RULES
OF
THE TENNESSEE BOARD OF PHARMACY

CHAPTER 1140-16
THIRD-PARTY LOGISTICS PROVIDER

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1140-16-.01 PURPOSE.

Pursuant to 21 U.S.C. § 360eee-4(b)(2) (2013), a Third-Party Logistics Provider (3PL), as defined, shall be licensed separately from a wholesale distributor.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, and 63-10-306.* ***Administrative History:*** *Original rules filed September 12, 2018; effective December 11, 2018.*

1140-16-.02 THIRD-PARTY LOGISTICS PROVIDER LICENSING.

(1) Before any 3PL provides or coordinates warehousing or other logistics services within this state for a prescription drug and/or prescription device on behalf of a manufacturer, wholesale distributor, or dispenser the 3PL shall be licensed by the Board in accordance with this Chapter whether physically located within this state or outside this state. Where operations are conducted at more than one location, each such location shall be licensed by the Board. A warehouse provided by a 3PL shall be inspected by the Board's inspector(s) or inspectors of the state where the warehouse is physically located prior to providing services.

(2) A 3PL that coordinates with facilities that are engaged in the act of wholesale drug distribution and are also located outside of this state, shall provide documentation to the Board within 60 days of issuance of a 3PL license that each facility used by the 3PL has received either:

(a) A Verified-Accredited Wholesale Distributors accreditation from the National Association of Boards of Pharmacy;

(b) A manufacturer, wholesaler, or distributor license issued by the Board, including any license modifiers and/or additional registrations; or

(c) A manufacturer, wholesaler, or distributor license issued by the state where the facility is physically located, including any license modifiers and/or additional registrations.

(3) Failure to provide the required documentation within 60 days of the issuance of a 3PL license or within 60 days from any change in status of any previously submitted documentation may result in disciplinary action.

(4) Each manufacturer, wholesaler, or distributor that ships prescription drugs and/or prescription devices into or from the State of Tennessee shall be licensed by the Board accordingly and shall comply with all requirements of Tenn. Comp. R. & Regs. 1140-01-.08 and 1140-09-.01 *et. seq*.

(5) Each wholesale distributor, who is also engaged in providing 3PL services, as defined in Tenn. Code Ann. § 63-10-204(46), shall obtain a license to operate as a wholesale distributor

(Rule 1140-16-.02, continued)

issued by the Board and shall obtain a separate license to operate as a 3PL issued by the Board.

(6) An applicant with physical facilities located 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/or prescription devices.

(7) Any 3PL that obtains controlled substances shall obtain the Board's controlled substance registration in accordance with Tenn. Comp. R. & Regs. 1140-01-11.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, and 63-10-306.* ***Administrative History:*** *Original rules filed September 12, 2018; effective December 11, 2018.*

1140-16-.03 MINIMUM INFORMATION REQUIRED.

(1) The Board shall require the following minimum information from an applicant applying for a license to operate as a 3PL or any renewal of such license:

(a) All trade or business names used by the 3PL (includes "is doing business as" and "formerly known as"), full business address, and telephone number of the 3PL;

(b) Addresses, telephone numbers, and the names of contact persons for all facilities used by the 3PL for storage, handling, and distribution;

(c) The name and contact information of the owner, the owner's agent, or another such individual employed at or contracted by the applicant who can be reached at any time by the Board, 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;

(d) A list of all state and federal licenses, registrations, or permits, including the number of each such license, registration, or permit issued to the 3PL by any other state and federal authority authorizing the 3PL to possess and/or distribute prescription drugs, and including any disciplinary action taken against the 3PL and/or its principals, owners, directors, or officers;

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

(f) The name(s) of the owner and operator of the 3PL, 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. United States Drug Enforcement Administration (DEA) registration number if applicable; and

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6. The results of a criminal background check for the owner and manager of the 3PL seeking licensure, submitted directly to the Board by the vendor identified in the Board's licensure application materials.

(2) Changes in any information in paragraphs (1)(a) through (f) of this rule shall be submitted in writing to the Board within one business day of the change.

Authority: *T.C.A. §§ 63-10-204, 63-10-304, and 63-10-306.* ***Administrative History:*** *Original rules filed September 12, 2018; effective December 11, 2018.*

1140-16-.04 MINIMUM QUALIFICATIONS.

(1) The Board shall consider, at a minimum, the following factors in reviewing an application for a license as a 3PL:

(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;

(c) The applicant's past experience in the distribution of prescription drugs and/or prescription devices, including controlled substances;

(d) The furnishing by the applicant of false or fraudulent material in any application made in connection with distribution;

(e) Suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant for the distribution of any drugs, including controlled substances, prescription drugs and/or 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 by 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, and 63-10-306.* ***Administrative History:*** *Original rules filed September 12, 2018; effective December 11, 2018.*

1140-16-.05 PERSONNEL. The Board shall require that personnel employed by a 3PL 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, and 63-10-306.* ***Administrative History:*** *Original rules filed September 12, 2018; effective December 11, 2018.*

1140-16-.06 MINIMUM REQUIREMENTS FOR GENERAL OPERATION. The following shall be the minimum requirements for the storage and handling of prescription drugs and/or prescription devices and for the establishment and maintenance of prescription drug and/or prescription device distribution records by a 3PL:

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

3. Entry into areas where prescription drugs and/or 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.

(d) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting.

(e) All common carriers used by a 3PL shall ensure security via one of the following:

1. A verifiable security system; or

2. A Board-approved accreditation or certification program.

(3) Storage. All prescription drugs and/or prescription devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in

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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, the prescription drug may be held at "controlled" room temperature, as defined in an official compendium such as USP-NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of prescription drugs and/or devices.

(c) Packaging of the prescription drugs and/or devices shall be in accordance with an official compendium such as USP-NF and identify any compromise in the integrity of the prescription drugs and/or devices due to tampering or adverse storage conditions.

(d) Controlled substance drugs shall be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

(e) The record keeping requirements in paragraph (7) of this Rule shall be followed for the distribution of all prescription drugs and/or devices.

(4) Reporting. A 3PL must comply with all reporting requirements and must exchange transaction history, transaction information, and transaction statements with authorized trading partners in accordance with all applicable state and federal reporting requirements.

(5) 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 and/or prescription devices 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 and/or prescription devices products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(6) Returned, damaged, and outdated prescription drugs and prescription devices.

(a) Prescription drugs prescription devices that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs and/or prescription devices until destroyed or returned.

(b) Any prescription drugs and/or 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/or prescription devices until either destroyed or returned.

(c) If the conditions under which a prescription drug and/or prescription device has been returned cast doubt on safety, identity, strength, quality, or purity, then the prescription drug and/or prescription device shall be destroyed, or returned, unless examination, testing, or other investigation proves that the prescription drug and/or prescription device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a prescription drug and/or prescription

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device has been returned cast doubt on safety, identity, strength, quality, or purity, the 3PL shall consider, among other things, the conditions under which the prescription drug and/or prescription device has been held, stored or shipped before or during return and the condition of the prescription drug and/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 (7) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and/or prescription devices and reported to all applicable state and federal authorities.

(7) Record Keeping.

(a) A 3PL shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs and/or devices as outlined in federal law. These records shall include:

1. Dates of receipt and distribution; or

2. Other disposition of the prescription drugs and/or devices.

(b) Such records shall include the inventories and transaction records and shall be made available for inspection and photocopying for a period of two (2) years following their creation date.

(c) Records described in this section 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 any state or federal governmental agency charged with enforcement of these rules.

(d) A 3PL shall maintain an ongoing list of persons with whom it provides services.

(e) All facilities shall establish and maintain procedures for reporting counterfeit and contraband or suspected counterfeit and contraband drugs and/or devices, as well as counterfeiting and contraband or suspected counterfeiting and contraband activities, to the Board and United States Food and Drug Administration (FDA).

(8) Written Policies and Procedures

(a) A 3PL shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, and shipping and distribution of prescription drugs and/or prescription devices, including policies and procedures for identifying, recording, and reporting losses or thefts and for correcting all errors and inaccuracies in inventories.

(b) A 3PL shall include in its written policies and procedures the following:

1. A procedure to be followed for handling recalls and withdrawals of prescription drugs and/or devices. Such procedure shall be adequate to deal with recalls and withdrawals due to any action initiated at the request of the FDA or any other federal, state, or local law enforcement or other government agency, including the Board;

2. A procedure to ensure that a 3PL prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire,

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flood, or other natural disaster, or other situations of local, state, or national emergency;

3. A procedure to ensure that any outdated prescription drugs shall be segregated from other prescription drugs and either returned to the manufacturer or destroyed in accordance with federal and state laws, including all necessary documentation and the appropriate witnessing. This procedure shall provide for written documentation of the disposition of outdated prescription drugs;

4. A procedure for the destruction of outdated prescription drugs in accordance with federal and state laws;

5. A procedure for the disposal and destruction of containers, labels, and packaging to ensure that the containers, labels, and packaging cannot be used in counterfeiting activities, including all necessary documentation, maintained for a minimum of two (2) years, and the appropriate witnessing of the destruction of any labels, packaging, immediate containers, or containers in accordance with all applicable federal and state requirements;

6. A procedure for identifying, investigating and reporting significant prescription drug inventory discrepancies involving counterfeit, contraband, or suspected counterfeit or contraband prescription drugs, including reporting of such discrepancies as required by federal and state law to the FDA, Board and/or appropriate federal or state agency upon discovery;

7. A procedure for reporting criminal or suspected criminal activities involving the inventory of prescription drug(s) and/or device(s) as required to the Board, FDA, and, if applicable, DEA;

8. A procedure to correct errors and inaccuracies in inventories;

9. A procedure for maintaining the capability to trace the receipt and outbound distribution of a product, and supplies and records of inventory; and

10. A procedure for verifying security provisions of common carriers.

(c) Responsible persons. A 3PL 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.

(d) Compliance with federal, state, and local law. A 3PL shall operate in compliance with applicable federal, state, and local laws and regulations.

1. A 3PL shall permit the Board and authorized federal, state, and local law enforcement officials to enter and inspect premises and delivery vehicles, if applicable, and to audit records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

2. A 3PL that handles controlled substances shall register with the Board and with the DEA and shall comply with applicable local, state, and federal laws and DEA regulations.

(9) Salvaging and reprocessing. A 3PL 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/or prescription devices.

(Rule 1140-16-.06, continued)
Authority: *T.C.A. §§ 63-10-204, 63-10-304, and 63-10-306.* ***Administrative History:*** *Original rules filed September 12, 2018; effective December 11, 2018.*

1140-16-.07 Upon request, the Board may waive selected portions of this Chapter 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, and 63-10-306.* ***Administrative History:*** *Original rules filed September 12, 2018; effective December 11, 2018.*