Ohio Administrative Code

Rule 4729:6-8-02 Manufacturers - recordkeeping.

Effective: March 1, 2021

(A) Manufacturers of dangerous drugs shall establish and maintain inventories and records of all transactions regarding the manufacture, 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 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 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) Manufacturers 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 manufacturer.

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

(C) Manufacturers shall submit applicable wholesale or retail sale information to the drug database in accordance with section 4729.78 of the Revised Code.