

481—553.6(124) Controlled substance accountability. Registrants located in Iowa will ensure accountability of all controlled substances under their control in accordance with this rule.

553.6(1) Perpetual inventory. Each registrant will maintain a perpetual inventory that accurately reflects the on-hand inventory of all Schedule II substances at all times. A perpetual inventory may be maintained to accurately reflect the on-hand inventory of all Schedules III through V substances in addition to or in lieu of the measures identified in subrule 553.6(2). The perpetual inventory record will include the following elements, including by supplement or reference, at a minimum, for each substance:

- a. Drug name and NDC number.
- b. Each receipt and disbursement.
- c. Current balance.
- d. Incident reports pursuant to subrule 553.6(5).
- e. Reconciliation reports pursuant to subrule 553.6(3).

553.6(2) Accountability measures to ensure accountability of Schedule III through V substances. In lieu of or in addition to a perpetual inventory pursuant to subrule 553.6(1), registrants will utilize one or more of the measures herein to ensure accountability of all Schedules III through V substances under their control.

- a. Documented audit and reconciliation of all substances every six months pursuant to paragraph 553.6(3)“b.”
- b. Routine documented cycle counts, so long as all substances are counted every 90 days and reconciled pursuant to paragraph 553.6(3)“b.”
- c. Other measures preapproved by the board.

553.6(3) Reconciliation.

a. *Perpetual inventory.* Individuals responsible for a disbursement will verify that the physical inventory matches the perpetual inventory following each transaction. At least annually, the registrant will verify that the physical inventory matches the perpetual inventory for any substance that was not disbursed in the year. Reconciliation will be documented in the perpetual inventory record to include, at a minimum, the date, the initials or unique identification of the individual, and any discrepancies identified.

b. *Schedules III through V reconciliation.* In accordance with paragraph 553.6(2)“a” or “b,” the registrant will verify that the physical inventory matches the expected inventory and will document the reconciliation to include the date, the initials or unique identification of the individual, and any discrepancies identified.

553.6(4) Discrepancies. Any discrepancy discovered will be investigated and reported to the registrant or responsible individual immediately but no later than one business day following the discovery. The registrant will determine the need for further investigation, and significant losses will be reported to the board pursuant to rule 481—553.7(124) and to the DEA pursuant to 21 CFR Part 1301.

553.6(5) Incident reports. In any instance where a controlled substance inventory record is changed, the individual making the change will complete an incident report to document the change. An electronic record system that documents and maintains the required elements is deemed compliant with this subrule. The report will include, at a minimum:

- a. The specific information that was changed, including the information before and after the change.
- b. The identity of the individual making the change.
- c. The date of the change.
- d. A detailed explanation for the change.

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