

**PHARMACY BOARD[657]**

**Adopted and Filed**

Pursuant to the authority of 2009 Iowa Code Supplement section 124.212B, the Board of Pharmacy and the Governor’s Office of Drug Control Policy hereby jointly adopt new Chapter 100, “Iowa Real-Time Electronic Pseudoephedrine Tracking System,” Iowa Administrative Code.

These rules 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. In addition, the rules identify the responsibilities of the parties involved. A pharmacy dispensing such products shall electronically report all such sales to a central repository under the control and administration of the Office of Drug Control Policy. These rules are in addition to the Board of Pharmacy rules amended in 657—Chapter 10 regarding the dispensing of these products by pharmacies. (See **ARC 8892B** herein.)

Notice of Intended Action was published in the April 7, 2010, Iowa Administrative Bulletin as **ARC 8666B**. The Governor’s Office of Drug Control Policy and the Board of Pharmacy received comments and action was taken on those comments.

The comments received included requests to remove the waiver provision, clarify the law enforcement release rule, elaborate on situations in which a pharmacy uses the override function, and clarify the rule on the liability of a pharmacy that uses the override function.

In response to those comments, the following changes have been made to the rules published under Notice:

In rule 657—100.1(124), the waiver provision was removed because the statute does not allow for any waivers. The qualifier “without a prescription” was added to rule 657—100.3(124), introductory paragraph, and to subrule 100.3(1) to clarify which products will be tracked. In subrule 100.3(3), documentation of the use of the override function was added to clarify the requirements for using that process. In subrules 100.4(1) and 100.4(2), language relating to the provision of information to law enforcement officers was moved to clarify different requirements based on federal and state laws. In subrule 100.4(4), the mailing address for the Governor’s Office of Drug Control Policy was changed because the planned relocation of the office to that address has been indefinitely postponed. In rule 657—100.5(124), the provision regarding administrative charges for violations of the rules was removed because professional licensing boards already provide for administrative action as a result of violations of rules and laws.

These rules were approved by the Governor’s Office of Drug Control Policy on May 14, 2010. These rules were approved by the Board of Pharmacy during the June 1, 2010, regular meeting of the Board.

These rules will become effective on September 1, 2010.

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

The following amendment is adopted.

Adopt the following **new** 657—Chapter 100:

CHAPTER 100  
IOWA REAL-TIME ELECTRONIC PSEUDOEPHEDRINE  
TRACKING SYSTEM

**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).

**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.

*"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.

*"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 detectable 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.

**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 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 who approved the dispensing of the product.

**100.3(2) Frequency and quantity.** Dispensing at retail to the same purchaser within any 30-day period shall be limited to products collectively containing no more than 7,500 mg of ephedrine, pseudoephedrine, or phenylpropanolamine; dispensing at retail to the same purchaser within a single calendar day shall not exceed 3,600 mg.

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

a. If an individual attempts to purchase a product in violation of these rules, the PTS shall:

- (1) Notify the dispenser at the time of sale; and
- (2) Recommend that the dispenser deny the transaction.

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 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) Availability of electronic PTS.** If the electronic PTS is unavailable for use:

a. A written record of each purchase shall be maintained pursuant to 657—subrule 10.32(6).

b. The information shall be provided to the office for inclusion in the PTS within 72 hours after the PTS becomes operational.

c. A PTS administrator shall enter the information from the written record into the PTS within 72 hours of receipt.

**657—100.4(124) Access to database information and confidentiality.** Information collected in the PTS is confidential unless otherwise ordered by a court or released by the office pursuant to state or federal law. Information may not be released except as provided by this rule.

**100.4(1) PTS administrators.** PTS administrators shall be provided access to the PTS for the purpose of searching and retrieving reports only by articulating reasonable suspicion or providing a case number or reference number for an ongoing investigation. PTS administrators shall also be provided information on purchasers directly from the PTS. This information may be sent directly to law enforcement officers pursuant to paragraph 100.4(2)“e” for purposes of investigation.

**100.4(2) Law enforcement release.** PTS reports may be provided to a law enforcement officer whose duty is to enforce the drug laws of this state, another state, or the United States pursuant to this subrule.

a. A law enforcement officer shall register with the PTS prior to requesting reports. To ensure the identity of the officer and to maintain confidentiality of PTS information, the officer’s identity shall be verified and registration shall be approved by the office.

b. A law enforcement officer may request information or data from the PTS by providing to a PTS administrator a case or reference number for an ongoing investigation and by articulating reasonable suspicion.

c. At the discretion of the office, law enforcement officers may be given direct access to data from the PTS pursuant to the federal Combat Methamphetamine Epidemic Act.

d. If a law enforcement officer requests PTS information on purchases or attempted purchases in excess of the monthly limit established in 657—subrule 10.32(3) or subrule 100.3(2), a subpoena or other court order is required.

e. Data collected on purchases in excess of limits established pursuant to the federal Combat Methamphetamine Epidemic Act may be released to law enforcement officers by PTS administrators without a court order or articulating reasonable suspicion.

**100.4(3) Statistical data.** The PTS administrator, following establishment of confidentiality, may provide summary, statistical, or aggregate data to public or private entities for statistical, research, or educational purposes. Prior to release of any such data, the administrator shall remove any information that could be used to identify an individual patient, dispenser, or other person who is the subject of or identified in the PTS information or data.

**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 deliver the request to the PTS administrator or authorized staff member of the office located at 401 S.W. 7th Street, Suite N, Des Moines, Iowa 50309. 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.* A patient who is unable to personally deliver the request to the office may submit a request via mail or commercial delivery service. The request shall comply with all provisions of paragraph "a" above, and the signature of the requesting patient shall be witnessed and the patient's identity shall be attested to by a currently registered notary public. In addition to the notary's signature and assurance of the patient's identity, the notary shall certify a copy of the patient's current government-issued photo identification, and that certified copy shall be submitted with the written request. The request shall be submitted to the governor's office of drug control policy at the address identified in paragraph 100.4(4) "a."

**100.4(5) Regulatory officers.** Regulatory agencies that supervise or regulate a health care practitioner shall be able to access information from the PTS only pursuant to an order, subpoena, or other means of legal compulsion relating to a specific investigation of a specific individual and supported by a determination of probable cause. A director of a regulatory agency with jurisdiction over a practitioner, or the director's designee, who seeks access to PTS information for an investigation shall submit to the PTS administrator in a format established by the office a written request via mail, facsimile, or personal delivery. The request shall be signed by the director or the director's designee and shall be accompanied by an order, subpoena, or other form of legal compulsion establishing that the request is supported by a determination of probable cause.

**100.4(6) Pharmacy administrators.** A pharmacy, an authorized employee of a pharmacy, or a licensed pharmacist shall be provided access to the stored PTS information only for the limited purpose of determining the sales made by the pharmacy. A pharmacy shall be able to print the pharmacy's sales records for any product during any specified period of time upon the request of the board or an agent of the board.

**100.4(7) Court orders and subpoenas.** The PTS administrator shall provide database information in response to a court order or a county attorney subpoena or other subpoena issued by a court upon a determination of probable cause.

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

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

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EDITOR'S NOTE: For replacement pages for IAC, see IAC Supplement 6/30/10.