

PHARMACY BOARD [657]

Adopted and Filed

The Board of Pharmacy hereby amends Chapter 10, “Controlled Substances,” and Chapter 100, “Iowa Real-Time Electronic Pseudoephedrine Tracking System,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in Iowa Code section 124.212B.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code section 124.212B.

Purpose and Summary

The amendments, developed with the approval of the Governor’s Office of Drug Control Policy, identify all registered pharmacy employees as authorized dispensers of pseudoephedrine products.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on July 31, 2019, as **ARC 4570C**. The board received no comments. The amendments are identical to those noticed.

Adoption of Rule Making

This rule making was adopted by the Board on _____, 2019.

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.

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 _____, 2019.

The following rule-making action is adopted:

ITEM 1. Amend rule 657—10.34(124) as follows:

657—10.34(124) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine without a prescription. A product containing ephedrine, pseudoephedrine, or phenylpropanolamine, which substance is a Schedule V controlled substance and is not listed in another controlled substance schedule, may be dispensed or administered without a prescription by ~~a pharmacist, pharmacist intern, or certified pharmacy technician~~ an authorized dispenser pursuant to 657—Chapter 100 to a purchaser at retail pursuant to the conditions of this rule.

10.34(1) Who may dispense. Dispensing shall be by ~~a licensed Iowa pharmacist, by a registered pharmacist intern under the direct supervision of a pharmacist preceptor, or by a registered certified pharmacy technician under the direct supervision of a pharmacist, except as authorized in~~ an authorized dispenser pursuant to 657—Chapter 100. This subrule does not prohibit, after the ~~pharmacist, pharmacist intern, or certified pharmacy technician~~ dispenser has fulfilled the professional and legal responsibilities set forth in this rule and has authorized the dispensing of the substance, the completion of the actual cash or credit transaction or the delivery of the substance by another pharmacy employee.

10.34(2) to 10.34(4) No change.

10.34(5) Identification. The ~~pharmacist, pharmacist intern, or certified pharmacy technician~~ dispenser shall require every purchaser under this rule to present a current government-issued photo identification, including proof of age when appropriate. The ~~pharmacist, pharmacist intern, or certified pharmacy technician~~ dispenser shall be responsible for verifying that the name on the identification matches the name provided by the purchaser and that the photo image depicts the purchaser.

10.34(6) Record. Purchase records shall be recorded in the real-time electronic pseudoephedrine tracking system (PTS) established and administered by the governor's office of drug control policy pursuant to 657—Chapter 100. If the PTS is unavailable for use, the purchase record shall be recorded in an alternate format and submitted to the PTS as provided in 657—subrule 100.3(4).

a. Alternate record contents. The alternate record shall contain the following:

(1) to (3) No change.

(4) The name or unique identification of the ~~pharmacist, pharmacist intern, or certified pharmacy technician~~ dispenser who approved the dispensing of the product.

b. and c. No change.

10.34(7) No change.

ITEM 2. Amend rule **657—100.2(124)**, definition of “Dispenser,” as follows:

“*Dispenser*” means a licensed Iowa pharmacist, a registered pharmacist-intern under the direct supervision of a pharmacist preceptor, ~~or~~ a registered pharmacy technician under the direct supervision of a pharmacist, except as authorized in 657—Chapter 13, or a registered pharmacy support person under the direct supervision of a pharmacist.

ITEM 3. Amend rule 657—100.3(124) as follows:

657—100.3(124) Electronic pseudoephedrine tracking system (PTS). Unless granted an exemption by the office pursuant to these rules, all pharmacies dispensing products as defined in rule 657—100.2(124) without a prescription are required to participate in the PTS pursuant to Iowa Code section 124.212B.

100.3(1) Reporting elements. The record of a completed purchase or attempted purchase of a product without a prescription shall contain the following:

a. to e. No change.

f. The name or unique identification of the ~~pharmacist, pharmacist intern, or pharmacy technician~~ dispenser who approved the dispensing of the product.

100.3(2) No change.

100.3(3) *Denial of transactions and overrides.*

a. No change.

b. The PTS shall provide an override feature for use by a dispenser to allow completion of the sale. ~~For security purposes and to ensure the integrity of the PTS, use of the override feature shall be restricted to authorized dispensers and may not be delegated to a pharmacy technician trainee or a pharmacy support person.~~ A dispenser utilizing the override feature shall document the reason that, in the professional judgment of the dispenser, it is necessary to override the recommendation of the PTS to deny the transaction.

100.3(4) No change.