

PHARMACY BOARD [657]

Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 10, “Controlled Substances”, Iowa Administrative Code, and Chapter 100, “Iowa Real-Time Electronic Pseudoephedrine Tracking System,” Iowa Administrative Code.

The amendments were approved at the _____, regular meeting of the Board of Pharmacy.

The proposed amendments are the result of a general review of administrative rules pursuant to Iowa Code subsection 17A.7(2), in collaboration with the Governor’s Office of Drug Control Policy. The amendments remove reference to the pseudoephedrine advisory council, which was repealed by 2013 Acts, ch 68, §2, and allow a certified pharmacy technician to approve a purchase under the direct supervision of a pharmacist.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on _____. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by email to terry.witkowski@iowa.gov.

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

These amendments are intended to implement Iowa Code sections 124.212, 124.212A, 124.212B, 124.213, and 17A.7(2).

The following amendments are proposed.

Item 1. Amend rule 657—10.32(124,155A) as follows:

657—10.32(124,155A) 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 to a purchaser at retail pursuant to the conditions of this rule.

10.32(1) Who may dispense. Dispensing shall be by a licensed Iowa pharmacist, ~~or~~ 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 657—Chapter 100. This subrule does not prohibit, after the pharmacist, pharmacist-intern, or certified pharmacy technician 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 a ~~nonpharmacist~~ another pharmacy employee.

10.32(2) to 10.32(4) No changes.

10.32(5) Identification. The pharmacist, pharmacist-intern, or certified pharmacy technician 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 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.

10.32(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 real-time electronic repository 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) The name, address, and signature of the purchaser.

(2) The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

(3) The date and time of the purchase.

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

b. to c. No Changes.

10.32(7) No changes.

Item 2. Amend rule 657—100.1(124) as follows:

657—100.1(124) Purpose and scope. ~~2009 Iowa Code Supplement~~ section 124.212B directs the governor's office of drug control policy to establish a real-time electronic repository to monitor and control the sale of Schedule V products that are not listed in another controlled substance schedule and that contain any detectible amount of pseudoephedrine, its salts, or optical isomers, or salts of optical isomers; ephedrine; or phenylpropanolamine. All pharmacies dispensing such products without a prescription shall electronically report all such sales to the repository. The real-time electronic repository shall be under the control of and administered by the governor's office of drug control policy. Both the governor's office of drug control policy and the board of pharmacy are directed to adopt rules relating to the real-time electronic repository and have

jointly adopted these rules. These rules establish the pseudoephedrine tracking system (PTS).

Item 3. Amend rule 657—100.2(124) as follows:

657—100.2(124) Definitions. As used in this chapter:

“Attempted purchase” means a proposed transaction for the dispensing of a product that is entered by a dispenser into the electronic pseudoephedrine tracking system, which transaction is not completed because the system recommends that the transaction be denied pursuant to the quantity limits established in ~~2009 Iowa Code Supplement~~ section 124.213.

“Board” means the board of pharmacy.

~~“Council” means the pseudoephedrine advisory council established pursuant to Iowa Code section 124.212C.~~

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

“Law enforcement officer” means all of the following:

1. State police officer.
2. City or county police officer.
3. Sheriff or deputy sheriff.
4. State or public university safety and security officer.
5. Department of natural resources officer.
6. Certified or full-time peace officer of this or another state.
7. Federal peace officer.
8. Criminal analyst assigned to a law enforcement agency.
9. Probation or parole officer.

“Office” means the governor’s office of drug control policy.

“Product” means a Schedule V drug product that is not listed in another controlled substance schedule and that contains any detectible amount of pseudoephedrine, its salts, or optical isomers, or salts of optical isomers; ephedrine; or phenylpropanolamine.

“Pseudoephedrine tracking system” or “PTS” means the real-time electronic repository established to monitor and control the sale of products and administered by the governor’s office of drug control policy.

“Purchaser” means an individual 18 years of age or older who purchases or attempts to purchase a product.

Item 4. 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 2009 Iowa Code Supplement section 124.212B. ~~The office has established a council to provide input and advise the office regarding the implementation, maintenance, and administration of the PTS. The council also assists the office in developing guidelines to ensure patient confidentiality and the integrity of the relationship established by the patient and the patient’s health care provider.~~

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. The name and address of the purchaser.
- b. A current government-issued photo identification number.
- c. The electronic signature of the purchaser. If a pharmacy is not able to secure or record an

electronic signature, a hard-copy signature logbook shall be utilized and maintained by the pharmacy. Each record in the logbook shall include the purchaser's signature and shall identify the purchase by transaction number.

d. Date and time of the purchase.

e. The name and quantity of the product purchased, including the total milligrams of ephedrine, pseudoephedrine, or phenylpropanolamine contained in the product.

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

100.3(2) No changes.

100.3(3) Denial of transactions and overrides.

a. No changes.

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 changes.

Item 5. Amend subrule 100.4(4) as follows:

100.4(4) Patients. A patient may request and receive information regarding products reported to have been purchased by the patient.

a. A patient may submit a signed, written request for records of the patient's purchases and attempted purchases during a specified period of time. The request shall identify the patient by

name, including any aliases used by the patient, and shall include the patient's date of birth and gender. The request shall also include any address where the patient resided during the time period of the request and the patient's current address and daytime telephone number. A patient may personally delivery the request to the PTS administrator or authorized staff member of the office located at ~~Wallace State Office Building, 502 E. 9th Street, First Floor,~~ Pape State Office Building, 215 East 7th Street, Fifth Floor, Des Moines, Iowa 50319. The patient shall be required to present current government-issued photo identification at the time of delivery of the request. A copy of the patient's identification shall be maintained in the records of the PTS.

b. No changes.

Item 6. Amend rule 657—100.5(124) as follows:

657—100.5(124) Violations. Violations of provisions of these rules or ~~2009~~ Iowa Code ~~Supplement~~ ~~section~~ sections 124.212A, 124.212B, or 124.213 may subject the violator to criminal prosecution.

Item 7. Amend implementation clause as follows:

These rules are intended to implement ~~2009~~ Iowa Code ~~Supplement~~ sections 124.212, 124.212A, 124.212B, and 124.213.