

4729:6-11-02

~~Third-party~~Third-party logistics providers - recordkeeping.

(A) ~~Third-party~~Third-party logistics providers shall establish and maintain inventories and records of all transactions regarding the receipt, sale, and distribution or other disposition 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~~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 ~~principle~~principal 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) ~~Third-party~~Third-party logistics providers located in this state intending to maintain records at a location other than the place licensed by the state board of pharmacy must obtain approval from the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or ~~contractor~~contractors of the ~~third-party~~third-party logistics provider.

(B) The recordkeeping requirements in paragraph (A) of this rule shall be followed for all damaged, deteriorated, misbranded, or adulterated dangerous drugs.

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: 4729.52
Prior Effective Dates: 03/01/2019, 03/01/2021