



## Ohio Administrative Code

### Rule 4729:6-7-01 Brokers - general operations.

Effective: August 31, 2024

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

(A) Brokers shall establish and maintain records of all transactions regarding the transfer, sale, or other disposition of dangerous drugs.

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

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

(b) The name, national drug code and 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 principal address of the purchaser or receiver and the address of the location where the drugs were shipped.

(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) Brokers 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 broker.



(4) A broker 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) Brokers shall only engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are unopened (i.e., no partial stock bottles) and packaged in the manufacturer's original container.

(C) Brokers shall operate in compliance with all applicable federal, state, and local laws, rules, and regulations.

(D) Brokers shall permit properly identified and authorized state board of pharmacy employees, federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit records and written operating procedures.

(E) A broker seeking to engage in activities relating to the distribution of dangerous drugs other than those of a broker shall obtain additional licensure for the operations conducted pursuant to those rules.

(F) Brokers shall verify that the seller and buyer are appropriately licensed or exempt from licensure in accordance with rule 4729:6-3-04 of the Administrative Code.

(G) Brokers shall not engage in the marketing, offering, or contracting for wholesale distribution and sale of dangerous drugs that are controlled substances.

(H) Brokers 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.

(I) An entity engaged in the brokering of dangerous drugs for the sole purpose of reverse distribution (e.g., disposal) shall not be required to obtain a license as a wholesale distributor of dangerous drugs



with a broker classification.

(J) Brokers 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.