

657—17.16 (124,155A) Record keeping. Wholesalers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs, including outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

17.16(1) *Transaction records.* Transaction records shall include 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 identity and quantity of the drugs received and distributed or disposed of;
- c. The dates of receipt and distribution or other disposition of the drugs; and
- d. If a distribution transaction, the recipient of the drugs, including the name and principal address of the purchaser or transferee and the address to which the drugs were shipped.

17.16(2) *Records maintained.* Inventories and records shall be made available for inspection and photocopying by any authorized official of the board or of any governmental agency charged with enforcement of these rules for a period of two years following disposition of the drugs. The annual inventory of controlled substances shall be maintained for a minimum of two years from the date of the inventory.

17.16(3) *Inspection of records.* Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be available for inspection within two working days of a request by an authorized official of the board or of any governmental agency charged with enforcement of these rules.

17.16(4) *Confidentiality of patient information.* A wholesaler shall obtain and maintain patient-specific data only as necessary for the health and safety of the patient. Any patient-specific information in the possession of a wholesaler shall be maintained in compliance with the patient confidentiality and security requirements of rules 657—8.16(124,155A) and 657—21.2(124,155A).

17.16(5) *Authorized collection program.* A licensee that is authorized to administer a collection program shall maintain all records and inventories as required by 657—Chapter 10, this chapter, and federal regulations.