

4729:6-11-01

Third-party logistics providers - general operations.

The following requirements shall apply to all persons licensed as ~~third-party~~third-party logistics providers:

(A) 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 damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened. Such drugs shall be stored in accordance with paragraph (B) of this rule;
- (4) Be maintained in a clean and orderly condition;
- (5) Be free from infestation by insects, rodents, birds, or vermin of any kind;
- (6) 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) Adulterated drugs shall be stored in a separate and secure area apart from the storage of drugs used for distribution and sale.

- (1) Adulterated drugs shall be stored no longer than two years from the date of adulteration or expiration. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.
- (2) Dangerous drugs, other than controlled substances, may be destroyed utilizing proper methods of disposal and following the record keeping requirements noted in paragraph ~~(B)(2)~~ ~~(a)~~ (B)(3) of this rule, or may be donated to a pharmacy school pursuant to sections 3715.88 to 3715.92 of the Revised Code. Methods of disposal of non-controlled dangerous drugs shall prevent the possession or use of the drugs by unauthorized persons.

~~Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive~~

~~identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.~~

(3) Records of dangerous drug destructions, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug destroyed, the date destroyed, the method of destruction, the positive identification of the responsible person that performed the destruction, and the positive identification of the person that witnessed the destruction.

~~(3)~~(4) Dangerous drugs that are controlled substances shall be disposed of pursuant to rule 4729:6-3-01 of the Administrative Code.

(C) All facilities used by ~~third-party~~third-party logistics providers 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 dangerous drugs are stored shall be limited to authorized personnel.

(4) All facilities where dangerous drugs are stored shall be equipped with an 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. The security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(D) 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 dangerous drug, the drug may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its 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. Temperature and humidity documentation shall be

made readily retrievable and maintained for a period of not less than ~~three~~five years from the last documented temperature and humidity reading.

(E) 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.

(F) All returned, damaged, and adulterated; dangerous drugs shall be handled in the following manner:

- (1) Dangerous drugs that are damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other dangerous drugs until they are destroyed or returned to the supplier.
- (2) Any dangerous drugs ~~whose~~where the 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~~identity, 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 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.

(G) ~~Third party~~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 in accordance with rule 4729:6-3-02 of the Administrative Code, and for correcting all errors and inaccuracies in inventories. ~~Third-party~~Third-party logistics providers shall include in their written policies and procedures all of the following:

- (1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall be appropriate 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.
 - (2) A procedure to ensure that ~~third-party~~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.
 - (3) A procedure to ensure that any adulterated 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 adulterated dangerous drugs. This documentation shall be maintained for ~~three~~five years after disposition of the adulterated drugs.
- (H) Personnel employed in the distribution of dangerous drugs shall be required to have appropriate education, experience, and training to assume responsibility for positions related to compliance with the requirements of this division of the Administrative Code.
- (I) ~~Third-party~~Third-party logistics providers shall operate in compliance with applicable federal, state, and local laws, rules, and regulations. This shall include, but is not limited to, all applicable laws, regulations, and standards set forth by the United States food and drug administration and the United States drug enforcement administration.
- (J) ~~Third-party~~Third-party logistics providers shall permit properly identified and authorized state board of pharmacy ~~agents~~employees and federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

- (K) ~~Third-party~~ Third-party logistics providers shall be subject to the provisions of any applicable federal, state, or local laws, rules, or regulations that relate to dangerous drug salvaging or reprocessing.
- (L) The state board of pharmacy shall be notified, in a manner specified by the Board, of any new facilities, work, or storage areas to be constructed or utilized for dangerous drugs.
- (M) The following minimum standards shall apply to the storage and transportation methods utilized by a third-party logistics provider for the storage, transportation, and delivery of dangerous drugs:
- (1) A licensee is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses.
 - (2) When distributing dangerous drugs through agents, a licensee is responsible for providing and requiring adequate security to guard against theft and diversion while the substances are being stored or handled by the agent or agents.

Effective: 8/31/2024

Five Year Review (FYR) Dates: 3/19/2024 and 08/31/2029

CERTIFIED ELECTRONICALLY

Certification

07/11/2024

Date

Promulgated Under: 119.03

Statutory Authority: 4729.26, 3719.28

Rule Amplifies: 4729.53

Prior Effective Dates: 04/01/2016, 02/15/2017, 03/01/2019