

ARKANSAS**PRODUCTS:**

- Any product containing ephedrine, pseudoephedrine, or phenylpropanolamine or any of their salts, isomers, or salts of isomers, alone or in a mixture. (A.C.A. 5-64-212)

PRODUCT EXEMPTIONS:

- Any ephedrine or pseudoephedrine in liquid, liquid capsule, or liquid gel capsule form if the drug is dispensed, sold, transferred, or otherwise furnished in a single transaction limited to no more than three (3) packages, with any single package containing not more than ninety-six (96) liquid capsules or liquid gel capsules or not more than three (3) grams of ephedrine or pseudoephedrine base (A.C.A. 5-64-212);
- The Department of Health, in collaboration with the Arkansas State Board of Pharmacy, may exempt products by rule and upon application of a manufacturer if the product has been formulated in such a way as to effectively prevent the conversion of the active ingredient into methamphetamine or its salts or precursors. (A.C.A. 5-64-212)

SALES LIMITS:

- No more than 3 packages containing one or more products; or a single package containing more than 96 pills, tablets, gels, capsules or other individual units; or a single package containing more than 3 g of ephedrine / pseudoephedrine / phenylpropanolamine; may not purchase more than 5 g ephedrine or 9 g pseudoephedrine / phenylpropanolamine in any 30-day period (A.C.A. 5-64-1103)

SALES RESTRICTIONS:

- Products are designated as schedule V, and may not be sold in excess of limit except pursuant to a prescription (A.C.A. 5-64-212);
- Products may only be sold in a licensed pharmacy by a licensed pharmacist or a registered pharmacy technician (A.C.A. 5-64-1103);
- Purchaser must be at least 18 years old. (AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section I)
- Except under a valid prescription, before dispensing a product containing EPH, PSE, PPA, a pharmacist shall make a professional determination, based on a pharmacist-patient centered relationship, as to whether or not there is a legitimate medical and pharmaceutical need for the drug.
- Determination may be based on factors including without limitation: prior medication filling history; patient screening; and other tools that provide

professional reassurance to the pharmacist that a legitimate medical and pharmaceutical need exists.

- Board of Pharmacy may adopt rules regarding determinants and take necessary disciplinary actions. (Arkansas Code § 5-64-1103(c)and (d))

RECORDKEEPING REQUIREMENTS:

- Sales in excess of the retail sales limit are subject to distribution recordkeeping requirements as detailed in 5-64-1001 (A.C.A. 5-64-1005);
- A pharmacy to maintain a written or electronic log, or receipts of transactions involving the sale of ephedrine, pseudoephedrine, or phenylpropanolamine (A.C.A. 5-64-1103);
- Purchaser to present current and valid proof of identity (which includes photo and date of birth, such as passport, military ID or driver's license that contains functioning magnetic stripe or barcode) at time of sale, and sign a written or electronic log or receipt that documents the purchaser's address, date of the transaction, the name of the person, the name and quantity of pseudoephedrine or ephedrine purchased, received, or otherwise acquired and the signature of the pharmacist or technician who issued the product to the purchaser (A.C.A. 5-64-1103; AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section I);
- Records must be maintained for 2 years (AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section I);

CENTRALIZED REAL-TIME ELECTRONIC LOGBOOK:

Pharmacies must enter any transaction required to be maintained in the logbook records into the real-time electronic logbook maintained by the Arkansas Crime Information Center. The log requirements may be satisfied by entering the information required to be produced into this real-time electronic logbook; (A.C.A. 5-64-1103)

- The Arkansas Crime Information Center will (free of charge) provide pharmacies access to the real-time electronic logbook that will have the capability to calculate both state and federal ephedrine, pseudoephedrine, or phenylpropanolamine purchase limitations; (A.C.A. 5-64-1104)
- Information entered into the real-time electronic logbook is confidential and not subject to the Freedom of Information Act. The Arkansas Crime Information Center may not disclose any information entered, collected, recorded, transmitted, or maintained in the real-time electronic logbook except as authorized by law. (A.C.A. 5-64-1105) Those authorized to access information in the real-time electronic logbook include:
 - persons authorized to prescribe or dispense the affected products;
 - local, state, or federal law enforcement officials or prosecutors;

- local, state, or federal officials requesting access for the purpose of facilitating a product recall;
- the Arkansas State Board of Pharmacy for the purpose of investigating a suspicious transaction(A.C.A. 5-64-1106)
- Real-time electronic logbook records will be destroyed by the state after two years. (A.C.A. 5-64-1108)
- This requirement is subject to available funding received on or before May 15, 2008. (A.C.A. 5-64-1104)
- Regulations to implement the real-time electronic logbook requirements will be promulgated by the Arkansas Crime Information Center. (A.C.A. 5-64-1107)

PRODUCT PLACEMENT:

- Not specified, though see under sales restrictions... where products may only be sold in a licensed pharmacy by a licensed pharmacist or a registered pharmacy technician. (A.C.A. 5-64-1103)

SECURITY REQUIREMENTS:

- Practitioners must provide effective controls and procedures to guard against theft and diversion. All C-V substances must be stored under double-lock security in a substantially constructed, permanently mounted cabinet. Pharmacies may, however, disperse controlled substances throughout the prescription area stock of non-controlled substances in such a manner as to obstruct the theft or diversion of the controlled substances. (AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section III)

VIOLATIONS AND PENALTIES:

- A person commits an offense if he or she knowingly releases or discloses to any unauthorized person any confidential information collected and maintained as part of the real-time electronic logbook or obtains confidential information for a purpose not authorized. Such violations are a Class A misdemeanor. (A.C.A. 5-64-1110)
- A person who knowingly sells in violation of sales limit is guilty of a Class A misdemeanor and also may be subject to a civil fine not to exceed five thousand dollars (\$5,000) for a first or second offense upon conviction.
- A person who knowingly sells in violation of sales limit is guilty of a Class D felony and also may be subject to a civil fine not to exceed five thousand dollars (\$5,000) for a third offense upon conviction.
- A person who knowingly sells in violation of sales limit is guilty of a Class C felony and also maybe subject to a civil fine to exceed ten thousand dollars (\$10,000) for a fourth or subsequent offense upon conviction. (A.C.A 5-64-1103)

OTHER:

- A wholesale distributor with exclusive rights to distribute pseudoephedrine to only licensed pharmacies is exempt from Schedule V requirements for the storage and distribution of pseudoephedrine. (A.C.A. 5-64-212)
- Pharmacies required to report suspicious orders to the Board of Pharmacy (A.C.A. 5-64-1006)
- A pharmacy is not liable civilly for a sale of ephedrine, pseudoephedrine, or phenylpropanolamine that occurs at another pharmacy. (A.C.A. 5-64-1109)
- A pharmacy or pharmacist is not civilly liable for a determination made under § 5-64-1103(c) or for any refusal to dispense, sell, transfer, or otherwise furnish ephedrine, pseudoephedrine, or phenylpropanolamine based on a determination of age or identity.
- A pharmacy or a pharmacist has the same immunity from civil liability with regard to actions regarding non-prescription drugs as is provided under § 5-64-1111 for actions concerning ephedrine, pseudoephedrine, or phenylpropanolamine.

OTHER NOTABLE IMPLICATIONS DUE TO C-V DESIGNATION:

- Registration
 - Every pharmacy, wholesale distributor (including chain drug warehouses) distributor or other institution or facility licensed, registered or otherwise permitted to distribute, dispense or conduct research with controlled substances that engages in the wholesale distribution of prescription drugs (definition of which includes controlled substances) must register annually with the board of pharmacy. A separate license / registration is required for each facility.
 - A.C.A. 20-64-505; AR Pharmacy Board Admin Rules 08-00-0003; AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section I.
- Marketing
 - It is unlawful to sell or offer for sale by advertisement, circular, letter, sign, oral solicitation, or any other means any prescription drug (definition of which includes controlled substances) unless the seller holds and possesses a sales permit.
 - A.C.A. 20-64-504; AR Pharmacy Board Admin Rules 08-00-0002
- Storage
 - Facilities used for wholesale distribution must be secured from unauthorized entry. Entry into areas where prescription drugs (definition of which includes controlled substances) must be limited to authorized personnel. Facilities must be equipped with an alarm system to detect after hours entry.
 - AR Pharmacy Board Admin Rules 08-00-0008

- Records
 - Every practitioner must keep a record of controlled substances received, administered, dispensed or professionally used otherwise than by prescription in order to maintain complete accountability. The record must show the date of receipt, the name and address of the person or business from whom received, and the kind and quantity of such substances received.
 - AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section VI
 - Each practitioner must maintain inventory records in one consolidated record system with all controlled substances which must be taken every two years as required by DEA.
 - AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section VI
 - Records of C III-V substances must be maintained either separately from all other records, or be readily retrievable from the ordinary business records for inspection and copying by authorized agencies.
 - AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section VI
- Theft / Loss Reporting
 - In the event of a theft or loss of a controlled substance, permit holders must notify the Arkansas Dept. of Health Division of Pharmacy Services and Drug Control, the nearest DEA Diversion Field Office, and the Board of Pharmacy immediately upon discovery by phone or fax, and deliver a completed DEA 106 form to all of the above listed agencies within 7 days.
 - AR Pharmacy Board Admin Rules 07-04-0006; AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section IV
- Surrender of Unwanted Substances
 - Controlled substances no longer usable because of deterioration or expired dating or are unwanted must be delivered in person, by registered mail or in another manner of shipment that allows for the package to be tracked from the shipping point to destination with return receipt. Must be accompanied by first two copies of the Report of Drugs Surrendered (form).
 - AR Department of Health Rules and Regulations Pertaining to Controlled Substances - Section VII