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Sequence Number: 04-07-14
Notice ID(s): 2182 - 2183
File Date: 6/11/14

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
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 :	09/10/2014		
Hearing Time:	9:00 a.m.	X CST/CDT	EST/EDT

Additional Hearing Information:

Revision Type (check all that apply):
X Amendment
___ 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-.04	Pharmacy Internship

1140-01-.08	Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses
1140-01-.10	Fees
1140-01-.12	Sterile Product Registration
1140-01-.13	Standards for Pharmacies and Prescription Department Safety
1140-01-.14	Standards for Manufacturers and Wholesalers/Distributors
1140-01-.15	Prescription Drugs Dispensed by Health Departments

Chapter Number	**Chapter Title**
1140-09	Manufacturers and Wholesalers/Distributors
Rule Number	**Rule Title**
1140-09-.01	Manufacturer and Wholesaler/Distributor Licensing
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

(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)

Chapter
1140-01
Introductory Rules

Amendments

Rule 1140-01-.01 Definitions is amended by adding paragraphs (21) and (22) and renumbering the remaining paragraphs, so that as amended, the new paragraphs (21) and (22) shall read:

(21) "Outsourcing facility" means a facility engaged in the compounding of sterile drugs which has elected to register as an outsourcing facility with the U.S. Food and Drug Administration and which complies with all relevant federal laws and regulations.

(22) "Oxygen supplier" means any person who sells, delivers, distributes or wholesales medical gases which require a prescription or medical order prior to administration, dispensing or delivery and which are considered legend drugs pursuant to the federal Food, Drug, and Cosmetic Act to any person residing in this state.

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

Rule 1140-01-.04 Pharmacy Internship is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

(1) An applicant for an initial pharmacist license by examination must show, on affidavit forms prescribed by the board, that the applicant has acquired a minimum of one thousand seven hundred (1,700) hours of pharmacy internship (practical pharmacy experience) under the instruction of a pharmacist in good standing, subject to all of the following conditions.

(a) The one thousand seven hundred (1,700) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand seven hundred (1,700) of these hours may be acquired in pharmacy programs or demonstration projects structured by the college or school of pharmacy.

(b) Pharmacy internship may be acquired in another state, provided that the preceptor's qualifications are certified by the appropriate authorities of such state.

(c) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-202, 63-10-404.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by deleting the rule title and paragraphs (1), (2), and (3) in their entirety and substituting instead the following language, so that as amended, the new rule title and new paragraphs (1), (2), and (3) shall read:

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

(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.

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

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses is amended by deleting subparagraph (3)(b) and parts (3)(b)1. and (3)(b)2. and substituting instead the following language, so that as amended, the new subparagraph and parts shall read:

(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. 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. Inspection reports which are more than one (1) year old at the time of submission shall not satisfy the requirements of this part.

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

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licenses is amended by deleting paragraphs (4) and (5) and substituting instead the following language, so that as amended the new paragraphs (4) and (5) shall read:

(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.

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

Rule 1140-01-.05 Fees is amended by deleting paragraphs (6), (7), and (10) in their entirety and substituting instead the following language, so that as amended, the new paragraphs (6), (7), and (10) shall read:

(6) All manufacturers, outsourcing facilities, oxygen suppliers 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. The Board may also to publish Pharmacy Drug Laws, Rules and Regulations electronically, and may make an electronic publication freely available on the Board's website.

(10) The fee for any duplicate or revised license, registration, modifier or license wall certificate shall be twenty five dollars ($25.00).

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

Rule 1140-01-.14 Standards for Manufacturers and Wholesalers is amended by deleting the rule and rule title in their entirety and substituting instead the following language, so that as amended, the new rule title and new rule shall read:

1140-01-.14 Standards for Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesaler/Distributors.

No license to operate a new or remodeled manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor location within the state of Tennessee, or an existing manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor location which changes location or ownership, will be issued unless the manufacturer, outsourcing facility, oxygen supplier 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.

New Rule

Chapter 1140-01
Introductory Rules

Rule 1140-01-.12
Sterile Compounding Registration

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

(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.

Chapter
1140-09
Manufacturers and Wholesaler/Distributors

Amendments

Chapter 1140-09 Manufacturers and Wholesaler/Distributors is amended by deleting the chapter title in its entirety and substituting the following language, so that as amended, the new chapter title shall read:

Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesaler/Distributors

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

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

Rule 1140-09-.01 Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor

(1) Every manufacturer, outsourcing facility, oxygen supplier 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 deleting the rule in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

(1) The board shall require the following minimum information from each manufacturer, outsourcing facility, oxygen supplier 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, outsourcing facility, oxygen supplier or wholesaler/distributor;

(b) All trade or business names used by the manufacturer, outsourcing facility, oxygen supplier or wholesaler/distributor;

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

(d) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and

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

1. If a person, the name of the person;

2. If a partnership, the name of each partner, and the name of the partnership;

3. If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

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

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 or outsourcing facilities shall provide the following materials to the Board of Pharmacy:

(a) Proof of registration with the Food and Drug Administration as a manufacturer or outsourcing facility 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 purchase a sterile compounding modifier 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;

(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 deleting paragraph (1) in its entirety and substituting instead the following language, so that as amended, the new paragraph (1) shall read:

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

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

Rule 1140-09-.04 Personnel is amended by deleting the rule in its entirety and substituting instead the following language, so that as amended, the new rule shall read:

The board shall require that personnel employed by a manufacturer, outsourcing facility, oxygen supplier 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 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, outsourcing facilities, oxygen suppliers 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, outsourcing facility , oxygen supplier 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, outsourcing facilities, oxygen suppliers 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, outsourcing facilities, oxygen suppliers 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, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall include in written policies and procedures the following:

(b) 2. Any voluntary action by the manufacturer, outsourcing facility, oxygen supplier 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, outsourcing facilities, oxygen suppliers 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, outsourcing facility, oxygen supplier 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, outsourcing facilities, oxygen suppliers 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, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(a) Manufacturers, outsourcing facilities, oxygen suppliers 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, outsourcing facilities, oxygen suppliers 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, outsourcing facilities, oxygen suppliers 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
Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesaler/Distributors
Chapter 1140-09

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

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

(1) Any manufacturer, outsourcing facility 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, outsourcing facility 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, outsourcing facility 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: 6/11/14

Signature:

Name of Officer: Stefan Cange

Title of Officer: Assistant General Counsel
Department of Health

Subscribed and sworn to before me on: 6-11-14

Notary Public Signature: Lorraine Mecklowski

My commission expires on:

MY COMMISSION EXPIRES
APRIL 19, 2017

Department of State Use Only

Filed with the Department of State on: 6/11/14

Tre Hargett
Secretary of State

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