ARC 6330C

PHARMACY BOARD[657]

Adopted and Filed

Rule making related to records, dispensing, and controlled substances

The Board of Pharmacy hereby amends 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 adopted 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

These 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 to be established to monitor and ensure controlled substance accountability;
- Require development and execution of a corrective action plan following the report of theft or loss of controlled substances; and
- Require a controlled substance inventory to be taken with each change in pharmacist in charge.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on August 11, 2021, as **ARC 5834C**. An Amended Notice of Intended Action was published in the Iowa Administrative Bulletin on February 9, 2022, as **ARC 6179C**. A public hearing was held on March 3, 2022, at 10 a.m. in the Health Professions Board Room, 400 S.W. 8th Street, Suite H, Des Moines, Iowa, and via Zoom. Comments received following publication of **ARC 6179C** are described below.

Comments received at the public hearing:

For Item 1, participants from hospital pharmacy practice settings expressed:

- Concern about the effective date for licensees to be compliant with the security parameters. The participants cited the need to submit budget requests for enhancements and possibility of back orders and backlogs for materials and installation that would impact timely compliance.
- Confusion about the applicability to the hospital setting while also acknowledging the need for controlled substance monitoring.

For Item 4, two participants (one each from hospital pharmacy practice and community pharmacy practice) commented that reconciliation of Schedule II controlled substances with each transaction is too onerous, while also supporting accountability of controlled substances. The participants suggested the Board retain the current language, which provides a registrant the option of either reconciling after each disbursement or at least once per year.

For Item 7, one participant from a hospital pharmacy practice setting expressed concern about reconciling Schedules III through V controlled substances, particularly when those products may be utilized in an automated medication dispensing system (AMDS).

Other comments received:

For Item 3, new paragraph 10.14(2)"f," a commenter recommended changing "reconciliation of" to "accountability measures for."

For Item 4:

- Amended subrule 10.18(4), a commenter recommended that the subrule qualify that only significant "negative" discrepancies be reported.
- Amended paragraph 10.18(4)"a," a commenter recommend reconciliation of Schedule II substances only after every tenth dispensing of a product or at least monthly if a product is dispensed fewer than ten times during the month.

For Item 5, amended subrule 10.19(1), a commenter recommended that paragraphs "f" and "h" be maintained with the current language allowing estimated quantities for certain Schedules III through V controlled substances on a registrant's inventory count.

For Item 6, amended subrule 10.19(4), a commenter suggested requiring the presence of the new owner when an inventory is conducted in response to a change of ownership.

For Item 8, new subrule 10.21(5), commenters suggested requiring an action plan only in situations when losses occurred as a result of internal theft and excluding an action plan when losses resulted from a robbery.

The Board was agreeable to many of the recommended changes, but declined others.

In response to the comments about Item 1, the Board acknowledges the challenges that might arise with supply chain backlogs and budgetary processes, particularly given the extended rule-making process with the Amended Notice of Intended Action. As a result, the Board changed the effective date of the security requirements to be one year following the effective date of this rule making. In response to the concerns raised by hospital practice personnel relating to video surveillance requirements, the Board revised paragraph 6.7(5)"b" to clarify that video surveillance would not be required when drugs are stored in an AMDS or an alternative electronic storage unit that uses biometric restricted access or other electronic monitoring mechanism.

In response to the comment about Item 3, the Board agreed, and paragraph 10.14(2)"f" was revised accordingly.

Regarding the responses to Item 4, the Board was not in agreement with the suggestion to retain the current language to allow registrants the option of annual reconciliation for Schedule II products. Reconciliation with each transaction ensures the perpetual inventory count is accurate and truly perpetual, ensuring that substances are accounted for.

Relating to the reporting of discrepancies, the Board further amended subrule 10.18(4) to clarify that only losses are required to be reported.

Regarding the comments about Item 5, the Board generally declined the requests to maintain the status quo for allowing estimates of certain Schedules III through V substances on an inventory count. The products that would now require an exact count would be bottles containing fewer than 100 dosage forms. Previously allowing estimated quantities of products has resulted in unreliable audits and assurances that substances are accounted for.

The Board agreed, however, with the concern about exact counts of liquid products contained in nonincremented containers since loss of product will inevitably occur if the product is poured into a separate incremented container for the purpose of an inventory count. As such, the Board revised the underscored language in subparagraph 10.19(1)"f"(3) to allow liquid products packaged in nonincremented containers to be estimated to the nearest one-fourth container.

For the comment about Item 6, the Board declined to require the presence of a new owner when an inventory is conducted due to a change in ownership. A new owner has the option, if the new owner chooses, of taking a complete controlled substance inventory prior to opening of business on the first day under the new ownership.

For the comment about Item 7, the Board declined to make any changes to the rule since it provides the registrant a variety of options for maintaining accountability for Schedules III through V substances.

For the comment on Item 8, the Board declined to limit an action plan to only situations involving internal theft or to exclude losses resulting from robbery. The Board finds that each situation, robberies

included, can be critically evaluated to determine the weaknesses that were exploited to result in the loss of controlled substances.

In addition to the changes described above, nonsubstantive changes have been made to clarify the rule language.

Adoption of Rule Making

This rule making was adopted by the Board on May 3, 2022.

Fiscal Impact

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

Jobs Impact

After analysis and review of this rule making, an impact on jobs cannot be determined.

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.

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).

Effective Date

This rule making will become effective on July 6, 2022.

The following rule-making actions are adopted:

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 July 6, 2023, a basic alarm system.

b. No later than July 6, 2023, a video surveillance system, except in areas where drugs are stored in an automated medication dispensing system or an alternative electronic storage unit which uses biometric restricted access or other electronic monitoring mechanism.

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"** to **"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 accountability measures for 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 following the discovery. The registrant shall determine the need for further investigation, and significant ~~discrepancies~~ 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 ~~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, except for liquid products packaged in nonincremented containers, which may be estimated to the nearest one-fourth container.

(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 on 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 657—paragraph 8.35(6)*"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 on the last day of duty of the outgoing pharmacist in charge. 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 pharmacist in charge and the incoming pharmacist in charge shall cause an inventory to be taken prior to the opening of business on the first day of duty of the incoming pharmacist in charge. 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.

1. 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).
2. Documented audit and reconciliation of all controlled substances every six months.
3. Routine documented cycle counts of substances, so long as all controlled substances are counted every 90 days and identified discrepancies are investigated and documented.
4. Other measure preapproved 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. The action plan shall include any directives, including, but not limited to, inventory counts, audits, and perpetual inventory counts provided by a board compliance officer.

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/1/22.