

657—10.34 (124,155A) Records. Every inventory or other record required to be kept under this chapter or under Iowa Code chapter 124 shall be kept by the registrant and be available for inspection and copying by the board or its representative for at least two years from the date of such inventory or record except as otherwise required in these rules. Controlled substances records shall be maintained in a readily retrievable manner that establishes the receipt and distribution of all controlled substances. Original hard-copy prescription and other pharmacy records more than 12 months old may be maintained in a secure storage area outside the licensed pharmacy department unless such remote storage is prohibited under federal law. A remote storage area shall be located within the same physical structure containing the licensed pharmacy department.

10.34(1) *Schedule I and II records.* Inventories and records of controlled substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.

10.34(2) *Schedule III, IV, and V records.* Inventories and records of controlled substances listed in Schedules III, IV, and V shall be maintained either separately from all other records of the registrant or in such form that the required information is readily retrievable from the ordinary business records of the registrant.

10.34(3) *Date of record.* The date on which a controlled substance is actually received, imported, distributed, exported, disposed of, or otherwise transferred shall be used as the date of receipt, importation, distribution, exportation, disposal, or transfer.

10.34(4) *Receipt and disbursement records.* Each record of receipt or disbursement of controlled substances, unless otherwise provided in these rules or pursuant to federal law, shall include the following:

- a. The name of the substance;
- b. The strength and dosage form of the substance;
- c. The number of units or commercial containers acquired from other registrants, including the date of receipt and the name, address, and DEA registration number of the registrant from whom the substances were acquired;
- d. The number of units or commercial containers distributed to other registrants, including the date of distribution and the name, address, and DEA registration number of the registrant to whom the substances were distributed; and
- e. The number of units or commercial containers disposed of in any other manner, including the date and manner of disposal and the name, address, and DEA registration number of the registrant to whom the substances were distributed for disposal, if appropriate.

10.34(5) *Dispensing records.* Each record of dispensing of controlled substances to a patient or research subject shall include the following information:

- a. The name and address of the person to whom dispensed;
- b. The date of dispensing;
- c. The name of the substance;
- d. The quantity of the substance dispensed; and
- e. The name or unique identification of the individual who dispensed or administered the substance.

10.34(6) *Ordering or distributing Schedule I or II controlled substances - DEA Form 222.* Except as otherwise provided by subrule 10.34(7) and under federal law, a DEA Form 222 is required for each distribution of a Schedule I or II controlled substance. An order form may be executed only on behalf of the registrant named on the order form and only if the registrant's DEA and Iowa registrations for the substances being purchased have not expired or been revoked or suspended by the issuing agency.

a. Order forms shall be obtained, executed, and filed pursuant to DEA requirements. Each form shall be complete, legible, and properly prepared, executed, and endorsed and shall contain no alteration, erasure, or change of any kind.

b. The purchaser shall submit Copy 1 and Copy 2 of the order form to the supplier.

c. The purchaser shall maintain Copy 3 of the order form in the files of the registrant. Upon receipt of the substances from the supplier, the purchaser shall record on Copy 3 of the order form the quantity

of each substance received, and the date of receipt, and shall initial each line identifying a substance received.

d. The supplier shall record on Copy 1 and Copy 2 of the order form the quantity of each substance distributed to the purchaser and the date on which the shipment is made. The supplier shall maintain Copy 1 of the order form in the files of the supplier and shall forward Copy 2 of the order form to the DEA district office.

e. Order forms shall be maintained separately from all other records of the registrant.

f. Each unaccepted, defective, or otherwise “void” order form and any attached statement or other documents relating to any order form shall be maintained in the files of the registrant.

g. If the registration of any purchaser of Schedule I or II controlled substances is terminated for any reason, or if the name or address of the registrant as shown on the registration is changed, the registrant shall return all unused order forms to the DEA district office.

10.34(7) *Ordering or distributing Schedule I or II controlled substances - electronic ordering system.* A registrant authorized to order or distribute Schedule I or II controlled substances via the DEA Controlled Substances Ordering System (CSOS) shall comply with the requirements of the DEA relating to that system, including the maintenance and security of digital certificates, signatures, and passwords and all record-keeping and reporting requirements.

a. For an electronic order to be valid, the purchaser shall sign the electronic order with a digital signature issued to the purchaser or the purchaser’s agent by the DEA.

b. An electronic order may include controlled substances that are not in Schedules I and II and may also include noncontrolled substances.

c. A purchaser shall submit an order to a specific wholesale distributor appropriately licensed to distribute in Iowa.

d. Prior to filling an order, a supplier shall verify the integrity of the signature and the order, verify that the digital certificate has not expired, check the validity of the certificate, and verify the registrant’s authority to order the controlled substances.

e. The supplier shall retain an electronic record of every order, including a record of the number of commercial or bulk containers furnished for each item and the date on which the supplier shipped the containers to the purchaser. The shipping record shall be linked to the electronic record of the order. Unless otherwise provided under federal law, a supplier shall ship the controlled substances to the registered location associated with the digital certificate used to sign the order.

f. If an order cannot be filled for any reason, the supplier shall notify the purchaser and provide a statement as to the reason the order cannot be filled. When a purchaser receives such a statement from a supplier, the purchaser shall electronically link the statement of nonacceptance to the original electronic order. Neither a purchaser nor a supplier may correct a defective order; the purchaser must issue a new order for the order to be filled.

g. When a purchaser receives a shipment, the purchaser shall create a record of the quantity of each item received and the date received. The record shall be electronically linked to the original order and shall identify the individual reconciling the order. A purchaser shall, for each order filled, retain the original signed order and all linked records for that order for two years. The purchaser shall also retain all copies of each unfilled or defective order and each linked statement.

h. A supplier shall retain each original order filled and all linked records for two years. A supplier shall, for each electronic order filled, forward to the DEA within two business days either a copy of the electronic order or an electronic report of the order in a format specified by the DEA.

i. Records of CSOS electronic orders and all linked records shall be maintained by a supplier and a purchaser for two years following the date of shipment or receipt, respectively. Records may be maintained electronically or in hard-copy format. Records that are maintained electronically shall be readily retrievable from all other records, shall be easily readable or easily rendered into a readable format, shall be readily retrievable at the registered location, and shall be made available to the board, to the board’s agents, or to the DEA upon request. Records maintained in hard-copy format shall be maintained in the same manner as DEA Form 222.

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