

657—10.33(124,155A) Schedule II perpetual inventory in pharmacy. Each pharmacy located in Iowa that dispenses Schedule II controlled substances shall maintain a perpetual inventory system for all Schedule II controlled substances pursuant to the requirements of this rule. All records relating to the perpetual inventory shall be maintained by the pharmacy 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.

10.33(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.

10.33(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 prescription filled and each shipment received. The record shall also include incident reports and reconciliation records pursuant to subrules 10.33(3) and 10.33(4).

10.33(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.

10.33(4) Reconciliation. The pharmacist in charge shall be responsible for reconciling the physical inventory of all Schedule II controlled substances with the perpetual inventory balance on a periodic basis but no less frequently than annually. In case of any discrepancies between the physical inventory and the perpetual inventory, the pharmacist in charge shall determine the need for further investigation, and significant discrepancies shall be reported to the board pursuant to rule 10.16(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 agents of the board for a period of two years from the date of the record. The reconciliation process may be completed using either of the following procedures or a combination thereof:

a. The dispensing pharmacist verifies that the physical inventory matches the perpetual inventory following each dispensing 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. All discrepancies shall be reported to the pharmacist in charge. If any Schedule II controlled substances in the pharmacy's current inventory have been dispensed and verified in this manner within the year, and there are no discrepancies noted, no additional reconciliation action is required. A drug that has had no activity within the year shall be reconciled pursuant to paragraph "b" of this subrule.

b. A physical count of each Schedule II controlled substance stocked by the pharmacy 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. Any discrepancies between the physical inventory and the perpetual inventory shall be reported to the pharmacist in charge.