and 63-10-304.

Rule 1140-01-.02 Violations Constitute Unprofessional Conduct is amended by deleting the language of the rule in its entirety and substituting instead the following language, so that as amended, the rule shall read:

(1) Any person who violates any rule of the board may be deemed guilty of dishonorable, immoral, unethical or unprofessional conduct within the meaning of *T.C.A. § 63-10-305(6)*.

Authority: T.C.A. §§ 63-10-301, 63-10-304 and 63-10-305.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler Licenses is amended by deleting the title in its entirety and substituting instead the following language, so that as amended, the new title shall read:

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

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by changing the word "wholesaler" to "wholesaler/distributor" each time it appears in paragraphs (1), (2), and (3) and subparagraph (3)(b) and its parts 1 and 2, so that as amended, the new paragraphs (1), (2), and (3) and subparagraph (3)(b) and its parts 1 and 2, shall read as follows:

(1) Application for a license to operate as a pharmacy practice site, manufacturer 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 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 or wholesaler/distributor physically located within the state of Tennessee must be filed when the pharmacy practice site, manufacturer 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 or wholesaler/distributor shall conduct business in the state of Tennessee until such pharmacy practice site, manufacturer or wholesaler/distributor obtains the required license from the board. In order to obtain a license for a pharmacy practice site, manufacturer or wholesaler/distributor physically located out-of-state the following standards must be met.

(b) Manufacturer or wholesaler/distributor.

1. Submit an application for a license, which shall include the address of the manufacturer 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 or wholesaler/distributor is physically located. Thereafter, the manufacturer 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 or wholesaler/distributor is physically located.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by changing the word "board" to "Board of Pharmacy" in part (3)(b)3. As amended, part (3)(b)3 shall read:

3. Comply with the requirements contained in Chapter 1140-09 of the rules of the Board of Pharmacy.

Authority: T.C.A. §§ 63-10-204, 63-10-301 and 63-10-304.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by deleting paragraph (4) in its entirety and substituting the following language, so that as amended, the new paragraph (4) shall read:

(4) Representatives of a manufacturer 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.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by adding new paragraph (5) and renumbering the remaining paragraphs accordingly, so that as amended, the new paragraph (5) shall read:

(5) A manufacturer 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.

Authority: T.C.A. §§ 63-10-204, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-01-.10 Fees is amended by deleting paragraph (3) in its entirety and substituting instead the following language, so that as amended, the new paragraph (3) shall read:

(3) Each person becoming licensed as a pharmacist shall pay a registration fee of one-hundred twenty-five dollars ($125.00). Each person licensed as a pharmacist who desires to continue in the practice of pharmacy shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of one-hundred twenty-five dollars ($125.00). Each person licensed as a pharmacist and who wishes to obtain an inactive license shall biennially, on or before the last day of the month that the person's license shall expire, pay a renewal fee of sixty-three dollars ($63.00).

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-306 and 63-10-308.

Rule 1140-01-.10 Fees is amended by deleting paragraphs (4), (5), (6), (7), (8) and (15) in their entirety and substituting instead the following language, and by adding new paragraph (16), so that as amended, the new paragraphs (4), (5), (6), (7), (8), (15), and (16) shall read:

(4) Each person becoming registered as a pharmacy technician shall pay a registration fee of seventy-five dollars ($75.00). Each person who desires to continue to practice as a pharmacy technician shall biennially, on or before the last day of the month that the person's registration shall expire, pay a renewal fee of seventy-five dollars ($75.00).

(5) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any establishment or institution where prescription drugs and devices and related materials are kept for the purpose of the compounding and dispensing of medical and prescription orders shall pay a registration fee of three-hundred dollars ($300.00) biennially. Any new pharmacy practice site to be opened or established, or any change in location, name or ownership of any existing pharmacy practice site, shall before active operation obtain a license from the Board of Pharmacy and shall pay a fee of three-hundred dollars ($300.00)

(6) All manufacturers and wholesalers/distributors of prescription drugs and devices and related materials doing business in the state of Tennessee must be licensed by the Board of Pharmacy by paying a registration fee of five-hundred twenty-five dollars ($525.00), and thereafter a biennial renewal fee of five-hundred twenty-five dollars ($525.00)

(7) The fee for the Board of Pharmacy's publication of Pharmacy Drug Laws, Rules and Regulations shall be an amount which covers the cost of publication and shipping, as determined by the Board of Pharmacy.

(8) The charge for a roster of Tennessee pharmacies, pharmacists and printing of mailing labels of Tennessee pharmacies and pharmacists shall be determined by the administration of the Department of Health.

(15) Any person who holds a license to manufacture, obtain, possess, administer or dispense a prescription drug or device or controlled substance for the purpose of scientific research, chemical analysis, instruction or training of detection animals shall pay a renewal fee of one-hundred dollars ($100.00) biennially from the date of issuance.

(16) Any person, partnership, firm, corporation or agency owning or operating a pharmacy practice site or any other establishment licensed pursuant to this chapter, where sterile products are compounded, manufactured, prepared, propagated, repackaged, processed, stored, or distributed shall pay a registration fee of two-hundred and fifty dollars ($250.00), and thereafter a biennial renewal fee of two-hundred and fifty dollars ($250.00).

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-306 and 63-10-308.

Rule 1140-01-.11 Controlled Substance Registration is amended by adding the word "distributor" to the unnumbered introductory paragraph of the rule which shall read:

No licensee may obtain, possess, administer, dispense, distribute, or manufacture any controlled substance in this state, and no representative of a manufacturer or wholesaler/distributor may distribute any controlled substance in this state, without obtaining a controlled substance registration from the board. Application for such registration shall be submitted on a form prescribed by the board, and shall be accompanied by a fee of forty dollars ($40.00) and thereafter a biennial renewal fee of forty dollars ($40.00).

Authority: T.C.A. §§ 53-10-303, 63-10-102, 63-10-404, 63-10-504, 63-10-504, and 63-10-508.

Rule 1140-01-.13 Standards for Manufacturers and Wholesalers is amended by deleting the title in its entirety and substituting instead the following language, so that as amended, the new title shall read:

1140-01-.13 Standards for Manufacturers and Wholesaler/Distributors.

Authority: T.C.A. §§ 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-01-.13 Standards for Manufacturers and Wholesaler/Distributors is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the rule shall read:

No license to operate a new or remodeled manufacturer or wholesaler/distributor location within the state of Tennessee, or an existing manufacturer or wholesaler/distributor location which changes location or ownership, will be issued unless the manufacturer or wholesaler/distributor meets the standards set forth in Chapter 1140-09 of the rules of the Board of Pharmacy.

Authority: T.C.A. §§ 63-10-301, 63-10-304 and 63-10-306.

Chapter 1140-07
Sterile Product Preparation in Pharmacy Practice

Amendments

Rule 1140-07-.03 Physical Requirements is amended by deleting paragraph (1) and its subparagraphs in their entirety and substituting instead the following language, so that as amended, the new paragraph (1) shall read:

(1) Any facility that compounds sterile products shall comply with applicable USP standards.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.04 Policy and Procedure Manual is amended by deleting paragraph (1) but not its subparagraphs, and also by deleting subparagraph (1)(n) in its entirety, and by substituting instead the following language, so that as amended, the new paragraph (1) and new subparagraph (1)(n) shall read:

(1) A policy and procedure manual related to 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:

(n) public safety relative to harmful 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;

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

Rule 1140-07-.04 Policy and Procedure Manual is amended by deleting subparagraph (1)(o) in its entirety and substituting instead the following language, and is further amended by adding subparagraphs (1)(q) and (1)(r) and paragraphs (2) and (3), so that as amended, the new subparagraphs (1)(o), (1)(q) and (1)(r) and the new paragraphs (2) and (3) shall read:

(o) attire;

(q) compliance with all applicable USP standards; 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 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 and 63-10-306.

Rule 1140-07-.05 Labeling is amended by deleting subparagraphs (1)(a), (1)(g), and (1)(j) in their entirety and substituting instead the following language, so that as amended, the new subparagraphs (1)(a), (1)(g), and 1(j) shall read:

(a) patient's name (if for outpatient use) or healthcare entity name;

(g) expiration date and, when applicable, expiration time, Beyond Use Dating (BUD);

(j) directions for use (if for outpatient), if applicable.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

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

(1) All pharmacists, pharmacy interns and pharmacy technicians shall wear applicable outer garments and shall use 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.

Rule 1140-07-.08 Quality Assurance is amended by adding paragraphs (3), (4), and (5) which shall read:

(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 and 63-10-306.

Chapter 1140-09
Manufacturers and Wholesalers

Amendments

Rule 1140-09-.01 Manufacturer and Wholesaler Licensing is amended by deleting the title in its entirety and substituting instead the following language, and is further amended by deleting paragraph (1) in its entirety and substituting instead the following language, so that as amended, the new title and new paragraph (1) shall read:

1140-09-.01 Manufacturers and Wholesaler/Distributors.

(1) Every manufacturer or wholesaler/distributor, before engaging in the manufacture, sale or distribution of prescription drugs and prescription devices in this state, must be licensed by the Board in accordance with this chapter.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by changing the word "wholesaler" to "wholesaler/distributor" each time it appears in paragraph (1) and in subparagraphs (1)(a), (1)(b), (1)(c), and (1)(e), so that as amended, the new paragraph (1) and subparagraphs (1)(a), (1)(b), (1)(c), and (1)(e) shall read as follows:

(1) The board shall require the following minimum information from each manufacturer or wholesaler/distributor applying for a license or any renewal of such license:

(a) The name, full business address, and telephone number of the manufacturer or wholesaler/distributor;

(b) All trade or business names used by the manufacturer or wholesaler/distributor;

(c) Addresses, telephone numbers, and the names of contact persons for all facilities used by the manufacturer or wholesaler/distributor for storage, handling, and distribution;

(e) The name(s) of the owner and/or operator of the manufacturer or wholesaler/distributor, including:

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by deleting the word "and" from part (1)(e)4. and is further amended by deleting the period and substituting a semicolon as well as the word "and" after part (1)(e)5. which shall read:

4. If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

5. DEA registration number if applicable; and

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by adding new part (1)(e)6 and by adding new paragraphs (2) and (3) and renumbering the existing paragraph accordingly, so that as amended, the new part (1)(e)6 and new paragraphs (2) and (3) shall read:

6. The results of a criminal background check for the owner or manager of the facility seeking licensure, submitted directly to the Board of Pharmacy by the vendor identified in the Board of Pharmacy's licensure application materials.

(2) Applicants seeking to register as manufacturers shall provide the following materials to the Board of Pharmacy:

(a) Proof of registration with the Food and Drug Administration as a manufacturer and the most current inspection by that agency, or correspondence or other written proof from the Food and Drug Administration which states that registration with that agency is unnecessary;

(b) The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant that can be reached at any time by the Board of Pharmacy, the Department of Health or any agents thereof in the event of a potential or actual public health threat related to the sterility or potency of any drug or biologic product manufactured, wholesaled or distributed by the applicant.

(3) Applicants seeking to register as sterile manufacturers shall provide the following materials to the Board of Pharmacy:

(a) Upon request by the Board of Pharmacy or the executive director, a list of sterile products currently being manufactured, wholesaled and distributed;

(b) The name and contact information for any laboratory, corporation, or other organization that may perform sterility and potency testing, or similar procedures for the purposes of quality assurance on any drug or biologic product produced by the applicant;

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.02 Minimum Information Required is amended by deleting newly-renumbered paragraph (4) in its entirety and substituting instead the following language, so that as amended, newly-renumbered paragraph (4) shall read:

(4) Changes in any information in paragraphs (1), (2), or (3) of this rule shall be submitted in writing to the Board of Pharmacy immediately.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.03 Minimum Qualifications is amended by changing the word "wholesaler" to "wholesaler/distributor" in paragraph (1), so that as amended, paragraph (1) shall read as follows:

(1) The board shall consider, at a minimum, the following factors in reviewing an application for a license as a manufacturer or wholesaler/distributor:

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

Rule 1140-09-.04 Personnel is amended by changing the word "wholesaler" to "wholesaler/distributor" so that as amended, the rule shall read as follows:

The board shall require that personnel employed by a manufacturer or wholesaler/distributor have appropriate education and/or experience to assume positions of responsibility for compliance with board requirements.

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

Rule 1140-09-.05 Minimum Requirements for Operation is amended by deleting the title in its entirety and substituting instead the following language, so that as amended, the new title shall read:

1140-09-.05 Minimum Requirements for General Operation.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

Rule 1140-09-.05 Minimum Requirements for General Operation is amended by deleting the title paragraph, subparagraphs (5)(c) and (6)(a) but not its parts, paragraph (7) and part (7)(b)2 as well as subparagraphs (7)(c) and (7)(d) in their entirety and substituting instead the following language, and is further amended by deleting paragraphs (8) and (9), subparagraphs (9)(a) and (9)(b), and paragraph (10) in their entirety and substituting

instead the following language, so that as amended, the new title paragraph, paragraphs, subparagraphs and part shall read:

The following shall be the minimum requirements for the storage and handling of prescription drugs and prescription devices and for the establishment and maintenance of prescription drug and prescription device distribution records by manufacturers and wholesalers/distributors:

(5) (c) If the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, then the prescription drug or prescription device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the prescription drug or prescription device meets appropriate standards of safety, identity, strength, quality and purity. In determining whether the conditions under which a prescription drug or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, the manufacturer or wholesaler/distributor shall consider, among other things, the conditions under which the prescription drug or prescription device has been held, stored or shipped before or during return and the condition of the prescription drug or device or related material and its container, carton, or labeling, as a result of storage or shipping.

(6) (a) Manufacturers and wholesalers/distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and prescription devices. These records shall include the following information:

(7) Written policies and procedures. Manufacturers and wholesalers/distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs and prescription devices; including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Manufacturers and wholesalers/distributors shall include in written policies and procedures the following:

(b)

2. Any voluntary action by the manufacturer or wholesaler/distributor to remove defective or potentially defective prescription drugs and prescription devices from the market; or

(c) A procedure to ensure that manufacturers and wholesalers/distributors prepare for, protect against, and respond to any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

(d) A procedure to ensure that any outdated prescription drugs and prescription devices shall be segregated from other prescription drugs and prescription devices and either returned to the manufacturer or wholesaler/distributor or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs and prescription devices. This documentation shall be maintained for two (2) years after disposition of the outdated prescription drugs and prescription devices.

(8) Responsible persons. Manufacturers and wholesalers/distributors shall establish and maintain lists of officers, directors, managers, and other persons in charge of distribution, storage, and handling, including a description of such persons' duties and a summary of such persons' qualifications.

(9) Compliance with federal, state, and local law. Manufacturers and wholesalers/distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(a) Manufacturers and wholesalers/distributors shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect premises and delivery vehicles, and to audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) Manufacturers and wholesalers/distributors that handle controlled substances shall register with the board and with the United States Drug Enforcement Administration (DEA) and shall comply with applicable state, local and DEA regulations.

(10) Salvaging and reprocessing. Manufacturers and wholesalers/distributors shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to salvaging or reprocessing of prescription drugs and prescription devices.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

New Rule

Chapter 1140-01
Introductory Rules

Rule 1140-01-.12
Sterile Compounding Registration

New Rule: 1140-01-.12 New Table of Contents.

1140-01-.01 Definitions
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1140-01-.07 Inactive Licenses and License Reinstatement
1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses
1140-01-.09 Renewal of Licenses
1140-01-.10 Fees
1140-01-.11 Controlled Substance Registration
1140-01-.12 Sterile Compounding Registration
1140-01-.13 Standards for Prescription Department Safety
1140-01-.14 Standards for Manufacturers and Wholesaler/Distributors
1140-01-.15 Prescription Drugs Dispensed by Health Departments

(1) No licensee may compound, manufacture, prepare, propagate, or process any sterile product to be dispensed, sold, traded, or otherwise distributed in or from this state without first obtaining a sterile compounding modifier registration from the Board of Pharmacy.

(2) A registration modifier to compound and dispense sterile products into or from this state may be suspended by the Board of Pharmacy, upon information that the registrant has:

(a) Knowingly furnished false or fraudulent material information in any application filed before the Board of Pharmacy; or

(b) Been convicted of a felony under any state or federal law relating to drugs or to the practice of pharmacy; or

(c) Had any of its licenses, permits, or registrations granted by the Food and Drug Administration (FDA), the Drug Enforcement Administration (DEA), the Department of Health and Human Services (DHHS), or any other federal agency or subdivision thereof, suspended, revoked, or voluntarily surrendered; or

(d) Been enjoined from operation by the court of any state or a federal court; or

(e) Been identified by the Commissioner of Health or the Commissioner's designee, the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or an investigator of the Board of Pharmacy as a source of adulterated, misbranded, or otherwise unsafe sterile products which have been, or pose an imminent risk of being dispensed, sold, traded, or otherwise distributed.

(3) An order of suspension issued by the Board of Pharmacy may contain additional directives or requirements necessary to protect public health, safety and welfare, including but not limited to:

(a) The quarantine or disposal of any sterile product compounded, manufactured, prepared, propagated or processed at the facility.

(b) The initiation of a recall of any sterile product compounded, manufactured, prepared, propagated or processed at the facility where such products or any label, container, packaging, or dosage form associated with such products may be adulterated, misbranded, contaminated, or otherwise unsafe.

(c) An order of suspension issued by the Board of Pharmacy may contain exceptions or allowances necessary to protect individual patients or the public health.

(4) Any order of suspension issued by the Board of Pharmacy pursuant to this chapter shall follow the procedures required by the Uniform Administrative Procedures Act, including those procedures required by T.C.A. § 4-5-320(d) where appropriate.

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-305 and 63-10-306.

New Rule

Chapter 1140-07
Sterile Product Preparation in Pharmacy Practice

1140-07-.02
Standards

New Rule: 1140-07-.02 New Table of Contents.

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

(1) All sterile products shall be prepared in compliance with applicable USP standards for pharmaceutical compounding.

(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 sterile products 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.

(5) Any licensed pharmacy which compounds and dispenses sterile 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:

(a) name, strength, and dosage form;

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

(c) all components and an accurate statement of the weight or measure of each component;

(d) the beyond-use date;

(e) storage requirements;

(f) labels and labeling with appropriate beyond-use date and instructions for storage and use.

(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.

Authority: T.C.A. §§ 63-10-204, 63-10-216, 63-10-301, 63-10-304 and 63-10-306.

New Rule

Chapter 1140-09
Manufacturers and Wholesalers/Distributors

1140-09-.06
Minimum Requirements for Sterile Product Operation.

New Rule: 1140-09-.06 New Table of Contents.

1140-09-.01 Manufacturers and Wholesaler/Distributors

1140-09-.02 Minimum Information Required
1140-09-.03 Minimum Qualifications
1140-09-.04 Personnel
1140-09-.05 Minimum Requirements for General Operation
1140-09-.06 Minimum Requirements for Sterile Product Operation

(1) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter that also holds an active sterile compounding registration from the Board of Pharmacy and that holds a license or registration from the Federal Food and Drug Administration, shall comply with all applicable federal laws, regulations, and guidelines including, but not limited to:

(a) FDA Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs 21 CFR 210;

(b) FDA Current Good Manufacturing Practice for Finished Pharmaceuticals 21 CFR 211;

(c) DEA regulations relating to controlled substances 21 CFR 1300-99.

(2) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy and who does not hold a license or registration from the federal Food and Drug Administration shall comply with all applicable USP standards.

(3) Any manufacturer or wholesaler/distributor licensed pursuant to this chapter who also holds an active sterile compounding registration from the Board of Pharmacy shall comply with all other applicable Board of Pharmacy rules and all other applicable laws of this State.

(4) The Board of Pharmacy may waive any applicable USP standards upon a showing by the applicant that good cause exists and that a waiver would better promote public health, safety, and welfare.

Authority: T.C.A. §§ 63-10-404 and 63-10-504.

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

Date: 5/12/14

Signature:

Name of Officer: Stefan Cange

Title of Officer: Asst. General Counsel

Subscribed and sworn to before me on: 5-12-14

Notary Public Signature: Suzanne Mechkowski

My commission expires on: MY COMMISSION EXPIRES APRIL 19, 2017

SUZANNE MECHKOWSKI NOTARY PUBLIC STATE OF TENNESSEE SUMNER COUNTY

Department of State Use Only

Filed with the Department of State on: 5/12/14

Tre Hargett
Secretary of State

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