

657—42.12(155A) Records. Distributors shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of products, including outdated, damaged, deteriorated, misbranded, or adulterated products.

42.12(1) *Transaction records.* Records for receipt and distribution transactions for all products shall include the following information:

- a.* The source of the products, including the name and principal address of the seller or transferor and the address of the location from which the products were shipped;
- b.* The identity and quantity of the products received or distributed;
- c.* The date of receipt or distribution of the products; and
- d.* The identity of the purchaser of the products, including the name and principal address of the purchaser or transferee and the address to which the products were shipped or distributed.

42.12(2) *Prescription order records.* Each prescription order that results in the distribution of a product shall be retained, in the original format received, and be available for inspection and copying by the board, its representative, or other authorized individual for at least two years from the date of last activity of the prescription order.

- a.* Prescription orders shall contain all the required elements identified in Iowa Code section 155A.27.
- b.* Prescription orders for noncontrolled prescription drugs shall be valid for no longer than 18 months following the date issued or 13 fills, whichever is less.
- c.* A one-month supply of a medical gas, such as oxygen, shall be considered to be a single refill. Such prescription must be reissued at least every 13 months.
- d.* Prescription orders for controlled substances shall be valid for no longer than six months following the date issued or six fills, whichever is less.

42.12(3) *Records maintained.* All records generated pursuant to the distributor's policies and procedures, this chapter, and all federal, state, and local rules, laws and regulations shall be maintained, readily retrievable, and available for inspection and copying by the board, its representative, or other authorized individual for at least two years from the date of the record.

42.12(4) *Confidentiality of patient information.* Any patient information in the possession of a distributor shall be maintained in compliance with the patient confidentiality and security requirements of 657—Chapter 8, 657—Chapter 21, and federal law.

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