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File Date: 3/24/15
Effective Date: 6/22/15

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:	Stefan Cange
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Revision Type (check all that apply):

- Amendment
 New
 Repeal

Rule(s) Revised (ALL chapters and rules contained in filing must be listed here. If needed, copy and paste additional tables to accommodate multiple chapters. 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-.14	Standards for Manufacturers and Wholesalers/Distributors

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 (23) and (24) and renumbering the remaining paragraphs, so that as amended, the new paragraphs (23) and (24) shall read:

- (23) "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.
- (24) "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 must 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. §§ 63-10-202, 63-10-304 and 63-10-306.

Rule 1140-01-.08 Application for Pharmacy Practice Site, Manufacturer and Wholesaler/Distributor Licenses is amended by deleting the rule title, paragraph (1), paragraph (2) but not its subparagraphs (a) and (b), and paragraph (3) but not its subparagraphs (a) and (b), 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, 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.
- (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, 63-10-210, 63-10-216, 63-10-301, 63-10-304, and 63-10-306.

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. but not (3)(b)3. 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, 63-10-210, 63-10-216, 63-10-301, 63-10-304, and 63-10-306.

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) in their entirety 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, 63-10-210, 63-10-216, 63-10-301, 63-10-304, and 63-10-306.

Rule 1140-01-.10 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 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/Distributors 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 Wholesalers/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.

Chapter
1140-09
Manufacturers and Wholesaler/Distributors

Amendments

Chapter 1140-09 Manufacturers and Wholesalers/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 Wholesalers/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 Licensing

- (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 obtain a sterile compounding modifier registration 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) but not its subparagraphs 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. §§ 63-10-204, 63-10-304, 63-10-305, and 63-10-306.

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. §§ 63-10-204, 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, subparagraph (5)(c), subparagraph (6)(a) but not its parts, paragraph (7) but not its subparagraphs and parts except as described herein, part (7)(b)2, subparagraph (7)(c), and subparagraph (7)(d), and substituting instead the following language, and is further amended by deleting paragraph (8), paragraph (9) including 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, and 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.

Rule 1140-09-.06 Minimum Requirements for Sterile Product Operation 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) 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. §§ 63-10-204, 63-10-216, 63-10-304, 63-10-305, and 63-10-306.

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

Board Member	Aye	No	Abstain	Absent	Signature (if required)
Debra Wilson				X	
Jason Kizer, D.Ph	X				
Nina Smothers, D.Ph.	X				
Joyce McDaniel				X	
Will Bunch, D.Ph.	X				
Kevin K. Eidson, Pharm. D.	X				
R. Michael Dickenson, D.Ph.	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Pharmacy (board/commission/ other authority) on 09/10/2014 (mm/dd/yyyy), 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: 6/11/14 (mm/dd/yy)

Rulemaking Hearing(s) Conducted on: (add more dates). 09/10/14 (mm/dd/yy)

Date: 2/6/15

Signature: [Handwritten Signature]

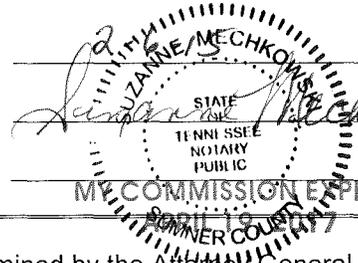
Name of Officer: Stefan Cange
Assistant General Counsel

Title of Officer: Department of Health

Subscribed and sworn to before me on: _____

Notary Public Signature: [Handwritten Signature]

My commission expires on: _____



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.

[Handwritten Signature]
Herbert H. Slattery III
Attorney General and Reporter
3/20/2015
Date

Department of State Use Only

Filed with the Department of State on: 3/24/15

Effective on: 6/22/15
Tre Hargett
Tre Hargett
Secretary of State

SECRETARY OF STATE
RECEIVED

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Public Hearing Comments

One copy of a document containing responses to comments made at the public hearing must accompany the filing pursuant to T.C.A. § 4-5-222. Agencies shall include only their responses to public hearing comments, which can be summarized. No letters of inquiry from parties questioning the rule will be accepted. When no comments are received at the public hearing, the agency need only draft a memorandum stating such and include it with the Rulemaking Hearing Rule filing. Minutes of the meeting will not be accepted. Transcripts are not acceptable.

The Board received one comment from Brenda Warren, DPh.

Dr. Warren asked whether rule changes requiring the provision of a state inspection forum prior to licensure would prevent some entities which are located overseas or only hold licenses from the FDA from getting a Tennessee license.

Responding for the Board, Mr. Cange indicated that the federal law would control in those instances, and that a licensee who could only provide an FDA inspection report would satisfy the requirement (and thus would be eligible for licensure).

Regulatory Flexibility Addendum

Pursuant to T.C.A. §§ 4-5-401 through 4-5-404, prior to initiating the rule making process as described in T.C.A. § 4-5-202(a)(3) and T.C.A. § 4-5-202(a), all agencies shall conduct a review of whether a proposed rule or rule affects small businesses.

(If applicable, insert Regulatory Flexibility Addendum here)

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

These proposed rule amendments do not overlap, duplicate, or conflict with other federal, state, and local governmental rules.

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

These proposed rule amendments exhibit clarity, conciseness, and lack of ambiguity.

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

These proposed rule amendments do not establish flexible compliance and/or reporting requirements for small businesses.

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

The proposed rule amendments do not contain a schedule or deadline for compliance. The proposed rules are more a matter of internal housekeeping; affected entities are already in compliance with the substantive requirements of the law (which are not changed by the proposed rule amendment), so there is no need to provide a timeline for them to come into compliance.

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

These proposed rule amendments do not consolidate or simplify compliance or reporting requirements for small businesses.

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

These proposed rule amendments do not establish performance standards for small business as opposed to design or operation standards required for the proposed rules.

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

These rule amendments do not create entry barriers or other effects that stifle entrepreneurial activity, curb innovation, or increase costs.

STATEMENT OF ECONOMIC IMPACT TO SMALL BUSINESSES

Name of Board, Committee or Council: Board of Pharmacy

Rulemaking hearing date: September 10, 2014

- 1. Type or types of small business and an identification and estimate of the number of small businesses subject to the proposed rule that would bear the cost of, and/or directly benefit from the proposed rule:**

Pharmacies, Pharmacists, Outsourcing Facilities, and Oxygen Suppliers will be subject to these proposed rule amendments. Any costs associated with these rule amendments should be minimal as the amendments will only add licensure categories for Outsourcing Facilities and Oxygen Suppliers. Pharmacy students and schools are affected by the internship hour change.

- 2. Projected reporting, recordkeeping and other administrative costs required for compliance with the proposed rule, including the type of professional skills necessary for preparation of the report or record:**

These rule amendments should not affect reporting, recordkeeping or other administrative costs.

- 3. Statement of the probable effect on impacted small businesses and consumers:**

These rule amendments should have a minimal effect on small businesses. The new licensure categories do not carry any additional regulatory requirements, nor do they raise fees for affected businesses. However, the proposed rules will help to clarify the legal responsibilities of small businesses, as well as help streamline state administrative and enforcement efforts. Consumers will benefit from the addition of these licensure categories as the rules will now provide improved oversight over these industries. Pharmacy schools and students will benefit from the internship hour change, which will make it easier for students to satisfy the internship requirement through school-sponsored programs.

- 4. Description of any less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rule that may exist, and to what extent, such alternative means might be less burdensome to small business:**

There are no less burdensome, less intrusive or less costly alternative methods of achieving the purpose and/or objectives of the proposed rules.

- 5. Comparison of the proposed rule with any federal or state counterparts:**

Federal: Pharmaceutical outsourcing facilities as well as oxygen suppliers are currently regulated by Food and Drug Administration.

State: Many other states have, or are in the process of developing, new licensure categories for outsourcing facilities as well as separate licenses for oxygen suppliers.

- 6. Analysis of the effect of the possible exemption of small businesses from all or any part of the requirements contained in the proposed rule.**

These rule amendments do not provide for exemptions of small businesses from all or any part of the requirements contained in the proposed rule.

Impact on Local Governments

Pursuant to T.C.A. §§ 4-5-220 and 4-5-228 "any rule proposed to be promulgated shall state in a simple declarative sentence, without additional comments on the merits of the policy of the rules or regulation, whether the rule or regulation may have a projected impact on local governments." (See Public Chapter Number 1070 (<http://state.tn.us/sos/acts/106/pub/pc1070.pdf>) of the 2010 Session of the General Assembly)

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

Rule Chapter 1140-01: adds definitions of "outsourcing facility" and "oxygen supplier" and include those terms in Rule Chapter 1140-09.

Rules 1140-01-.08 [Application for Pharmacy Practice Site, Manufacturer, and Wholesaler/Distributor Licenses] and 1140-01-.09 [Renewal of Licenses]: add terms "outsourcing facility" and "oxygen supplier."

Rule 1140-01-.04 increases the current required number of hours in internships from one thousand five hundred (1,500) to one thousand seven hundred (1,700).

1140-01-.04: delete subparagraph (4)(c).

1140-01-.10 [Fees] new paragraph (7) will allow the Board to post a free electronic copy of the Pharmacy Drug Laws on the Board's website and amend paragraph

1140-01-.10 [Fees] new paragraph (10) will allow the Board to charge the same fee for all replacement licenses, registrations, or modifiers granted by the Board.

1140-01-.14 [Standards for Manufacturers and Wholesalers/Distributors] will require outsourcing facilities and oxygen facilities to meet the standards of Rule Chapter 1140-09 before being granted a new license in the event of a change in location or ownership.

1140-09-.01 adds a licensure requirement for outsourcing facilities and oxygen suppliers in the State.

1140-09-.02 to detail the minimum information required from such oxygen suppliers and outsourcing facilities by amending paragraphs (1), (2) and (3). These two new licensure types will also be added in Rules 1140-09-.03, 1140-09-.04, 1140-09-.05 and 1140-09-.06.

- (B)** 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;

None.

- (C)** 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;

These rules affect all licensed pharmacies and pharmacists, outsourcing facilities, and oxygen suppliers.

- (D)** Identification of any opinions of the attorney general and reporter or any judicial ruling that directly relates to the rule;

None.

- (E)** 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 result in any increase or decrease in state and local government revenues and expenditures.

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

Stefan Cange, Assistant General Counsel, Department of Health.

- (G) Identification of the appropriate agency representative or representatives who will explain the rule at a scheduled meeting of the committees;

Stefan Cange, Assistant General Counsel, Department of Health.

- (H) 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

Office of General Counsel, Department of Health, 665 Mainstream Drive, Nashville, Tennessee 37205, (615)741-1611, Stefan.Cange@tn.gov.

- (I) Any additional information relevant to the rule proposed for continuation that the committee requests.

None.

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-01
INTRODUCTORY RULES**

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1140-01-.01 DEFINITIONS.

- (1) "ACPE" means the Accreditation Council for Pharmaceutical Education.
- (2) "Alternate or alternative infusion pharmacy practice site" means a pharmacy practice site where parenteral, enteral or respiratory therapies, and ancillary supplies, medications and equipment are provided to patients in a non-institutional setting.
- (3) "Accreditation Council for Pharmacy Education (ACPE)" means the national organization for accreditation of professional degree programs in pharmacy and for accreditation of providers of continuing pharmacy education.
- (4) "Blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing.
- (5) "Blood fraction/component" means that part of blood separated by physical or mechanical means.
- (6) "Centralized Prescription Processing" is the filling or refilling of a lawful prescription order written by the patient's authorized prescriber by one (1) pharmacy licensed by the State of Tennessee at the request of another pharmacy licensed by the State of Tennessee for the delivery of the prescription drugs to the patient or patient's agent.
- (7) "Certified pharmacy technician" means an individual who is certified by a national or state agency that offers a certification program that is recognized by the board.
- (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 pharmaceutical ingredient, intended for use in the compounding of a drug product, including those that may not appear on the product label.

(Rule 1140-01-.01, continued)

- (10) "Consultant pharmacist" means a pharmacist retained on a routine basis to consult with organizations, institutional facilities or patients in areas that pertain to the practice of pharmacy.
- (11) "Contact hour" means any hour of completed continuing pharmaceutical education programming which is:
 - (a) accredited by ACPE (including, but not limited to, live programs, independent study courses, home correspondence courses, and audio or video cassettes); or
 - (b) approved by the board (including, but not limited to, attendance at state, district, or local pharmacy association meetings).
- (12) "Continuing education unit" means ten (10) hours of participation in an ACPE approved or board-approved continuing pharmaceutical education program under responsible sponsorship, capable direction, and qualified instruction.
- (13) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the prescription drug.
- (14) "Electronic medical or prescription order" means a medical or prescription order which is transmitted by computer technology other than by electronic image transmission.
- (15) "Facsimile (FAX) medical or prescription order" means a medical or prescription order which is transmitted by an electronic image transmission.
- (16) "Foreign pharmacy graduate" means a person whose undergraduate pharmacy degree was conferred by any college or school of pharmacy not accredited by the ACPE but which is listed in the World Health Organization World Directory of Colleges and Schools of Pharmacy, or otherwise approved by the Foreign Pharmacy Graduate Examination Committee (FPGEC) certification program as established by the National Association of Boards of Pharmacy.
- (17) "Hazardous product" means any substance that may be cytotoxic, genotoxic, oncogenic, mutagenic, teratogenic, or otherwise pose a potential health hazard.
- (18) "Institutional facility" means any organization whose primary purpose is to provide a physical environment for patients to obtain health care services, and where patients spend a majority of their time within the facility, including but not limited to a(n):
 - (a) adult care facility;
 - (b) assisted living facility;
 - (c) correctional facility;
 - (d) developmental disability center;
 - (e) hospital;
 - (f) inpatient psychiatric center;
 - (g) intermediate care facility for the mentally retarded;
 - (h) mental health facility;
 - (i) nursing facility;
 - (j) personal care home;
 - (k) rehabilitation center;
 - (l) residential drug or alcohol treatment center;
 - (m) rest home;
 - (n) retirement center;
 - (o) sub-acute care facility; and

(Rule 1140-01-.01, continued)

- (p) university health center.
- (19) "Institutional pharmacy practice site" means a pharmacy practice site serving patients within an institutional facility.
- (20) "Medication order" means a prescription order for any prescription drug or device or related material issued by an authorized prescriber to authorized healthcare personnel in an institutional facility or institutional pharmacy practice site.
- (21) "National Association of Boards of Pharmacy (NABP)" means the professional organization that represents the individual state boards of pharmacy.
- (22) "Nuclear pharmacy practice site" means a pharmacy practice site providing radiopharmaceutical services.
- (23) "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.
- (24) "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.
- ~~(25)~~(23) "Patient counseling" means communication by the pharmacist of information to the patient or caregiver in order to improve therapeutic outcome.
- ~~(26)~~(24) "Pharmaceutical care" is the responsible provision of drug therapy through, among other things, pharmacists identifying potential and actual drug-related problems and resolving and preventing drug-related problems, for the purpose of achieving definite outcomes that improve a patient's quality of life. The outcomes include but are not limited to cure of a disease, elimination or reduction of a patient's symptomatology, arresting or slowing of a disease process and the preventing of a disease or symptomatology.
- ~~(27)~~(25) "Pharmacy internship" is a period of practical pharmacy experience under the direct supervision of a licensed pharmacist and pursuant to the rules of the board.
- ~~(28)~~(26) "Pharmacy practice site" means any place within this state where prescription drugs or prescription devices are dispensed and where pharmaceutical care is provided, and any place outside of the state where prescription drugs or prescription devices are dispensed and pharmaceutical care is provided to persons residing in this state.
- ~~(29)~~(27) "Preceptor" means an individual who is currently licensed as a pharmacist and who meets the qualifications of a preceptor under the rules of the board and participates in the education of pharmacy interns.
- ~~(30)~~(28) "Prescription department" means the area of a pharmacy practice site in which prescription drugs and devices and related materials are stocked and medical and prescription orders are compounded and dispensed.
- ~~(31)~~(29) "Quality assurance" means a system for identifying problems in patient care that are resolved via administrative, clinical, or educational actions to ensure that final products and outcomes meet applicable specifications.
- ~~(32)~~(30) "Radiopharmaceutical service" means, but is not limited to:

(Rule 1140-01-.01, continued)

- (a) the compounding, dispensing, labeling, and delivering of radiopharmaceuticals;
 - (b) the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews;
 - (c) the proper and safe storage and distribution of radiopharmaceuticals;
 - (d) the maintenance of radiopharmaceutical quality assurance;
 - (e) the responsibility for advising, where necessary or where regulated, of the diagnostic and therapeutic value, hazards, and use of radiopharmaceuticals; and
 - (f) the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management, and control of a nuclear pharmacy practice site.
- ~~(33)~~~~(34)~~ "Reciprocity" means to issue a license to an applicant who furnishes satisfactory proof of licensing by examination in another state or territory pursuant to the rules of the board.
- ~~(34)~~~~(32)~~ "Shall" means that compliance is mandatory.
- ~~(35)~~~~(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.
- ~~(36)~~~~(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.
- ~~(37)~~~~(35)~~ "Third party pharmacy program" means any system of providing for the reimbursement of medical or prescription orders and/or pharmaceutical care services under a contractual arrangement or agreement between a provider of such services and the third party program administrator who is not the consumer of those services.
- ~~(38)~~~~(36)~~ "Third party pharmacy program administrator" means, but is not limited to, insurance companies, managed care organizations, health maintenance organizations, preferred provider organizations, pharmacy benefit managers, and pharmacy services administrative organizations.
- ~~(39)~~~~(37)~~ "Unit dose packaging" means that packaging which is designed to hold a quantity of a drug product intended for administration as a single dose.
- ~~(40)~~~~(38)~~ "USP" means the United States Pharmacopeia.
- ~~(41)~~~~(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. §§ 63-10-101, 63-10-102, 63-10-204, 63-10-216, 63-10-301, 63-10-304, 63-10-304(b)(1), 63-10-404(5), (6), (14), (22), (26), (28), and (29), 63-10-504(b)(1), and Chapter 966 of the Public Acts of 2008 §1. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010. Emergency rule filed January 31, 2014; effective through

(Rule 1140-01-.01, continued)

July 30, 2014. Emergency rule filed January 31, 2014 expired effective July 31, 2014. The rule reverted to its previous status. Amendment filed July 11, 2014; effective October 9, 2014.

1140-01-.02 VIOLATIONS CONSTITUTE UNPROFESSIONAL CONDUCT.

- (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. Administrative History:* Original rule certified June 7, 1974. Amendment filed August 14, 1974; effective September 13, 1974. Repeal filed January 11, 1977; effective February 10, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule filed January 31, 2014 expired effective July 31, 2014. The rule reverted to its previous status. Repeal and new rule filed July 11, 2014; effective October 9, 2014.

1140-01-.03 APPLICATION FOR A PHARMACIST LICENSE.

- (1) An applicant for a license to engage in the practice of pharmacy shall submit the following to the Board office at time of application:
 - (a) A completed application on a form approved by the Board;
 - (b) Application and registration fees 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 licensure application materials.
 - (d) Any application submitted which lacks required information or reflects a failure to meet any of the requirements for licensure 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 licensure 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) For the purpose of *T.C.A. § 63-10-506(d)*, a "recognized" college or school of pharmacy is a college or school of pharmacy which meets the minimum standards of the ACPE and appears in the ACPE "Annual Directory of Accredited Professional Programs of Colleges and Schools of Pharmacy."
- (3) No applicant shall be eligible for a license if the applicant has engaged in conduct or suffers a condition which would constitute grounds for revocation or suspension of a license under *T.C.A. § 63-10-505*, unless the applicant can show cause why a license should be issued.
- (4) No license shall be issued to a reciprocal applicant from a state which denies reciprocal privileges to a pharmacist currently licensed and in good standing in Tennessee.
- (5) 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.
- (6) An applicant initially licensed in another state and who wishes to obtain a Tennessee license may, in the discretion of the board, transfer to Tennessee the applicant's score on NAPLEX taken in another state. Provided, however, if the applicant has been licensed for twelve (12) or more months in another state, then the applicant shall apply for a license in Tennessee by reciprocity. No license shall be issued to a score transfer applicant from a state which denies

score transfer privileges to a pharmacist currently licensed and in good standing in Tennessee.

Authority: T.C.A. §§ 63-10-101, 63-10-102(a), 63-1-116, 63-10-202, 63-10-304, 63-10-306, 63-10-404(2), (13), (17), and (26), 63-10-404(2), (13), (17), and (26), 63-10-504(b)(1), 63-10-506, and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed January 4, 2012; effective April 3, 2012.

1140-01-.04 PHARMACY INTERNSHIP.

- ~~(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 five hundred (1,500) hours of pharmacy internship (practical pharmacy experience) under the instruction of a pharmacist in good standing, subject to all of the following conditions.~~
- (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 five hundred (1,500) hours must be acquired after enrollment in a recognized college or school of pharmacy; one thousand one hundred (1,100) of these hours may be acquired in pharmacy programs or demonstration projects structured by the college or school of pharmacy.~~
- (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 must 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.~~
- (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) Four hundred (400) of these hours may be acquired in non-traditional pharmacy internship programs which have received prior approval of the board.~~
- (c) Foreign pharmacy graduates shall complete five hundred (500) hours of pharmacy internship in Tennessee within a period of six (6) consecutive months.
- ~~(d) 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(29), and 63-10-504(b)(1).
Administrative History: Original rule filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed December 17, 1984; effective March 16, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.05 LICENSING EXAMINATIONS.

- (1) An applicant for an initial license to engage in the practice of pharmacy in the State of Tennessee shall take the National Association of Boards of Pharmacy (NABP) Multistate Pharmacy Jurisprudence Examination (MPJE®) and the NABP North American Pharmacy Licensing Examination (NAPLEX®), which shall be administered on the dates scheduled by the NABP. An applicant shall also meet the minimum acceptable passing scores on the NAPLEX® and MPJE® as established and nationally accepted.
- (2) An applicant to obtain a pharmacy license by reciprocity shall successfully complete the MPJE®.

- (3) In addition to completing the requirements in paragraph (1) of this rule, a pharmacy foreign graduate shall successfully complete the foreign pharmacy equivalency examination, the Test of Spoken English (TSE®) examination and any other requirements established by the NABP.
- (4) Any applicant who fails either the NAPLEX® or MPJE® may retake the examinations at any of the next examination dates scheduled by the NABP. If an applicant fails the NAPLEX® or MPJE® three (3) consecutive times, then the Board may require that applicant to take review courses prior to any following reexamination.

Authority: T.C.A. §§ 63-10-304 and 63-10-306. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed November 24, 2008; effective February 7, 2009.

1140-01-.06 SUMMARY SUSPENSION OF LICENSE.

Pursuant to T.C.A. § 4-5-320, if the board finds that public health, safety or welfare imperatively requires emergency action and incorporates a finding to that effect in its order, summary suspension of a license may be ordered pending proceedings for revocation or other action.

Authority: T.C.A. §§ 4-5-320, 63-10-101, 63-10-102, 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-505. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed November 15, 1989; effective December 30, 1989. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.07 INACTIVE LICENSES AND LICENSE REINSTATEMENT.

- (1) A pharmacist may apply for an inactive license by:
 - (a) Completing the biennial license renewal application form; and
 - (b) Paying the biennial renewal fee for an inactive license.
- (2) A pharmacist maintaining an active license to practice pharmacy in another state or jurisdiction is ineligible for inactive license status in Tennessee.
- (3) A pharmacist seeking active status for an inactive, delinquent, suspended or revoked license must fulfill the following minimum requirements.
 - (a) If the license has been inactive, delinquent, suspended or revoked for less than one (1) year, the pharmacist shall:
 1. Provide written notice to the board requesting an active license;
 2. Satisfy all past due continuing pharmaceutical education as required by the board; and
 3. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked.
 - (b) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than five (5) consecutive years, the pharmacist shall:
 1. Provide written notice to the board requesting an active license;

(Rule 1140-01-.07, continued)

2. Satisfy all past due continuing pharmaceutical education as required by the board;
 3. Successfully complete the jurisprudence examination;
 4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and
 5. Complete a period of pharmacy internship in Tennessee as follows.
 - (i) If the license has been inactive, delinquent, suspended or revoked from one (1) year to not more than three (3) consecutive years, one hundred sixty (160) hours within ninety (90) consecutive days.
 - (ii) If the license has been inactive, delinquent, suspended or revoked for more than three (3) consecutive years but not more than five (5) consecutive years, three hundred twenty (320) hours within one hundred eighty (180) consecutive days.
- (c) If the license has been inactive, delinquent, suspended or revoked for more than five (5) consecutive years, the pharmacist shall:
1. Provide written notice to the board requesting an active license;
 2. Satisfy all past due continuing pharmaceutical education as required by the board;
 3. Successfully complete the NAPLEX and jurisprudence examinations;
 4. Pay all cumulative license renewal fees and any applicable penalty fees for the period during which the license was inactive, delinquent, suspended or revoked; and
 5. Complete a period of pharmacy internship of three hundred twenty (320) hours within one hundred eighty (180) consecutive days.
- (d) Fulfill any other requirements which may be contained in any order of the board suspending or revoking the applicant's license.
- (e) The board shall consider a written notice requesting reinstatement of an inactive, delinquent, suspended or revoked license within ninety (90) days of the notice being received by the director.
- (f) The board shall consider a waiver upon request.

Authority: T.C.A. §§ 63-10-101, 63-10-102, 63-10-210, 63-10-404(17), and 63-10-504(b)(1).
Administrative History: Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed September 23, 1975; effective October 23, 1975. Amendment filed January 11, 1977; effective February 10, 1977. Amendment filed April 11, 1979; effective July 30, 1979. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed January 26, 1987; effective April 29, 1987. Repeal and new rule filed May 11, 1998; effective July 25, 1998.

1140-01-.08 APPLICATION FOR PHARMACY PRACTICE SITE, MANUFACTURER AND WHOLESALER/DISTRIBUTOR LICENSES.

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 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.~~
- (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 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.~~
- 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.

(Rule 1140-01-.08, continued)

~~(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.~~

(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.
5. Maintain records of prescription orders dispensed 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.

(Rule 1140-01-.08, continued)

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.

~~(b) Manufacturer or wholesaler/distributor.~~

(b) Manufacturer, outsourcing facility, oxygen supplier 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.~~

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 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.~~

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.

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

~~(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.~~

(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) 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.~~

(Rule 1140-01-.08, continued)

- (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.

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, 63-10-301, 63-10-304, 63-10-306, 63-10-404(18), (28), and (37), 63-10-504(b)(1), § 63-10-504(b)(2), and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed September 30, 1985; effective October 30, 1985. Amendment filed January 19, 1988; effective April 27, 1988. Amendment filed August 25, 1989; effective October 9, 1989. Amendment filed October 30, 1991; effective December 14, 1991. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule filed January 31, 2014 expired effective July 31, 2014. The rule reverted to its previous status. Amendments filed July 11, 2014; effective October 9, 2014.

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.

Authority: T.C.A. §§ 53-11-301, 53-11-302, 56-1-302(b)(1)(2), 63-10-102(a), 63-10-404(17), 63-10-504(1) and (2), 63-10-304(b)(1) and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Repeal and new rule filed February 7, 1983; effective March 9, 1983. Amendment filed April 12, 1990; effective July 29, 1990. Amendment filed November 17, 1994; effective March 30, 1995. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed December 23, 2009; effective March 23, 2010.

1140-01-.10 FEES.

- (1) An applicant for examination for a license as a pharmacist shall pay a fee of fifty dollars (\$50.00) plus cost of the examination and materials.

(Rule 1140-01-.10, continued)

- (2) An applicant for a reciprocal license or NAPLEX score transfer shall pay a fee of three hundred dollars (\$300.00).
- (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).
- (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)~~
- (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.~~
- (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 publish Pharmacy Drug Laws, Rules and Regulations electronically, and may make an electronic publication freely available on the Board's website.
- (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.
- (9) The fee for certification of license examination grades shall be twenty five dollars (\$25.00).
- ~~(10) The fee for a duplicate or revised pharmacist license wall certificate shall be twenty five dollars (\$25.00).~~

(Rule 1140-01-.10, continued)

- (10) The fee for any duplicate or revised license, registration, modifier or license wall certificate shall be twenty five dollars (\$25.00).
- (11) If any person fails to renew a license, such license may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
- (12) If any person fails to renew a license or registration certificate, such license or registration certificate may be reinstated upon complying with rule 1140-01-.07 and upon the payment of the appropriate renewal fee plus a penalty fee of ten dollars (\$10.00) for each month or fraction thereof that payment for renewal is delinquent. In the event such renewal is not procured within six (6) months from the date on which the last renewal became delinquent, the board may refuse to issue the renewal.
- (13) A penalty of fifty dollars (\$50.00) may, in the discretion of the board, attach to each failure of a licensee or registration certificate holder to provide any required notice to the director as may be required by the rules of the board.
- (14) Any licensee who wishes to modify the terms or conditions of 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 file those modifications with a non-refundable fee of five dollars (\$5.00).
- (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. §§ 4-5-202, 63-10-102(a), 63-10-216, 63-10-301, 63-10-304, 63-10-306, 63-10-308, 63-10-404(17), 63-10-504(b)(1), 63-10-504(b)(2), and 63-10-508. **Administrative History:** Original rule certified June 7, 1974. Amendment filed June 7, 1974; effective July 7, 1974. Amendment filed December 15, 1977; effective January 16, 1978. Amendment filed September 26, 1978; effective December 29, 1978. Repeal and new rule file February 7, 1983; effective March 9, 1983. Amendment filed May 23, 1986; effective August 12, 1986. Amendment filed January 26, 1987; effective April 29, 1987. Amendment filed October 1, 1987; effective January 27, 1988. Amendment filed November 18, 1989; effective February 28, 1989. Amendment filed October 18, 1990; effective January 29, 1991. Amendment filed May 3, 1991; effective August 28, 1991. Amendment filed December 22, 1992; effective March 31, 1993. Amendment filed June 25, 1993; effective September 28, 1993. Amendment filed October 19, 1996; effective February 28, 1996. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule filed January 31, 2014 expired effective July 31, 2014. The rule reverted to its previous status. Amendments filed July 11, 2014; effective October 9, 2014.

1140-01-.11 CONTROLLED SUBSTANCE REGISTRATION.

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

(Rule 1140-01-.12, continued)

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, 63-10-102(a), 63-10-404, 63-10-404(6), 63-10-504, 63-10-504(b)(1) and (2), and 63-10-508. **Administrative History:** Original rule filed October 30, 1991; effective December 14, 1991. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Amendment filed July 11, 2014; effective October 9, 2014.

1140-01-.12 STERILE PRODUCT REGISTRATION.

- (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.

(Rule 1140-01-.12, continued)

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-305, and 63-10-306. **Administrative History:** Original rule filed July 11, 2014; effective October 9, 2014.

1140-01-.13 STANDARDS FOR PHARMACIES AND PRESCRIPTION DEPARTMENT SECURITY.

A license to operate a new or remodeled pharmacy practice site, or an existing pharmacy practice site which changes location or ownership, will not be issued unless the pharmacy practice site meets the following standards.

- (1) The pharmacy practice site and equipment therein shall be maintained in a clean, sanitary, orderly and well-lighted condition, and all persons working in the pharmacy practice site shall be required to keep themselves and their apparel in a clean and sanitary condition.
- (2) All new or relocated pharmacies opening after July 1, 1998 shall provide a consultation area which offers sufficient privacy to the patient before a license will be issued. All existing pharmacies shall be in compliance with this requirement on or before January 1, 2000.
- (3) The prescription department at the pharmacy practice site shall meet the following standards.
 - (a) The department shall have necessary counters and storage space.
 - (b) The department shall have a representative stock of prescription drugs and devices and related materials sufficient to compound and dispense medical and prescription orders as indicated by experience.
 - (c) The department shall have the apparatus and equipment needed to compound and dispense medical and prescription orders properly.
 - (d) The department shall occupy a space of not less than one hundred eighty (180) square feet.
 - (e) The department shall have hot and cold running water and immediate area refrigeration.
 - (f) The department shall have a physical barrier sufficient to protect against unauthorized entry and pilferage of prescription drugs and devices and related materials.
 - (g) Keys or other access devices to the physical barriers shall be subject to the following standards.
 1. Only pharmacists practicing at the pharmacy and pharmacists authorized by the pharmacist in charge shall be in possession of any keys or other access devices.
 2. The pharmacist in charge shall place a key or other access device in a sealed envelope bearing the signature of the pharmacist in charge affixed across the seal and placed in a safe or vault in a secured place outside of the department. The key or access device may be used to allow emergency entrance to the department.
 - (h) Access to the department is restricted to pharmacists, pharmacy interns and pharmacy technicians who are practicing at the pharmacy. Other persons designated by the pharmacist in charge may be allowed access but only during hours that a pharmacist is on duty.

(Rule 1140-01-.13, continued)

- (i) Notwithstanding any rule or regulation to the contrary, a pharmacy which was established before June 6, 1945, and which serves food, and which has continuously had a soda fountain, may allow a customer to go through the pharmacy area to the restroom, and not be required to have a gate or door to separate the pharmacy from the restroom or other parts of the establishment.
- (4) All licenses and certificates of registration for a pharmacy practice site shall at all times be conspicuously displayed at the practice site.
- (5) If a pharmacy practice site is located in a mercantile establishment (such as a discount store, grocery store, department store, or other similar establishment), then such pharmacy practice site shall be:
 - (a) open for business during the same hours as the mercantile establishment, unless the pharmacy practice site is capable of being closed-off by physical barrier from floor to ceiling; and
 - (b) under the supervision of a pharmacist at all times; except as provided in rule 1140-03-.07.
- (6) The pharmacist shall not at any time be denied access to the prescription department of a pharmacy practice site located in a mercantile establishment; provided, however, that entry of the pharmacist at times when the pharmacy is closed to the public may be subject to reasonable and prudent conditions.
- (7) A pharmacy practice site where prescription drugs and devices and related materials are received, stored, compounded and dispensed shall not be opened for business or any other reason unless a licensed pharmacist is present. Furthermore, no medical or prescription order shall be dispensed except during the presence and under the direct supervision of a pharmacist.
- (8) Nothing in this rule applies to a pharmacy practice site or prescription department operating in an institutional facility.
- (9) In cases of practical difficulty or undue hardship, the board may permit exceptions to the standards specified in this rule.

Authority: T.C.A. §§ 63-10-404(28), 63-10-504(b)(1), and 63-10-504(b)(1) and (2). **Administrative History:** Original rule filed May 11, 1998; effective July 25, 1998. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule filed January 31, 2014 expired effective July 31, 2014. The rule reverted to its previous status. Rule filed July 11, 2014 and was previously numbered 1140-01-.12, but was changed effective October 10, 2014 with an addition of a new 1140-01-.12. Rule was renumbered 1140-01-.13.

1140-01-.14 STANDARDS FOR MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS. STANDARDS FOR MANUFACTURERS, OUTSOURCING FACILITIES, OXYGEN SUPPLIERS AND WHOLESALERS/DISTRIBUTORS.

~~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~~

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

(Rule 1140-01-.13, continued)

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. **Administrative History:** Original rule filed May 11, 1998; effective July 25, 1998. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule filed January 31, 2014 expired effective July 31, 2014. The rule reverted to its previous status. The rule reverted to its previous status. Rule previously was previously numbered 1140-01-.13, but was renumbered 1140-01-.14. with the addition of a new 1140-01-.12. Rule was filed July 11, 2014; effective October 9, 2014.

1140-01-.15 PRESCRIPTION DRUGS DISPENSED BY HEALTH DEPARTMENTS.

For purposes of T.C.A. § 63-10-405, the following drugs are hereby approved as not subject to abuse:

- (1) Tuberculosis Control Agents:
 - (a) Capreomycin Injection
 - (b) Cycloserine Capsules
 - (c) Ethambutol Tablets
 - (d) Ethionamide Tablets
 - (e) Isoniazid Tablets
 - (f) Para-Aminosalicyclate Tablets
 - (g) Pyrazinamide Tablets
 - (h) Rifampin Capsules
 - (i) Streptomycin Injection
 - (j) Tuberculin Skin Test (Mantoux only)
 - (k) Rifampin/Isoniazid
 - (l) Ofloxacin
 - (m) Rifampin-isoniazid-pyrazinamide
- (2) Venereal Disease Control Agents:
 - (a) Ampicillin Capsules
 - (b) Doxycycline Capsules
 - (c) Erythromycin Tablets
 - (d) Penicillin
 1. Benzathine Penicillin G Injection
 2. Procaine Penicillin G Injection

(Rule 1140-01-.15, continued)

- (e) Probenecid Tablets
 - (f) Spectinomycin Injection
 - (g) Tetracycline Capsules
 - (h) Ceftriaxone
 - (i) Ciprofloxacin
 - (j) Lidocaine Injection
 - (k) Azithromycin
 - (l) Acyclovir Tablets, Ointments
 - (m) Trichloroacetic Acid
 - (n) Salicylic Acid
 - (o) Podophyllin/Salicylic Acid
 - (p) Aldara (Imiquimod)
- (3) Biologicals/Immunizations:
- (a) Antiserums
 - (b) Antitoxins
 - (c) Immune Serum Globulin
 - (d) Toxoids
 - (e) Vaccines
 - (f) Antigens
- (4) Reproductive Health Agents:
- (a) Metronidazole Tablets
 - (b) Oral Contraceptives
 - (c) Podophyllin
 - (d) Prenatal Vitamins
 - (e) Triple Sulfa Vaginal Cream/Tabs
 - (f) Vaginal Antifungal Cream/Tabs
 - 1. Clotrimazole
 - 2. Miconazole

(Rule 1140-01-.15, continued)

3. Nystatin
 4. Terconazole (Terazole)
- (g) Amino-Cerv
 - (h) Nitrofurantoin
 - (i) Ibuprofen, 600 mg Tablets
 - (j) Metronidazole (vaginal jell)
 - (k) Fluconazole Tablets
 - (l) Clindamycin Vaginal Cream
 - (m) Premarin Tablets (for use in estrogen trials for the evaluation of atypical cells in certain inflammatory atrophic pap smears)
 - (n) Medroxyprogesterone Acetate Injectable (Depo Provera®)
 - (o) Norelgestromin/ethinyl estradiol transdermal system (Ortho Evra®)
 - (p) Etonogestrel/ethinyl estradiol vaginal ring (Nuvaring®)
- (5) Child Health Agents:
- (a) Fluoride Tablets and Drops
 - (b) Lindane Cream, Lotion, Shampoo
 - (c) Mebendazole Tablets
 - (d) Pyrantel Pamoate Liquid
 - (e) Sulfadiazine Tablets
 - (f) Trimethoprim and Sulfamethoxazole
 - (g) Permethrin
 - (h) Crothamiton
 - (i) Nystatin Oral Suspension
 - (j) Nystatin Triamcinolone Cream
 - (k) Ibuprofen, Suspension Liquid
- (6) Emergency Agents:
- (a) Aminophylline Injection
 - (b) Benztropine Injection

(Rule 1140-01-.15, continued)

- (c) Diphenhydramine Injection
 - (d) Epinephrine Injection
 - (e) Glucagon Injection
 - (f) Hydralazine Injection
 - (g) Hydrocortisone Sodium Succinate
 - (h) Insulin, Regular
 - (i) Intravenous Fluids
 - (j) Oxygen
 - (k) Phenylephrine Injection
 - (l) Sodium Bicarbonate Injection
 - (m) Atropine Injection
 - (n) Nitroglycerin Sublingual Tablets
 - (o) Dexamethasone Injection
 - (p) Norepinephrine
- (7) Antihypertensive Agents:
- (a) Methyldopa
 - (b) Reserpine
 - (c) Hydrochlorothiazide
 - (d) Hydralazine
 - (e) Propranolol
 - (f) Potassium Supplements
 - (g) Nicotine Patches

Authority: T.C.A. §§ 63-10-404(14), 63-10-205, 63-10-304, 63-10-304(b)(1), 63-10-405, 63-10-504(b), 63-10-504(b)(1), and 63-10-504(b)(2). **Administrative History:** Original rule filed May 11, 1998; effective July 25, 1998. Amendment filed August 19, 2002; effective November 2, 2002. Amendment filed November 24, 2008; effective February 7, 2009. Amendment filed December 23, 2009; effective March 23, 2010. Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule filed January 31, 2014 expired. Rule reverted on July 31, 2014 to its previous status. Rule was previously numbered 1140-01-.14 but was renumbered 1140-01-.15 with the addition of a new 1140-01-.12. Rule filed July 11, 2014; October 9, 2014.

1140-01-.16 RESERVED.

Authority: T.C.A. §§ 63-10-301, 63-10-304, 63-10-3-5, and 63-10-308. **Administrative History:** Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rule filed January 31, 2014 expired. The rule reverted to reserved status on July 31, 2014. The rule reverted to its previous status. Rule was previously numbered 1140-01-.15, but renumbered 1140-01-.16 with the addition of a new 1140-01-.12. Rule filed July 11, 2014; effective October 9, 2014.

**RULES
OF
THE TENNESSEE BOARD OF PHARMACY**

**CHAPTER 1140-09
MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS
Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesalers/Distributors**

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1140-09-.01 MANUFACTURER AND WHOLESALER/DISTRIBUTOR LICENSING. ~~Manufacturer, Outsourcing Facility, Oxygen Supplier and Wholesaler/Distributor Licensing.~~

- ~~(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.~~
- (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.
- (2) An applicant with physical facilities in this state must obtain and display prominently a separate license for each principal place of business where the applicant manufactures or distributes prescription drugs and prescription devices.
- (3) The requirement of a license shall not apply to the following types of distributions:
- (a) Intracompany sales;
 - (b) The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
 - (c) The sale, purchase or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
 - (d) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control; for purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization whether by ownership of stock, voting rights, by contract or otherwise;
 - (e) The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons; for purpose of this subparagraph,

(Rule 1140-09-.01, continued)

"emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy practice site to alleviate a temporary shortage;

- (f) The sale, purchase, or trade of a prescription drug, an offer to sell, purchase or trade a prescription drug, or the dispensing of a prescription drug pursuant to a medical or prescription order;
- (g) The distribution of prescription drug samples by manufacturers' representatives; or
- (h) The sale, purchase, or trade of blood and blood components intended for transfusion.
- (i) The sale, purchase, or trade of a prescription drug, or an offer to sell, purchase or trade of a prescription drug by a pharmacy practice site to another pharmacy practice site or to authorized prescribing practitioners, except that the total gross dollar volume of such transfers shall not exceed five percent (5%) of the total medical and prescription orders sales revenue of either the transferor or transferee pharmacy during any twelve (12) consecutive month period.

Authority: T.C.A. § 63-10-204, 63-10-304, 63-10-305, 63-10-306, 63-10-404(2), (8), (14), (18), (37), 63-10-504(b)(1), and 63-10-506(f). **Administrative History:** Original rule filed January 7, 1992; effective February 21, 1992. 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. Amendment filed July 11, 2014; effective October 9, 2014.

1140-09-.02 MINIMUM INFORMATION REQUIRED.

- ~~(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;~~
 - ~~(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 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~~

(Rule 1140-09-.02, continued)

- ~~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;~~
- ~~(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.~~
- (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

(Rule 1140-09-.02, continued)

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 obtain a sterile compounding modifier registration 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, 63-10-306, 63-10-404 (2), (18), (37), 63-10-504(b)(1), and 63-10-506(f). **Administrative History:** Original rule filed January 7, 1992; effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. Amendments filed July 11, 2014; effective October 9, 2014.

1140-09-.03 MINIMUM QUALIFICATIONS.

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

(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:

- (a) Any convictions of the applicant under any federal, state, or local laws relating to drug samples or distribution of controlled substances;

(Rule 1140-09-.03, continued)

- (b) Any felony convictions of the applicant under federal, state, or local laws;
 - (c) The applicant's past experience in the manufacturing or distribution of prescription drugs and prescription devices, including controlled substances;
 - (d) The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distribution;
 - (e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances, prescription drugs and prescription devices;
 - (f) Compliance with licensing requirements under previously granted licenses, if any;
 - (g) Compliance with requirements to maintain and/or make available to the board or to federal, state, or local law enforcement officials those records required federal, state or local laws; and
 - (h) Any other factors or qualifications the board considers relevant to and consistent with the public health and safety.
- (2) The board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be in the public interest.

Authority: T.C.A. § 63-10-404, 63-10-404 (2), (6), (8), (14), (18), (37), 63-10-504, and 63-10-504(b)(1).
Administrative History: Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1999, effective July 25, 1998. Emergency rules filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. Amendment filed July 11, 2014; effective October 9, 2014.

1140-09-.04 PERSONNEL.

~~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.~~

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~~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.~~

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Authority: T.C.A. § 63-10-404, 63-10-404 (2), (18), (37), 63-10-504, and 63-10-504(b)(1).
Administrative History: Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. Amendment filed July 11, 2014; effective October 9, 2014.

1140-09-.05 MINIMUM REQUIREMENTS FOR GENERAL OPERATION.

~~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:~~

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~~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.~~

(Rule 1140-09-.05, continued)

- (1) Facilities. All facilities at which prescription drugs and prescription devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:
 - (a) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
 - (b) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
 - (c) Have a quarantine area for storage of prescription drugs and prescription devices that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
 - (d) Be maintained in a clean and orderly condition, and
 - (e) Be free from infestation by insects, rodents, birds, or vermin of any kind.
- (2) Security.
 - (a) All facilities shall be secure from unauthorized entry.
 1. Access from outside the premises shall be kept to a minimum and be well-controlled.
 2. The outside perimeter of the premises shall be well-lighted.
 3. Entry into areas where prescription drugs and prescription devices are held shall be limited to authorized personnel.
 - (b) All facilities shall be equipped with an alarm system to detect entry after hours.
 - (c) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
- (3) Storage. All prescription drugs and prescription devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs and devices, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).
 - (a) If no storage requirements are established for a prescription drug or prescription device it may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that identity, strength, quality, and purity are not adversely affected.
 - (b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs and prescription devices.
 - (c) The record keeping requirements in paragraph (6) of this section shall be followed for all prescription drugs and prescription devices.
- (4) Examination of materials.

(Rule 1140-09-.05, continued)

- (a) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
 - (b) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
 - (c) The record keeping requirements in paragraph (6) of this section shall be followed for all incoming and outgoing prescription drugs.
- (5) Returned, damaged, and outdated prescription drugs and prescription devices.
- (a) Prescription drugs and prescription devices that are outside, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs and prescription devices until destroyed or returned.
 - (b) Any prescription drugs and prescription devices whose immediate or sealed outer or sealed secondary containers have been opened or used shall be quarantined and physically separated from other prescription drugs and prescription devices until either destroyed or returned.
 - ~~(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.~~
 - (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.
 - (d) The record keeping requirements in paragraph (6) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and prescription devices.
- (6) Record keeping.
- ~~(a) Manufacturers and wholesalers/distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition~~

(Rule 1140-09-.05, continued)

~~of prescription drugs and prescription devices. These records shall include the following information:~~

- (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:
1. The source of the prescription drugs and prescription devices including the name and principal address of the seller or transferor, and the address of the location from which the prescription drugs and prescription devices were shipped;
 2. The identity and quantity of the prescription drugs and prescription devices received and distributed or disposed of; and
 3. The dates of receipt and distribution or other disposition of the prescription drugs and prescription devices.
- (b) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the prescription drugs and prescription devices.
- (c) Records described in this paragraph that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.
- ~~(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:~~
- (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:
- (a) A procedure whereby the older approved stock of a prescription drug or prescription device is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.
 - (b) A procedure to be followed for handling recalls and withdrawals of prescription drugs and prescription devices. Such procedures shall be adequate to respond to recalls and withdrawals due to:
 1. Any action initiated at the request of the United States Food and Drug Administration or other federal, state, or local law enforcement or other government agency, including the board;

(Rule 1140-09-.05, continued)

- ~~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~~
 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
 3. Any action undertaken to promote public health and safety by replacing of an existing product with an improved product or new package design.
- (e) ~~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.~~
- (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 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.~~
- (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 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.~~
- (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 and wholesalers/distributors shall operate in compliance with applicable federal, state, and local laws and regulations.~~
- (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 and wholesalers/distributors shall permit the board and authorized federal, state, and local law enforcement officials to enter and inspect premises and~~

(Rule 1140-09-.05, continued)

~~delivery vehicles, and to audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.~~

- (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 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.~~
- (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 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~~
- (10) Salvaging and reprocessing. Manufacturers, outsourcing facilities, oxygen suppliers and wholesalers/distributors shall be subject to the provisions of any applicable federal, state, and 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, 63-10-404 (8), (18), (33), (37), and 63-10-504(b)(1). **Administrative History:** Original rule filed January 7, 1992 effective February 21, 1992. Repeal and new rule filed May 11, 1998; effective July 25, 1998. Emergency rules filed January 31, 2014 expired effective July 31, 2014. The rules reverted to their previous status. Amendment filed July 11, 2014; effective October 9, 2014.

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.~~

(Rule 1140-09-.05, continued)

- ~~(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.~~

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

- (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. **Administrative History:** Emergency rule filed January 31, 2014; effective through July 30, 2014. Emergency rules filed January 31, 2014 expired effective July 31, 2014. The rules reverted to reserved status. Original rule filed July 11, 2014; effective October 9, 2014.