

657—10.32(124,155A) Dispensing products containing ephedrine, pseudoephedrine, or phenylpropanolamine.

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 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. This subrule does not prohibit, after the pharmacist 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.

10.32(2) Packaging of nonliquid forms. A nonliquid form of a product containing ephedrine, pseudoephedrine, or phenylpropanolamine includes gel caps. Nonliquid forms of these products to be sold pursuant to this rule shall be packaged either in blister packaging with each blister containing no more than two dosage units or, if blister packs are technically infeasible, in unit dose packets or pouches.

10.32(3) 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.

10.32(4) Age of purchaser. The purchaser shall be at least 18 years of age.

10.32(5) Identification. The pharmacist shall require every purchaser under this rule to present a current, valid government-issued photo identification, including proof of age when appropriate. The pharmacist 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. ~~A legible dispensing record shall be created and maintained for the dispensing of ephedrine, pseudoephedrine, and phenylpropanolamine products pursuant to this rule.~~ Purchase records shall be recorded in the real-time electronic repository (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. ~~Record~~ 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 who approved the dispensing of the product.

b. ~~Record~~ Alternate record format. The record shall be maintained using one of the following options:

- (1) A hard-copy record ~~maintained in a bound logbook (i.e., with pages sewn or glued to the spine).~~
- (2) A record in the pharmacy's electronic prescription dispensing record-keeping system that is capable of producing a hard-copy printout of a record.

(3) A record in an electronic data collection system that captures each of the data elements required by this subrule. ~~The electronic data collection system shall be~~ and that is capable of producing a hard-copy printout of a record.

c. PTS records retrieval. Pursuant to 657 subrule 100.4(6), the pharmacy shall be able to produce a hard-copy printout of transactions recorded in the PTS by the pharmacy for one or more specific products for a specified period of time upon request by the board or its representative or to such other persons or governmental agencies authorized by law to receive such information.

10.32(7) Notice required. ~~The pharmacy shall ensure that the following notice shall be included in the logbook required pursuant to subrule 10.32(6) or shall be~~ is provided to purchasers of ephedrine, pseudoephedrine, or phenylpropanolamine products, is displayed with or on the electronic signature device, or is displayed in the dispensing area and be visible to the public:

“WARNING: Section 1001 of Title 18, United States Code, states that whoever, with respect to the logbook, knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any materially false, fictitious, or fraudulent statement or representation, or makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry, shall be fined not more than \$250,000 if an individual or \$500,000 if an organization, imprisoned not more than five years, or both.”