4729-9-29 **Licensure as a third party logistics provider.**

(A) "Third party logistics provider" means any person who:

(1) Contracts with a manufacturer or wholesale distributor of dangerous drugs to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer or wholesaler, but does not take title ~~to~~ of the dangerous drug or have general responsibility to direct the dangerous drug's sale or disposition;

(2) Is licensed by the state board of pharmacy as a wholesale distributor pursuant to section 4729.52 of the Revised Code with a third party logistics provider classification; and

(3) Shall be registered as a business entity with the appropriate state or local authority(s) and must operate out of a location that is zoned for commercial use and not out of a residence or personal dwelling.

(B) The following information shall be required on a form supplied by the state board of pharmacy from each person making application for a license as a wholesale distributor of dangerous drugs with a third party logistics provider classification:

(1) The name, full physical business address (not a post office box), and telephone number~~;~~.

(2) All trade, fictitious, or business names used by the licensee (e.g. "doing business as" or "formerly known as"). Trade or business names shall not be identical to the name used by another, unrelated wholesale distributor permitted to purchase drugs in the state;

~~(2) All trade or business names used by the licensee, any trade or business names under which licensee was previously or is presently licensed;~~

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the licensee for the storage, handling, and distribution of dangerous drugs~~;~~.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency)~~;~~.

(5) The following information for the owner(s) and/or operator(s) of the wholesale distributor:

(a) For a partnership:

(i) the full name, business address, Social Security number, and date of birth of each partner; if the partner is not a natural person each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person;

(ii) the name of the partnership; and

(iii) the partnership's federal employer identification number.

(b) For a corporation:

(i) the full name, business address, Social Security number and date of birth of the corporation's president, vice-president, secretary, treasurer and chief executive officer, or any equivalent position;

(ii) the name or names of the corporation;

(iii) the state of incorporation;

(iv) the corporation's federal employer identification number;

(v) the name of the parent company, if applicable; and

(vi) if a corporation is not publicly traded on a major stock exchange, the full name, business address, and Social Security number of each shareholder owning ten percent or more of the voting stock of the corporation.

(c) For a sole proprietorship:

(i) the full name, business address, Social Security number, and date of birth of the sole proprietor; and

(ii) if applicable, the federal employer identification number of the business entity.

(d) For a government agency: the full name, business address, Social Security number, and date of birth of the agency director.

~~(5) The full name(s) of the owner and/or operator of the licensee, including:~~

~~(a) If a sole proprietorship, the full name of the sole proprietor, and the name of the business entity;~~

~~(b) If a partnership, the full name of each partner, and the name of the~~

~~partnership;~~

~~(c) If a corporation, the full name and title of each corporate officer and director, the corporate names, the name of the state of incorporation, the corporation number, and a copy of the corporation papers;~~

~~(d) If a government agency, the name of the agency, and the full name of each officer and director of the agency.~~

(6) A copy of any existing licensure the entity has from the state or jurisdiction in which it is located or a letter from a ~~state~~ licensing authority in that state or jurisdiction ~~entity~~ where ~~it is~~the third party logistics provider is located that indicates that the state or jurisdiction does not license such entities;

(7) A copy of any applicable federal licensure or registration;

(8) If the entity making application for a wholesale distributor of dangerous drugs license with a third party logistics provider classification is located outside the boundaries of the state of Ohio, part of the licensing process shall be an inquiry to the licensing authority of the state or jurisdiction in which that entity is located. This inquiry will determine whether the entity possesses a current and valid license to distribute dangerous drugs in that state or jurisdiction and the experience the licensing authority has had with the entity. This information will be used as part of the consideration in licensing the entity by the board of pharmacy. The board will respond to inquiries of a similar nature from other state or jurisdictional licensing authorities regarding Ohio licensed entities. If a state does not license such entities, the facility must maintain verified-accredited wholesale distributors (VAWD) accreditation from the national association of boards of pharmacy.

(9) Pursuant to section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license will not be issued until the following submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check:

(a) The responsible person on the application for licensure of a wholesale distributor pursuant to 4729-5-11; and

(b) The following persons based upon the wholesale distributor's business type:

(i) All partners of a partnership;

(ii) The sole proprietor of a sole proprietorship;

(iii) The president, vice president, secretary, treasurer, and chief executive officer, or any equivalent position of a corporation and if a corporation is not publicly traded on a major stock exchange, each shareholder owning ten percent or more of the voting stock of the corporation;

(iv) The agency director of a government agency.

(c) The persons listed in paragraph (B)(9)(b) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure. In the event the applicant is not owned by a natural person, each business entity with an ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person, who shall be subject to a background check in accordance with this rule.

(10) All criminal records checks conducted in accordance with this rule shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the licensing process will proceed. The persons listed in paragraph (B)(9) of this rule may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or, if located outside of Ohio, they may submit ink fingerprint impressions in a manner approved by the board.

(11) If there is a change in any of the following persons listed in paragraph (B)(9) of this rule, the new persons shall submit to a criminal records check within thirty days of the change.

(12) Any additional information required on the application as determined by the board.

(13) Any follow-up information as deemed necessary upon receipt of the application materials.

~~(9) Pursuant to division (A)(1) of section 4729.53 of the Revised Code, a new wholesale distributor of dangerous drug license with a third party logistics provider classification will not be issued until the owner(s), the officers (if incorporated) or agency directors (if a government agency) of the operation submit fingerprints to the Ohio bureau of criminal identification and investigation (BCI&I) for a criminal records check. If there is a change in officers, owners or agency directors, all new officers, owners or agency directors shall submit to a criminal records check. The criminal records check~~

~~shall consist of both a BCI&I criminal records check and a federal bureau of investigations records check (FBI). The results of the criminal records check must be sent directly to the Ohio state board of pharmacy from BCI&I. To be considered valid, the criminal records check must have been performed within the past twelve months. After the board receives the results of all of the required criminal records checks the license process will proceed. The owner(s) or officers may submit electronic fingerprint impressions pursuant to rule 4729-5-12 of the Administrative Code, or, if located outside of Ohio, they may submit ink fingerprint impressions as instructed on a form provided by the board.~~

~~(10) Any additional information as the state board of pharmacy may require.~~

(C) Prior to the end of the licensing period, a renewal application requesting such information as the state board of pharmacy may require will be sent to the attention of the responsible person. Such a renewal application shall be completed and returned with the applicable fee on or before the established deadline. As part of the renewal application, a person meeting the definition of a third party logistics provider that was licensed by the board as a wholesale distributor of dangerous drugs prior to the effective date of this rule shall demonstrate compliance with the requirements in paragraph (B)(8) of this rule. Failure to do so may result in a refusal by the board to renew the license.

(D) All facilities where dangerous drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) Have a quarantine area for storage of dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored no longer than two years pursuant to rule 4729-9-17 of the Administrative Code;

(4) Be maintained in a clean and orderly condition;

(5) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(E) All facilities used for wholesale drug distribution 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 dangerous drugs are held shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are held shall be equipped with a state board of pharmacy approved alarm system to detect unauthorized entry after hours.

(5) 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.

(F) All dangerous drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States pharmacopoeia/national formulary (USP/NF).

(1) If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

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

(3) The recordkeeping requirements in paragraph (~~H~~I) of this rule shall be followed for all stored drugs.

(G) All shipments of dangerous drugs shall be examined in accordance with the following:

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs or

dangerous 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;

(2) Each outgoing shipment shall be visually examined for identity and to prevent the shipping of contaminated dangerous drugs or dangerous 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;

(3) The recordkeeping requirements in paragraph (~~H~~I) of this rule shall be followed for all incoming and outgoing dangerous drugs.

(H) All returned, damaged, and outdated, dangerous drugs shall be handled in the following manner:

(1) Dangerous drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to their supplier.

(2) Any dangerous drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined and physically separated from other dangerous drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a dangerous drug has been returned cast doubt on the drug's safety, identify, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in paragraph (~~H~~I) of this rule shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated dangerous drugs.

(I) Wholesale drug distributors with a third party logistics provider classification shall establish and maintain inventories and records of all transactions regarding the

receipt and distribution or other disposition of dangerous drugs.

(1) These records shall include but not be limited to the following information:

(a) The source of the drugs, including the name and principle address of the seller or transferor, and the address of the location from which the drugs were shipped.

(b) The identity and quantity of the drugs received, and distributed, or disposed or returned. of.

(c) The dates of receipt and distribution of the drugs.

(d) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized by division (B) ofin accordance with section 4729.51 of the Revised Code.

(e) A system shall be designed and operated to disclose orders for controlled substances and other dangerous drugs subject to abuse. Reports, generated by the system, shall be furnished to the state board of pharmacy within three working days of receipt of a request from the board. The reports shall include the name and address of the purchaser, date of purchases, product trade name, national drug code (NDC) number, size of package, and quantity purchased.

(2) Inventories and records shall be made available for inspection and photocopying by properly identified and authorized state board of pharmacy designated agents,and federal, state, or local law enforcement agency officials for a period of three years following disposition of the drugs.

(3) Records described in this rule 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.

(a) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by properly identified and authorized state board of pharmacy designated agents,and federal, state, or local law enforcement agency officials.

(b) Third party logistics provider intending to maintain records, described in

this rule, at a location other than the place licensed by the state board of pharmacy, must obtain approval from the board.

(J) Third party logistics providers shall inform the state board of pharmacy of suspicious orders for controlled substances and other dangerous drugs subject to abuse, immediately upon discovery. Suspicious orders are those which, in relation to the wholesaler's records as a whole, are of unusual size, unusual frequency, or deviate substantially from established buying patterns.

(K) Third party logistics providers shall establish, maintain, and adhere to written policies and procedures which shall be followed for the receipt, security, storage, inventory, and distribution of dangerous drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a dangerous drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

(a) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the state board of pharmacy;

(b) Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market;

(c) Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that third party logistics providers prepare for, protect against, and handle 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.

(4) A procedure to ensure that any outdated dangerous drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of

outdated dangerous drugs. This documentation shall be maintained for three years after disposition of the outdated drugs.

(L) Third party logistics providers shall establish and maintain accurate and current lists of officers, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(M) Personnel employed by the third party logistics providers shall be required to have appropriate education and/or experience to assume responsibility for positions related to compliance with the licensing regulations.

(N) Third party logistics providers shall operate in compliance with applicable federal, state, and local laws and regulations.

(1) Third party logistics providers shall permit properly identified and authorized state board of pharmacy designated agents~~,~~ and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures at reasonable times and in a reasonable manner, to the extent authorized by law.

(2) A third party logistics provider making a wholesale sale of a controlled substance shall be required to possess a license as a wholesale distributor of dangerous drugs and a license as a wholesaler or manufacturer of controlled substances, except that a licensed terminal distributor of dangerous drugs may make an occasional sale of a controlled substance pursuant to rule 4729-9-10 of the Administrative Code.

(O) Third party logistics providers shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to dangerous drug salvaging or reprocessing.

(P) The state board of pharmacy shall be notified within thirty days of any new facilities, work or storage areas to be constructed or utilized for dangerous drugs or of any changes in operation of the ~~registrant~~ third party logistics provider being used or implemented.

(Q) The wholesale distributor with a third party logistics ~~providers~~ provider classification shall comply with Title II of the Drug Quality and Security Act (9/3/2015).

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