

**MISSOURI****PRODUCTS:**

- All products (single entity & combination) containing any detectible quantity of PSE PPA, or EPH. (V.A.M.S. 195.017)

**PRODUCT EXEMPTIONS:**

- All products dispensed upon prescription exempt from the sales limit, the age restriction, and requirements to show photo ID. (V.A.M.S. 195.417);
- There may be exemptions, by rule, for drug products that the Department of Health and Senior Services (DHSS) determines are not used to manufacture methamphetamine. (V.A.M.S. 195.017)
- PSE products that may only be dispensed pursuant to a prescription (rx-only) are not C-V, and as such, do not need to comply with the annual inventory requirements that would otherwise be required for PSE products. Nurse practitioners and physician assistants may prescribe rx-only PSE products. (November 2006 Missouri Board of Pharmacy Newsletter)

**SALES LIMITS:**

- 3.6 grams per person per 24 hour period for all products without regard to the number of transactions. (V.A.M.S. 195.417)
- 9 grams per person per 30-day period for all products without regard to the number of transactions (V.A.M.S. 195.417; 19 CSR 30-1.074)

**SALES RESTRICTIONS:**

- Designates single entity ephedrine as C-IV (V.A.M.S. 195.017);
- Designates single entity PSE products and combination EPH or PSE products as C-V (V.A.M.S. 195.017);
- Single entity PSE products and combination EPH or PSE products may only be sold by a registered pharmacist or registered pharmacy technician (V.A.M.S. 195.017; 19 CSR 30-1.074);
- Single entity PSE products and combination EPH or PSE products may only be sold in businesses holding state and federal controlled substances registration (ie – pharmacy only) (V.A.M.S. 195.017);
- Single entity PSE products and combination EPH or PSE products may not be sold to anyone under 18 years of age. (V.A.M.S. 195.017)
- Seller must deliver purchased products directly into custody of purchaser. (V.A.M.S. 195.017)

**ID REQUIREMENT:**

- Pharmacist, intern pharmacist, or technician must require purchaser, prior to purchase, to furnish suitable photo ID issued by state or federal government, or

another acceptable document sharing DOB. (V.A.M.S. 195.017; V.A.M.S. 195.417; 19 CSR 30-1.074)

**RECORDKEEPING REQUIREMENTS:**

- Must maintain an electronic log of each transaction that includes purchaser name and address, and signature; amount purchased; date and time of purchase; and name or initial of the pharmacist, intern pharmacist, or technician who dispensed to the purchaser. Pharmacies must comply with log requirements within 90 days after law enacted. This requirement does apply to sales of products pursuant to a prescription. (V.A.M.S. 195.017; V.A.M.S. 195.417; 19 CSR 30-1.074)
- Each pharmacy must submit electronic log information for sales of any PSE, PPA, or EPH product in accordance with transmission methods and frequency established by the Department. All logs, records, documents, and electronic information maintained for the dispensing of these products must be open for inspection and copying by municipal, county, and state or Federal law enforcement officers. (V.A.M.S. 195.417; V.A.M.S. 195.017)
- An auxiliary written log must be established for the documentation of C-V substances dispensed, sold, distributed or otherwise provided if the electronic log is inoperative for any reason (19 CSR 30.1.074);
- Any electronic logs must be capable of providing a listing of utilization of any C-V substances for a minimum of the preceding 12 month period. Utilization information shall be available by both specific C-V product and purchaser name. (19 CSR 30.1.074)

**PRODUCT PLACEMENT:**

- Products not sold pursuant to a prescription must be offered for sale only from behind a pharmacy counter where the public is not permitted. (V.A.M.S. 195.017; V.A.M.S. 195.417)

**PENALTIES:**

- Persons who knowingly or recklessly violate sales restrictions, limits, placement, record and ID requirements are guilty of a class A misdemeanor. (V.A.M.S. 195.017; V.A.M.S. 195.417)

**WHOLESALE DISTRIBUTION REQUIREMENTS:**

- DHSS to promulgate rules for the security and storage of C-V designated EPH / PSE products (V.A.M.S. 195.017);
- Entities registered with the Department of Health and Senior Services as distributors shall be deemed to have met security requirements for storage of C-V EPH and PSE products if those products are stored in compliance and consistent with DEA requirements (19 CSR 30-1.032);

- Distributors are required to conduct background checks on employees with access to these substances and to report losses as required by 19 CSR 30-1.034. (19 CSR 30-1.032)

**PREEMPTION:**

- All local ordinances (even previously grandfathered ordinances, and those enacted by any political subdivision of the state) are preempted. (V.A.M.S. 195.417)

**FUNDING:**

- \$ 700, 000 for program operations appropriated to Dept. Health & Senior Services from federal grant funds received through the Byrne/Justice Assistance Grant Program. \$611,445 for Information Technology Services Division of the Office of Administration to implement and administer program.

**OTHER NOTABLE IMPLICATIONS DUE TO C-V DESIGNATION:**

- Registration
  - All persons who engage in distribution of controlled substances must register with the Department of Health and Senior Services. 19 CSR 30-1.013
  - Separate registrations are required for each distribution site; however, dispensers distributing less than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year shall be exempt from obtaining a separate registration for distributing. Dispensers distributing more than 5% of the total combined dosage units of controlled substances distributed and dispensed in a calendar year must obtain a separate registration as a distributor, but are exempt from maintaining separate distribution inventories. 19 CSR 30-1.026
- Inventory
  - Inventories required for all schedules of controlled substances and must be taken for all those drugs on hand on the date the inventory was taken. 19 CSR 30-1.042
  - Following initial inventory, registrant must at least annually take a new inventory of all stocks on hand. 19 CSR 30-1.042
  - For newly controlled substances not previously listed in a schedule, every registrant must take an inventory of all stocks of that substance on hand on the effective date of the rule adding the drug into the specified schedule. After the initial inventory, the substance must then be inventoried each time a registrant performs an inventory thereafter. 19 CSR 30-1.042
  - Distributor and dispenser registrants separately must include the following information in the inventory:

- For each CDS in finished form, the name of the substance; each finished form of the substance (for example, 10 mg tablet or 10 mg concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (for example, four 100 tablet bottles or 3 ml vials); the number of commercial containers of each finished form (for example, four 100 tablet bottles or six 3 ml vials);
  - For each CDS such as those damaged, defective or impure substances awaiting disposal, substances held for quality control purposes or substances maintained for extemporaneous compoundings, the name of the substance; the total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; the reason for the substance being maintained by the registrant and whether the substance is capable of use in the manufacture of any controlled substance in finished form.
- Dispensers may make estimated counts or measures when inventorying C-V unless containing holds more than 1000 tablets. 19 CSR 30-1.042
- Security
  - C-V substances must be stored in a securely locked, substantially constructed cabinet; however, pharmacies may disperse these substances throughout the stock of non-controlled substances. 19 CSR 30-1.034
- Theft / Loss Reporting
  - Registrants must notify Department of Health of any theft or significant loss of any controlled substances upon discovery by completing and submitting a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals to the Department of Health no later than seven business days after the discovery of such a loss. Registrant may attach a copy of a completed DEA Loss Form in lieu of completing the back or second page of a Report of Loss, Theft or Diversion of Controlled Substances or Regulated Chemicals form. In the event of theft, diversion or suspected theft or diversion, the report submitted to the Department of Health shall be accompanied by or followed by a summary of the internal investigation performed, the outcome of the investigation, and a copy of any law enforcement agency report completed if applicable. 19 CSR 30-1.032
- Dispensing Prescription vs. Non-Prescription C-V
  - Dispensing of non-prescription C-V substances is limited to no more than 120 cc 4 oz. of or 24 dosage units of a controlled substance to any one purchaser within a 48 hour period. 19 CSR 30-1.072

- No nonprescription C-V substance may be dispensed to a purchaser under 18 years old. 19 CSR 30-1.072
- The pharmacist must require every purchaser of nonprescription C-V substances to furnish suitable ID (including proof of age) and record in a bound record book the name and address of purchaser, name and quantity of controlled substance purchased, purchase date and the name or initials of the pharmacist who dispensed the substance to the purchaser. 19 CSR 30-1.07