

**IOWA****PRODUCTS:**

- All EPH and PPA are Schedule V.
- All products containing PSE are Schedule V unless exempted (see below)

**PRODUCT EXEMPTIONS:**

- PSE products purchased pursuant to a prescription in a pharmacy may be obtained in quantities greater than otherwise limited (IA Code 124.212);
- Products containing 360 mg or less of PSE in liquid, liquid capsule, or liquid-filled gel capsule form are accepted from C-V designation and may be warehoused, distributed, and sold over the counter by a 'retailer' (which includes pharmacies that sell such products). (IA Code 126.23A(1); IA Code 124.212)
- All PSE products sold pursuant to a prescription are exempt from purchase limit,

**SALES LIMITS:**

- Retailer or employee of retailer may not knowingly sell more than one package containing 3.6 mg of PSE to a person in a twenty-four-hour period (IA Code 126.123A);
- Retailer or pharmacy may not sell more than 7.5 mg of PSE to the same purchaser within any 30-day period (IA Admin. Code 657-10.31(124,155A));

**PURCHASE LIMITS:**

- No person may purchase more than 7.5 mg of PSE either separately or collectively per 30 days from a pharmacy or retailer unless the person has a prescription (IA Code 126.123) and violation is serious misdemeanor;
- No person may purchase more than 3.6 mg of PSE either separately or collectively per 24 hr period or 1 package per 24 hour period. (IA Code 126.123) ( IA ST Section 124.213)

**SALES RESTRICTIONS:**

- All EPH and PPA products; solid PSE products; and PSE products in liquid, liquid capsule or liquid-filled gel capsule products containing more than 360 mg of PSE are classified as schedule V drugs (IA Code 124.212);
- For all C-V EPH, PSE & PPA products may only be dispensed in licensed pharmacy by a pharmacist, pharmacist-intern, or pharmacy technician under the direct supervision of a pharmacist. The purchaser must be at least 18 years old (IA Admin. Code 657-10.31(124,155A));
- No retailer may sell a product that contains more than 360 mg of PSE (IA Code 126.123A);
- Retailers prohibited from selling a package of a PSE product that can be further broken down or subdivided into 2 or more separate and distinct packages or offer

promotions where a PSE product is given away for free as part of any purchase transaction. (IA Code 126.123A)

**ID REQUIREMENTS:**

- Purchaser must present government-issued photo ID card to retailer prior to purchasing a PSE product and retailer must require purchaser to present the government issued photo ID prior to purchase (IA Code 124.212; IA Code 126.123A);
- Purchaser must present government-issued photo ID including proof of age. (IA Admin. Code 657-10.31(124,155A))

**RECORDKEEPING REQUIREMENTS/ ELECTRONIC LOGBOOK REQUIREMENT:**

- For sales of PSE products containing up to 3.6 mg of PSE, purchaser must print the name and address and legibly sign an electronic logbook maintained by retailer and pharmacist. If an electronic logbook is not available, retailer and pharmacist must require a signature that is associated with a transaction number. A retailer and pharmacist must require the purchaser to legibly sign the log book and print name and address, and determine that signature in the electronic logbook corresponds with the name on the government-issued photo ID card. Retailer must print the name of the PSE product purchased and quantity sold next to the name of each purchaser in the logbook. Logbook to be kept for 24 months from the date of last entry. (IA Code 126.123A);
- The following shall be required for C-V PSE, EPH & PPA products sales until sufficient funding is received to implement and maintain the state real-time central repository and the repository is established: the purchaser must sign log book and include name and address of purchaser, name and quantity of product purchased including the total mg of PSE contained in the product, purchase date, and the name or unique identification of the pharmacist who dispensed the substance to the purchaser; pharmacy must maintain a dispensing record for each sale for these products which can be maintained as a hard copy record, a record in the pharmacy's electronic prescription dispensing record system, or a record in an electronic data collection system. (IA Admin. Code 657-10.31(124,155A))
- If sufficient funding is received to implement and maintain the state real-time central repository and the repository is established, pharmacies must use an electronic logbook to record information for all C-V PSE product sales. The logbook must be used as follows:
  - Purchaser must sign log book
  - Pharmacist or other pharmacy employee must determine that signature in electronic logbook corresponds with name on the government issued photo ID and enter purchaser's name and address; date and time of purchase; and name and quantity of product purchased.

- If electronic logbook is unavailable for purchaser to sign, seller must require a signature that is associated with a transaction number, and an alternative record must be kept that complies with Board rules
  - (IA Code 124.212A)
- A pharmacy that sells a PSE product with 3.6mg or less at retail must comply with the product placement, ID, and log book requirements; however, a pharmacy selling these PSE products as a C-V is exempted. (IA Code 126.123A (6)).
- Must affix notification to the logbook that a purchaser entering a false statement or misrepresentation in the electronic logbook may subject to criminal penalties under 18 U.S.C. section 1001. (IA Code 124.212A; IA Code 126.23A)

**PRODUCT PLACEMENT:**

- PSE products sold at retail must be maintained in locked cabinet or behind a sales counter where the public is unable to reach the product and where the public is not permitted. (IA Code 124.212A)

**SALES NOTICE:**

- Retailer must post notice in a clear and conspicuous manner in a location where PSE products are offered for sale stating “Iowa law prohibits the over-the-counter purchase of more than one package of a product containing pseudoephedrine in a twenty-four-hour period or of more than seven thousand five hundred milligrams of pseudoephedrine within a thirty-day period. If you purchase a product containing pseudoephedrine, you are required to sign a logbook which may be accessible to law enforcement officers.” (IA Code 126.123A)

**STATE REAL-TIME CENTRAL REPOSITORY:**

- State to establish a real-time central repository to monitor and control the sale of schedule V products containing any detectible amount of PSE, ephedrine; or phenylpropanolamine. A pharmacy dispensing such products shall report all such sales electronically to a central repository under the control of the governor’s office drug control policy.
- Information collected in the central repository is confidential unless otherwise ordered by a court, or released by the lawful custodian of the records pursuant to state or federal law.
- A pharmacy, an employee of a pharmacy, or a licensed pharmacist shall be provided access to the stored information for the limited purpose of determining what sales have been made by the pharmacy.
- A pharmacy, an employee of a pharmacy, or a licensed pharmacist shall not be given the obligation or duty to view the stored information.

- A pharmacy or an employee of a pharmacy, or a licensed pharmacist shall not be given the obligation or duty to seek information from the central repository if the real-time electronic logbook becomes unavailable for use.
- If the electronic logbook is unavailable for use, a paper record for each sale shall be maintained including the purchaser's signature. Any paper record maintained by the pharmacy shall be provided to the governor's office of drug control policy for inclusion in the electronic real-time central repository as soon as practicable.
- The state real-time central repository will not become operational unless sufficient funding is received to implement and maintain the program and the office establishes the statewide real-time central repository.

#### **PENALTIES:**

- An employee of a retailer who sells a product containing more than 360 mg of PSE or knowingly sells more than 1 package in a 24-hour period commits a simple misdemeanor punishable by a scheduled fine (IA Code 126.123A);
- If a retailer or an employee of a retailer sells in excess of limits or in violation of sales limits, restrictions and product placement; does not meet ID or record keeping requirements; or does not post sign, a city or county may assess a civil penalty against the retailer upon hearing and notice. Penalties that may be assessed by cities or counties range from \$300 for first violation to \$3000 and possible revocation of ability to sell products for fourth and subsequent violations (IA Code 126.123A; IA Code 124.123B);
- If a retailer or an employee of a retailer sells in excess of limits or in violation of sales limits, restrictions and product placement; does not meet ID or record keeping requirements; or does not post sign, additional fines may be imposed by state / local law enforcement that range from \$100 for first offense to \$500 for third and subsequent offenses. (IA Code 805.8C)
- If a pharmacy, an employee of a pharmacy or licensed pharmacist discloses information stored in the central repository in violation of 124.212B (7) commits a simple misdemeanor.

#### **RETAILER LIABILITY EXEMPTION:**

- A retailer or an employee of a retailer that reports to any law enforcement agency any alleged criminal activity related to the purchase or sale of PSE or who refuses to sell a PSE product to a person is immune from civil liability for that conduct, except in cases of willful misconduct. (IA Code 126.123A)
- A pharmacy, an employee of a pharmacy or licensed pharmacist shall not be liable, if acting reasonably and in good faith, to any person for any claim which may arise when reporting sales of products to the state real-time central repository.

#### **WHOLESALE DISTRIBUTION REQUIREMENTS:**

- PSE products warehoused by a distributor located in IA which is warehoused for export to a retailer outside of IA are accepted from C-V schedule. A distributor warehousing and exporting a PSE product must still register with the pharmacy board and comply with any rules adopted by the board and relating to the diversion of PSE products from legitimate commerce. (IA Code 124.212)

**PREEMPTION:**

- Prohibits adoption of local ordinances regulating the display or sale of products containing PSE - an ordinance adopted in violation of this is void and unenforceable and any enforcement activity of an ordinance in newly enacted law is void. (IA Code 126.123A)

**TRAINING:**

- A pharmacy, an employee of a pharmacy, or licensed pharmacist following electronic logbook requirements must comply with training requirements pursuant to federal law. ( 124.212A)
- A retailer or an employee of a retail following electronic logbook requirements must comply with training requirements pursuant to federal law. ( 126.23A)

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

- Registration
  - Every person who distributes or dispenses any controlled substance within Iowa must obtain and maintain a biennial registration. A separate registration is required for each principle place of business. Also, businesses engaged in any combination of manufacturing, distributing and dispensing must obtain a separate registration for each independent activity. IC 124.302; 657 IAC 10.1 (124); 657 IAC 10.5 (124); 657 IAC 10.6 (124)
  - Warehouses are exempt from registration requirement, except if controlled substances are distributed directly from the warehouse to registered locations other than the registered location from which the substances were delivered to the warehouse OR if controlled substances are delivered directly from the warehouse to persons exempt from registration (employees, carriers, etc.) 657 IAC 10.6 (124)
  - As a part of the registration process, the board may inspect the establishment of an applicant or registrant and review the application for registration and other information regarding an applicant or registrant in order to determine whether they have met the applicable standards. 657 IAC 10.10 (124, 147, 155A)
- Inventories
  - Persons registered to distribute or dispense controlled substances must maintain inventories in conformance with the record keeping and

inventory requirements of federal law and additional rules that may be issued by the board. IC 124.306

- Each inventory must contain a complete and accurate record of all controlled substances on hand on the date and at the time the inventory is taken. If the substance is listed in C-V, the quantity may be an estimated count or measure unless then container holds more than 1,000 dosage units and has been opened. 657 IAC 10.35 (124, 155A)
- A separate inventory is required for each registered location and for each independent activity registered. 657 IAC 10.35 (124, 155A)
- On the effective date of an addition of a previously non-controlled substance to any schedule, any registrant who possesses the newly controlled substance must take an inventory of all stocks of the substance on hand. The inventory record must be maintained with the most recent controlled substances inventory. Thereafter, the newly controlled substance must be included in each inventory made by the registrant. 657 IAC 10.35 (124, 155A)
- Marketing
  - No person may distribute complimentary packages of controlled substances to a practitioner (the definition of which includes a pharmacy) unless that person prepares and leaves with the practitioner a specific written list of the items so distributed... and this list must also be sent to the pharmacy board. IC 124.306; 657 IAC 10.36 (124)
- Security
  - Controlled substances listed as C-V may be stored in a securely locked, substantially constructed cabinet. However, pharmacies may disperse these substances throughout the stock of non-controlled substances in a manner so as to obstruct the theft or diversion of the substance. 657 IAC 10.15 (124, 155A)
- Theft / Loss Reporting
  - Registrants must report in writing, on the forms provided by the board, any theft or significant loss of any controlled substance upon discovery. The report must be submitted to the board office within 2 weeks of discovery. Thefts must be reported whether or not the controlled substances are subsequently recovered or the responsible parties are identified and action is taken against them. Copies of theft / loss reports must be maintained in files. 657 IAC 10.16 (124)
- Dispensing Non-Prescription C-V
  - Sales restrictions, limits, purchaser age & ID requirement, and log requirement detailed in the above meth law summary 657 IAC 10.31 (124, 155A)