PHARMACY BOARD [657]

Notice of Intended Action

The Board of Pharmacy hereby proposes to amend Chapter 6, "General Pharmacy Practice," Chapter 8, "Universal Practice Standards," 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; allow a pharmacist, under specific conditions, to delegate the dispensing of a prescription which otherwise requires pharmacist counseling while the pharmacist is on a break; require Iowa pharmacies to maintain a perpetual inventory system for all controlled substances; and require an exact count or measure of all schedules of controlled substances for a controlled substance inventory count.

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.

Public Comment

Any interested person may submit 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 S.W. 8th Street, Suite E
Des Moines, IA 50309

Public Hearing

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 proposed:

ITEM 1. Amend subrule 6.7(4) as follows:

6.7(4) *Refill sales during pharmacist break.* At the discretion of the on-duty supervising pharmacist and pursuant to established policies and procedures, the pharmacist may delegate to a technician the dispensing of previously verified prescriptions ~~which have been identified to not require pharmacist counseling pursuant to rule 657—6.14(155A)~~ when the pharmacist is on a break of limited duration and is absent from the pharmacy department. A prescription that has been identified to require pharmacist counseling pursuant to rule 657—6.14(155A) may be dispensed only if the following conditions are met:

a. the pharmacy develops a list of drugs that may not be dispensed in the pharmacist's absence without the patient or caregiver receiving pharmacist counseling, when counseling would normally be required;

b. the patient or caregiver is told that the pharmacist is on a break and is offered the opportunity to wait until the pharmacist returns from break to receive counseling;

c. if the patient or caregiver declines to wait, a telephone number at which the patient or caregiver can be reached is obtained;

d. after returning from break, the pharmacist makes a reasonable effort to contact the patient or caregiver by telephone and provides counseling; and

e. the pharmacist documents the counseling that was provided or documents why counseling was not provided, including a description of the efforts made to contact the patient or caregiver. The documentation shall be retained and available for inspection or copying by the board or its authorized representatives for two years from the date of dispensing.

ITEM 2. Adopt the following **new** subrule 6.7(5):

6.7(5) *Minimum physical security and monitoring system requirements.* No later than December 1, 2022, a pharmacy located in Iowa shall utilize the minimum physical security and monitoring system requirements as provided herein. Each pharmacy shall develop and implement a documented site-specific analysis of pharmacy security methods to be utilized. At least annually, each pharmacy shall document evaluation and testing of the pharmacy's security and monitoring systems. Minimum physical security and monitoring system requirements include:

a. Appropriate physician security methods to prevent unauthorized access to prescription drugs, including controlled substances, and records when the pharmacy is closed.

b. A basic alarm system with off-site monitoring and perimeter and motion sensors.

c. Controlled access to computer records.

d. If the pharmacy maintains stocks of controlled substances,

(1) Secure storage such as a safe.

(2) An electronically monitored security system which requires and records the unique identification of the individual accessing the pharmacy, including the date and time of access. Complete access records shall be maintained for a minimum of two years following the date of access. A security system maintained onsite shall be secure and protected from unauthorized access.

(3) A continuous system of video surveillance and recording of the pharmacy department that includes maintenance of recordings for a minimum of 60 days following the date of the recording. A security system maintained onsite shall be secure and protected from unauthorized access.

e. A designated location, away from drug storage areas, where pharmacy staff personal items may be stored while onsite that can be monitored.

ITEM 3. Adopt the following **new** paragraph **8.3(3)"e"**:

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

ITEM 4. Adopt the following **new** paragraph **10.14(2)"d"**:

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

ITEM 5. Amend rule 657—10.18(124) as follows:

657—10.18(124) ~~Schedule II~~ Controlled substances 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. Additionally, each pharmacy located in Iowa that maintains controlled substances shall maintain a perpetual inventory system for all 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~~ controlled 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) No change.

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) No change.

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 discrepancies between the physical inventory and the perpetual inventory, the registrant shall be notified immediately. 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 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. Any discrepancies discovered shall be investigated and reported to the PIC or the responsible individual within one business day. 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 subrule 10.18(4), paragraph "a", shall be completed at least once each year, and that count shall be reconciled with the perpetual inventory record balance. Any discrepancies discovered shall be investigated and reported to the PIC or the responsible individual within one business day. 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 6. 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.~~