



## Ohio Administrative Code

### Rule 4729:6-6-01 Virtual wholesalers - general operations.

Effective: [March 1, 2021](#)

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The following requirements shall apply to all persons licensed as a wholesale distributor of dangerous drugs with a virtual wholesaler classification:

(A) Virtual wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt, sale and distribution or other transfer of dangerous drugs.

(1) The 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 name, national drug code, quantity of the drugs received, distributed, sold, disposed or returned.

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

(d) The name and principle address of the purchaser or receiver and the address of the location where the drugs were shipped.

(e) A system of records and procedures shall be maintained which prevent the sale or other distribution of dangerous drugs to any person not authorized in accordance with section 4729.51 of the Revised Code. Such procedures and records shall meet the requirements set forth in rule 4729:6-3-04 of the Administrative Code.

(2) All records maintained in accordance with this rule shall be made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents and federal, state, or local law enforcement agency officials for a period of five years following disposition of the drugs.



(3) Virtual wholesalers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the wholesale distributor.

(4) A virtual wholesaler maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this division within three business days.

(B) Virtual wholesalers 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. At a minimum, virtual wholesalers shall include in their written policies and procedures with all the following:

(1) A procedure to be followed for handling recalls and withdrawals of dangerous drugs. Such procedure shall address 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 virtual wholesalers 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 years after disposition of the adulterated drugs.

(C) Personnel employed in the wholesale 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.

(D) Virtual wholesalers 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.

(E) Virtual wholesalers shall permit properly identified and authorized state board of pharmacy agents 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.

(F) Virtual wholesalers 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.

(G) Virtual wholesalers shall submit wholesale sale information to the drug database in accordance with section 4729.78 of the Revised Code.

(H) The following minimum standards shall apply to the storage and transportation methods utilized by virtual wholesalers 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 storing dangerous drugs in a public warehouse, a licensee is responsible for selecting a facility which will provide adequate security to guard against storage losses. The licensee shall store



controlled substances in a public warehouse which complies with the requirements set forth in section 1301.72 of the code of federal regulations (2/28/2018). In addition, the licensee shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled substances) to guard against storage or in- transit losses.

(3) 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.

(I) A virtual wholesaler seeking to engage in any other activities relating to the distribution of dangerous drugs shall obtain additional licensure for the operations conducted pursuant to those rules.

(J) The requirement to obtain licensure as a virtual wholesaler pursuant to section 4729.52 of the Revised Code does not apply to any of the following:

(1) A board of health, as defined in section 3701.048 of the Revised Code, that is licensed as a terminal distributor of dangerous drugs for the purpose of distributing dangerous drugs to another terminal distributor during a declared public health emergency or emergency preparedness incident; or

(2) A board of health, as defined in section 3701.048 of the Revised Code, that is a certified covered entity as defined in Section 340B(a)(4) of the Public Health Service Act (1/24/2020) to perform the functions of a virtual wholesaler with a contracted pharmacy licensed as a terminal distributor of dangerous drugs that has a "ship to, bill to" arrangement in accordance with all applicable requirements of the federal health resources and services administration (HRSA). A certified covered entity shall be responsible for all of the following:

(a) Maintaining records of drug distribution in accordance with paragraph (A) of this rule; and

(b) Ensuring the contracted pharmacy is appropriately licensed as a terminal distributor of dangerous drugs in accordance with Chapter 4729. of the Revised Code.