

657—10.18(124) Schedule II perpetual inventory. Each registrant located in Iowa that maintains Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to this rule. All records relating to the perpetual inventory shall be maintained at the registered location and shall be available for inspection and copying by the board or its representative for a period of two years from the date of the record. The perpetual inventory shall accurately reflect the on-hand inventory of Schedule II substances, and the registrant is responsible for ensuring that the perpetual inventory record is accurate and matches the actual on-hand inventory at all times.

10.18(1) Record format. The perpetual inventory record may be maintained in a manual or an electronic record format. Any electronic record shall provide for hard-copy printout of all transactions recorded in the perpetual inventory record for any specified period of time and shall state the current inventory quantities of each drug at the time the record is printed.

10.18(2) Information included. The perpetual inventory record shall identify all receipts for and disbursements of Schedule II controlled substances by drug or by national drug code (NDC) number. The record shall be updated to identify each receipt, disbursement, and current balance of each individual drug or NDC number. The record shall also include incident reports and reconciliation records pursuant to subrules 10.18(3) and 10.18(4).

10.18(3) Changes to a record. If a perpetual inventory record is able to be changed, the individual making a change to the record shall complete an incident report documenting the change. The incident report shall identify the specific information that was changed including the information before and after the change, shall identify the individual making the change, and shall include the date and the reason the record was changed. If the electronic record system documents within the perpetual inventory record all of the information that must be included in an incident report, a separate report is not required.

10.18(4) Reconciliation. The registrant shall be responsible for reconciling or ensuring the completion of a reconciliation of the perpetual inventory balance with the physical inventory of all Schedule II controlled substances at least annually. Any discrepancies discovered during reconciliation shall be investigated and reported to the pharmacist in charge or responsible individual immediately but no later than one business day following the discovery. The registrant shall determine the need for further investigation, and significant losses shall be reported to the board pursuant to rule 657—10.21(124) and to the DEA pursuant to federal DEA regulations. Periodic reconciliation records shall be maintained and available for review and copying by the board or its authorized agents for a period of two years from the date of the record. The reconciliation process shall be completed using the following procedures or a combination thereof:

a. The individual responsible for a disbursement shall verify that the physical inventory matches the perpetual inventory following each transaction and documents that reconciliation in the perpetual inventory record. If controlled substances are maintained on the patient care unit, the nurse or other responsible licensed health care provider verifies that the physical inventory matches the perpetual inventory following each dispensing and documents that reconciliation in the perpetual inventory record. If any Schedule II controlled substances in the registrant's current inventory have been disbursed and verified in this manner within the year and there are no discrepancies noted, no additional reconciliation action is required. A perpetual inventory record for a drug that has had no activity within the year shall be reconciled pursuant to paragraph 10.18(4) "b."

b. A physical count of each Schedule II controlled substance stocked by the registrant that has not been reconciled pursuant to paragraph 10.18(4) "a" shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. The physical count and reconciliation may be completed over a period of time not to exceed one year in a manner that ensures that the perpetual inventory and the physical inventory of Schedule II controlled substances are annually reconciled. The individual performing the reconciliation shall record the date, the time, the individual's initials or unique identification, and any discrepancies between the physical inventory and the perpetual inventory.

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