

BOARD OF PHARMACY [657]
Amended Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 6, “General Pharmacy Practice,” Chapter 8, “Universal Practice Standards,” and Chapter 10, “Controlled Substances,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code sections 124.301, 147.76 and 155A.13.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code sections 124.301 and 155A.13.

Purpose and Summary

The proposed amendments provide minimum security and monitoring system requirements to be utilized by Iowa pharmacies to prevent and detect unauthorized access to prescription drugs and records; require an exact measure or count of all schedules of controlled substances for a controlled substance inventory count; require a program be established to monitor controlled substance accountability; require a system be established to ensure controlled substance accountability; require development and execution of a corrective action plan following the report of the theft or loss of controlled substances; and require a controlled substances inventory to be taken with each change in pharmacist in charge.

Reason for Amendment of Notice of Intended Action

Notice of Intended Action was published in the Iowa Administrative Bulletin on August 11, 2021, as **ARC 5834C**. Following the board’s review of the comments received in response to the proposed amendments, the board made significant changes to the proposed amendments to revise, or remove entirely, some of the proposed requirements. The proposed amendments remove the provision allowing a pharmacist to delegate the dispensing of a prescription which otherwise requires pharmacist counseling while the pharmacist is on a break. The amendments that were adjusted or added include:

- Requirement to maintain basic alarm system and video surveillance system, required by December 1, 2022, but allowing each pharmacy to determine utilization commensurate with the pharmacy operation;

- Requirement to maintain accountability of schedules III-V controlled substances, but with a range of options for the registrant to employ in that effort;
- Requirement to develop and implement a corrective action plan in response to a report of theft or loss from the registrant which addresses the conditions which contributed to the theft or loss; and
- Requirement to conduct a controlled substance inventory count with every change in pharmacist in charge, including when the incoming pharmacist in charge is interim or temporary.

Fiscal Impact

This rule making has no fiscal impact to the state of Iowa.

Jobs Impact

After analysis and review of this rule making, no impact on jobs has been found.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Board for a waiver of the discretionary provisions, if any, pursuant to 657—Chapter 34.

Public Comment

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Board no later than 4:30 p.m. on _____, 2021. Comments should be directed to:

Sue Mears, RPh
Iowa Board of Pharmacy
400 SW 8th Street, Suite E
Des Moines, IA 50309

Public Hearing

{If no public hearing scheduled:agency} No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1) “b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making action is proposed:

ITEM 1. Adopt the following **new** subrule 6.7(5):

6.7(5) *Minimum physical security and monitoring system requirements.* Each pharmacy located in Iowa shall develop and implement policies and procedures to ensure appropriate physical security and monitoring of the pharmacy to prevent unauthorized access to prescription drugs, including controlled substances, and pharmacy records. The physical security and monitoring shall include the components identified herein and the policies and procedures shall establish the utilization of such components commensurate with the pharmacy operation. The policies and procedures shall establish the retention of documentation of activities or recordings retained from the alarm and video surveillance systems as well as contingencies when the systems are temporarily unavailable.

a. No later than December 1, 2022, a basic alarm system.

b. No later than December 1, 2022, a video surveillance system.

c. Controlled access to computer records.

d. A designated location that can be monitored, away from drug storage and handling areas, where personal items of pharmacy staff may be stored while on site.

ITEM 2. Adopt the following **new** paragraph **8.3(3)“e”**:

e. Ensuring that the pharmacy provides adequate security to prevent unauthorized access and diversion.

ITEM 3. Adopt the following **new** paragraphs **10.14(2)“d” through “g”**:

d. To the extent possible, a separation of duties related to the purchasing, receiving, stocking, dispensing, and reconciling of controlled substance inventory.

e. The reconciliation of controlled substances in schedule II pursuant to subrule 10.18(4).

f. The reconciliation of controlled substances in schedules III through V pursuant to rule 657—10.20(124).

g. A controlled substance accountability program to document review of controlled substance inventory adjustments, review patterns of controlled substance loss, and create an action plan following a report of theft or loss pursuant to subrule 10.21(5).

ITEM 4. Amend subrule 10.18(4) as follows:

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. ~~In case of any~~ Any discrepancies ~~between the physical inventory and the perpetual inventory, the registrant shall be notified~~ discovered during reconciliation shall be investigated and reported to the pharmacist in charge or responsible individual immediately but no later than one business day. The registrant shall determine the need for further investigation, and significant discrepancies 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 ~~may~~ shall be completed using ~~either~~ of the following procedures or a combination thereof:

a. The individual responsible for a disbursement ~~verifies~~ shall verify that the physical inventory matches the perpetual inventory following each ~~disbursement~~ 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.

ITEM 5. Amend subrule 10.19(1) as follows:

10.19(1) *Record and procedure.* Each inventory record, except the periodic count and reconciliation required pursuant to subrule 10.18(4), shall comply with the requirements of this subrule and shall be maintained for a minimum of two years from the date of the inventory.

a. to e. No change.

f. The inventory record, unless otherwise provided under federal law, shall include the following information:

(1) and (2) No change.

(3) The quantity of the substance, which shall be an exact count or measure of the substance and may not be an estimated count or measure.

(4) to (6) No change.

~~*g.* For all substances listed in Schedule I or II, the quantity shall be an exact count or measure of the substance.~~

~~*h.* For all substances listed in Schedule III, IV, or V, the quantity may be an estimated count or measure of the substance unless the container has been opened and originally held more than 100 dosage units. If the opened commercial container originally held more than 100 dosage units, an exact count of the contents shall be made. Products packaged in nonincremented containers may be estimated to the nearest one-fourth container.~~

ITEM 6. Amend subrule 10.19(4) as follows:

10.19(4) *Change of ownership, pharmacist in charge, or registered location.*

a. When there is a change in ownership, pharmacist in charge, or location for a registration, an inventory shall be taken of all controlled substances in compliance with subrule 10.19(1). The inventory shall be taken following the close of business the last day under terminating ownership, terminating pharmacist in charge's employment, or at the location being vacated. The inventory shall serve as the ending inventory for the terminating owner, terminating pharmacist in charge, or location being vacated, as well as a record of the beginning inventory for the new owner, pharmacist in charge, or location.

b. When there is a change of pharmacist in charge, including when the incoming pharmacist in charge is temporary or interim pursuant to subrule 8.35(6), paragraph "d", an inventory shall be

taken of all controlled substances in compliance with subrule 10.19(1). An inventory shall be taken following the close of business the last day of the outgoing pharmacist in charge's duty. The inventory may serve as the beginning inventory for the incoming pharmacist in charge unless the incoming pharmacist in charge did not immediately assume the duties of pharmacist in charge following the outgoing pharmacist in charge. Any lapse in time between the outgoing and incoming pharmacists in charge shall cause an inventory to be taken prior to the opening of business on the first day of the incoming pharmacist in charge's duty. An inventory count shall not be required in the case of an interim pharmacist in charge if the pharmacy maintains perpetual inventory logs for all controlled substances pursuant to rule 657—10.20(124).

ITEM 7. Adopt the following **new** rule 657—10.20(124):

657—10.20(124) Schedule III through V accountability. A registrant shall ensure accountability of schedule III through V controlled substances through one or more of the measures identified herein.

a. Perpetual inventory log, which may be maintained by electronic means so long as the system complies with the perpetual inventory requirements in rule 657—10.18(124).

b. Documented audit and reconciliation of all controlled substances every six months.

c. Routine documented cycle counts of substances so long as all controlled substances are counted every 90 days and identified discrepancies are investigated and documented.

d. Other measure pre-approved by the board.

ITEM 8. Adopt the following **new** subrule 10.21(5):

10.21(5) Action plan following loss. Within seven days following the report of theft or loss, a registrant shall develop and initiate implementation of an action plan to address the conditions which contributed to the theft or loss, which shall include any directives including, but not limited to, inventory counts, audits, and perpetual inventory counts provided by a board compliance officer.