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Sequence Number:	02-01-22
Rule ID(s):	9670
File Date:	2/1/2022
Effective Date:	5/2/2022

Rulemaking Hearing Rule(s) Filing Form

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

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

Agency/Board/Commission:	Board of Pharmacy
Division:	
Contact Person:	Matthew Gibbs, Deputy General Counsel
Address:	665 Mainstream Drive, Nashville, TN
Zip:	37243
Phone:	(615) 741-1611
Email:	Matthew.Gibbs@tn.gov

Revision Type (check all that apply):

___ Amendment
X New
___ Repeal

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 Please make sure that **ALL** new rule and repealed rule numbers are listed in the chart below.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

Chapter Number	**Chapter Title**
1140-09	Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesalers/Distributors
Rule Number	**Rule Title**
1140-09-.07	Inspections of Manufacturers and Wholesalers/Distributors of Medical Devices

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

Chapter 1140-09
Manufacturers, Outsourcing Facilities, Oxygen Suppliers and Wholesalers/Distributors
New Rule Section

Table of Contents

Authority: T.C.A. §§ 63-10-304; 63-10-306, and 63-10-311.

Rule 1140-09-.07. Inspections of Manufacturers and Wholesalers/Distributors of Medical Devices.

(1) Between December 1 and December 31 of each calendar year, manufacturers and wholesalers/distributors of a medical device shall submit any of the documents referenced in paragraphs (1)(a) – (c), below, which shall demonstrate immediate and continuous compliance with any and all federal and state laws and regulations and shall serve in lieu of a physical, on-site inspection conducted by the Board, subject to paragraph 3, below:

(a) A Form 482 issued by the United States Food and Drug Administration ("FDA") as evidence of a facility inspection, and, if applicable, a response letter, as documented on a Form 483, from the FDA that indicates responses to the most recent inspection findings and demonstrates no further action is warranted by the manufacturer, wholesaler/distributor or FDA; or

(b) Documented evidence, such as International Organization for Standardization ("ISO") 13485 certification number, date of visit and expiration date of certificate, from a Notified Body that the firm is in good standing and their ISO 13485 certification is valid. Responses may include dates of Phase 1 and Phase 2 assessments from a Notified Body/Registrar in the certification process; or

(c) Evidence of successful Medical Device Single Audit Program certification. Alternatively, a report including corrective action plans for a Medical Device Single Audit Program certification and approval.

(2) Failure to submit documents referenced in subparagraphs 1(a) – (c), above, or submission of a self-audit which does not demonstrate immediate and continuous compliance with any and all federal and state laws and regulations may result in a request from the Board for the production of any and all corresponding documents related to any mandatory reporting or compliance requirements directed by the federal government or its agencies, the International Standards Organization or the Medical Device Single Audit Program.

(3) Notwithstanding any rule provision to the contrary, the Board retains authority to conduct any inspection or investigation of a manufacturer or wholesalers/distributors of a medical device when, in the Board's sole determination, public health, safety, and welfare necessitates such an inspection or investigation.

Authority: T.C.A. §§ 63-10-304; 63-10-306, and 63-10-311.

* 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)
Dr. Katy Wright			X		
Dr. Adam Rodgers	X				
Dr. Shanea McKinney	X				
Mr. Jake Bynum	X				
Dr. Rissa Pryse	X				
Dr. Melissa McCall				X	
Dr. Richard Breeden	X				

I certify that this is an accurate and complete copy of rulemaking hearing rules, lawfully promulgated and adopted by the Board of Pharmacy on 09/14/2021, 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: 06/16/2021

Rulemaking Hearing(s) Conducted on: (add more dates). 09/14/2021

Date: January 14, 2022

Signature:

Name of Officer: Matthew Gibbs

Title of Officer: Deputy General Counsel, Department of Health

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Agency/Board/Commission: Board of Pharmacy

Rule Chapter Number(s): 1140-09

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.

Herbert H. Slatery III

Herbert H. Slatery III
Attorney General and Reporter

1/21/2022

Date

Department of State Use Only

Filed with the Department of State on: 2/1/2022

Effective on: 5/2/2022

Tre Hargett

Tre Hargett
Secretary of State

RECEIVED
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Division of Publications

Public Hearing Comments

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

There were no oral comments at the rulemaking hearing. Also, there were no changes to the text of the rule language.

Attached hereto are written comments received by the Department of Health which support this rule change. Smith and Nephew; Medtronic; Life Science Tennessee; and Relay Life Science submitted the comments. The comment from Smith and Nephew also asked the Board of Pharmacy for general guidance as to the types of circumstances where the Board may utilize its sole discretion to initiate an inspection or investigation. The Board considered this request. Counsel for the Board indicated the difficulty in predicting each scenario where the Board may use its discretion and further indicated this type of guidance is best suited for a policy once the rule becomes effective.

Regulatory Flexibility Addendum

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

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

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

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

The proposed rules are established with clarity, conciseness, and lack of ambiguity to the extent the concepts of the rule are utilized by the medical device industry.

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

The rules are created for the purpose of flexible compliance with the Tennessee Board of Pharmacy's inspection obligations.

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

The proposed rules allow a full calendar year to eclipse before documentation is required.

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

The proposed rules cannot be consolidated or simplified.

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

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

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

The entire purpose of the rule is to create an exception to physical inspections.

Impact on Local Governments

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

The proposed rule 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;

The proposed rules allow manufacturers and wholesalers/distributors of a medical device ("M/D") to submit one of three different types of documentation to serve in lieu of a physical inspection by the Board.

(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;

Manufacturers and wholesalers/distributors of medical devices are afforded the opportunity to demonstrate regulatory compliance through multiple types of third-party inspections, assuming all necessary, supporting documentation is properly submitted. The intended impact of the proposed rule is a regulatory process which eliminates duplicity for manufacturers and wholesalers/distributors of medical devices.

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

None.

(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 impact revenues or expenditures.

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

Matthew Gibbs, Deputy 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;

Matthew Gibbs, Deputy 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

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

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

None.

Smith & Nephew, Inc.
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Memphis, TN 38116
Tennessee, USA

T: + 1-901-396-2121
T: + 1-800-821-5700 (USA toll free)
www.smith-nephew.com

September 10, 2021

Mr. Matthew Gibbs
Senior Associate Counsel
Tennessee Department of Health
665 Mainstream Drive
Nashville, TN 37243

RE: Board of Pharmacy Rulemaking; Inspections of manufacturers and distributors of medical devices [Rule No. 1140-09-.07]

Dear Mr. Gibbs:

On behalf of Smith & Nephew, Inc. (S+N), I wish to submit comments in advance of the September 14 Board of Pharmacy (Board) rulemaking hearing regarding inspections of manufacturers and distributors of medical devices.

S+N is a portfolio medical technology business that exists to restore people's bodies and their self-belief by using technology to take the limits off living. We call this purpose "Life Unlimited." Our more than 17,500 employees—including more than 2,200 working in Tennessee—deliver this mission every day, making a difference to patients' lives through the excellence of our product portfolio, and the invention and application of new technologies across our three global franchises of Orthopedics, Advanced Wound Management, and Sports Medicine & ENT.

S+N supports the proposed rule, which would allow medical device manufacturers and distributors to maintain regulatory compliance with the State by submitting evidence of a U.S. Food and Drug Administration inspection, ISO 13485 certification, or successful Medical Device Single Audit Program certification. By relying on these well-recognized standards, the Board can streamline its oversight process while continuing to ensure a high standard of safety.

Given that the Board is maintaining the "sole discretion" to initiate an inspection or investigation, it would be helpful if the Board could provide additional guidance to companies as to the types of circumstances under which the Board might find it necessary to conduct an inspection or investigation if submitted documents are otherwise valid and satisfactory.

We appreciate the thoughtful dialogue that led to the development of this rule and look forward to working with the Board as this policy is implemented.

Sincerely,

Paul A. Seltman

Paul A. Seltman
Senior Vice President, Global Public Policy & Government Affairs

Medtronic
1800 Pyramid Place, Memphis, TN 38132
4340 Swinnea Road, Memphis, TN 38118

September 13, 2021

Mr. Matthew Gibbs
Senior Associate Counsel
Tennessee Department of Health
665 Mainstream Drive
Nashville, TN 37243

RE: Board of Pharmacy Rulemaking; Inspections of manufacturers and distributors of medical devices [Rule No. 1140-09-.07]

Dear Mr. Gibbs:

On behalf of Medtronic, Inc., I wish to convey our company's support for the Tennessee Board of Pharmacy's proposed Rule No. 1140-09-.07 regarding inspection of medical device manufacturers and distributors. In my role as head of Quality for our Cranial and Spinal Technologies Operating Unit, whose Spine headquarters is based in Tennessee, I have a unique perspective regarding the importance of patient and product safety.

You may be aware that Medtronic has a more than seventy-year-old mission founded on "alleviating pain, restoring health, and extending life." Our medical products and therapies cover some 78 different disease states which help improve the lives of two people every second across the world. In Tennessee, Medtronic employs 1,442 residents with more than 1,200 in or around the Shelby County and greater Memphis area. Our Tennessee employees create an annual payroll of $109 million and generate nearly half a million in charitable contributions, and throughout the last year supported various needs by giving 26,389 community service hours across Tennessee.

For several years, Medtronic has worked alongside many stakeholders within the medical device industry, including Life Science Tennessee, to help find solutions that ensure patient safety while also streamlining the regulatory processes between federal and state compliance. Our company supports this Rule which is intended to permit medical device manufacturers and distributors with an efficient, compliant way to maintain regulatory compliance with Tennessee by submitting evidence of a U.S. Food and Drug Administration inspection (FDA), ISO 13485 certification, or by submitting a successful Medical Device Single Audit Program certification. The Board of Pharmacy should be able to use these long-accepted standards to streamline its oversight process while continuing to ensure a high level of safety.

We appreciate the thoughtful engagement with medical device industry to draft this Rule and look forward to working with the Board as this policy is implemented.

Sincerely,

Alison Webster

Alison Webster
Vice President, Quality
Medtronic Cranial and Spinal Technologies

LIFE SCIENCE
TENNESSEE

September 10, 2021

Mr. Matthew Gibbs
Senior Associate Counsel
Tenneesee Department of Health
665 Mainstream Dr.
Nashville, TN 37243

Dear Mr. Gibbs:

Life Science TN supports the TN Board of Pharmacy proposed Rule No. 1140-09-.07 regarding inspection of medical device manufacturers and distributors. We'd like to thank the Board of Pharmacy for working with Tennessee's medical device industry to find a solution that ensures patient safety while also streamlining the regulatory process between for federal and state compliance.

According to the most recent report released last year from the Biotechnology Innovation Organization (BIO) and TEConomy, the medical device industry in Tennessee supports more than 9,000 direct jobs in the state at an average wage of more than $93,000. The report also states there are more than 160 medical device establishments across our state.

We feel the new rule supports the expansion of our industry in Tennessee while also ensuring patient safety.

Sincerely,

Abby Trotter
Executive Director

From:	Jim Monsor
To:	Matthew Gibbs
Cc:	Abby Trotter
Subject:	[EXTERNAL] Proposed Rule No. 1140-09-.07
Date:	Monday, September 13, 2021 12:10:44 PM

***** This is an EXTERNAL email. Please exercise caution. DO NOT open attachments or click links from unknown senders or unexpected email - STS-Security. *****

Matthew Gibbs
Board of Pharmacy
TN Department of Health
Via email: matthew.gibbs@tn.gov

Dear Mr. Gibbs:

I write to express my support for proposed Rule No. 1140-09-.07 regarding the regulation and inspection of medical device manufacturing and distribution facilities in Tennessee. From the perspective of over 37 years of experience working with large and small medical device manufactures in Tennessee and across the country, I feel this proposed rule will streamline the inspection process for the industry while ensuring the safety of Tennesseans. This new regulation will rely on processes and procedures recognized by national and international regulatory bodies which ensure medical device manufacturers' compliance to quality management systems regulations for the design and manufacturing of devices across the globe.

I thank you for working with the industry on this matter and I look forward to supporting the rule's implementation as I am able.

Sincerely,
Jim Monsor

Relay Life Science

Jim Monsor / CEO, Co-Founder
jmonsor@relaylifescience.com / (615) 497-2657

Relay Life Science
relaylifescience.com

RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-09
MANUFACTURERS, OUTSOURCING FACILITIES, OXYGEN SUPPLIERS AND WHOLESALERS/DISTRIBUTORS

TABLE OF CONTENTS

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.

(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, "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;

(Rule 1140-09-.01, continued)

(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.

(4) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

***Authority**: T.C.A. §§ 63-10-204, 63-10-304, 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. Amendments filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-09-.02 MINIMUM INFORMATION REQUIRED.

(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;

(Rule 1140-09-.02, continued)

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.

(5) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-305, and 63-10-306.* ***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. Repeal and new rule filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017.*

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, 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;

(b) Any felony convictions of the applicant under federal, state, or local laws;

(Rule 1140-09-.03, continued)

(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.

(3) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-404, 63-10-404(2), (6), (8), (14), (18), (37), 63-10-304, 63-10-305, 63-10-306, 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. Amendment filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017.*

1140-09-.04 PERSONNEL.

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.* ***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. Repeal and new rule filed March 24, 2015; effective June 22, 2015.*

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, outsourcing facilities, oxygen suppliers and wholesalers/distributors:

(1) Facilities. All facilities at which prescription drugs and prescription devices are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(Rule 1140-09-.05, continued)

(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.

(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.

(Rule 1140-09-.05, continued)

(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, 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, 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.

(Rule 1140-09-.05, continued)

(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, 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;

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.

(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.

(Rule 1140-09-.05, continued)

(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.

(11) Upon request, the Board may waive selected portions of these requirements so long as any waiver granted is consistent with the Board's authority under Tenn. Code Ann. Title 63, Chapters 1 and 10, and Tenn. Code Ann. Title 4, Chapter 5.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, 63-10-305, 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. Amendments filed March 24, 2015; effective June 22, 2015. Amendments filed November 22, 2016; effective February 20, 2017.*

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

(Rule 1140-09-.05, continued)

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.* ***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. Repeal and new rule filed March 24, 2015; effective June 22, 2015.*

1140-09-.07 INSPECTIONS OF MANUFACTURERS AND WHOLESALERS/DISTRIBUTORS OF MEDICAL DEVICES.

(1) Between December 1 and December 31 of each calendar year, manufacturers and wholesalers/distributors of a medical device shall submit any of the documents referenced in paragraphs (1)(a) – (c), below, which shall demonstrate immediate and continuous compliance with any and all federal and state laws and regulations and shall serve in lieu of a physical, on-site inspection conducted by the Board, subject to paragraph 3, below:

(a) A Form 482 issued by the United States Food and Drug Administration ("FDA") as evidence of a facility inspection, and, if applicable, a response letter, as documented on a Form 483, from the FDA that indicates responses to the most recent inspection findings and demonstrates no further action is warranted by the manufacturer, wholesaler/distributor or FDA; or

(b) Documented evidence, such as International Organization for Standardization ("ISO") 13485 certification number, date of visit and expiration date of certificate, from a Notified Body that the firm is in good standing and their ISO 13485 certification is valid. Responses may include dates of Phase 1 and Phase 2 assessments from a Notified Body/Registrar in the certification process; or

(c) Evidence of successful Medical Device Single Audit Program certification. Alternatively, a report including corrective action plans for a Medical Device Single Audit Program certification and approval.

(2) Failure to submit documents referenced in subparagraphs 1(a) – (c), above, or submission of a self-audit which does not demonstrate immediate and continuous compliance with any and all federal and state laws and regulations may result in a request from the Board for the production of any and all corresponding documents related to any mandatory reporting or compliance requirements directed by the federal government or its agencies, the International Standards Organization or the Medical Device Single Audit Program.

(3) Notwithstanding any rule provision to the contrary, the Board retains authority to conduct any inspection or investigation of a manufacturer or wholesalers/distributors of a medical device when, in the Board's sole determination, public health, safety, and welfare necessitates such an inspection or investigation.

Authority: T.C.A. §§ 63-10-304; 63-10-306, and 63-10-311.