

**TITLE 475. OKLAHOMA STATE BUREAU OF NARCOTICS AND  
DANGEROUS DRUGS CONTROL  
CHAPTER 55. PSEUDOEPHEDRINE CONTROL**

**Section**

- 475:55-1-1 Purpose
- 475:55-1-2 Characteristics of exempt pseudoephedrine products
- 475:55-1-3 Pharmacy requirements
- 475:55-1-4 Dispensing pseudoephedrine products
- 475:55-1-5 Thirty-day requirement
- 475:55-1-6 Special registration for distribution centers
- 475:55-1-7 Lawful possession of Schedule V pseudoephedrine
- 475:55-1-8 Records and invoices
- 475:55-1-9 Labeling
- 475:55-1-10 Prescriptions
- 475:55-1-11 Distributor and warehouse storage of Schedule V pseudoephedrine products
- 475:55-1-12 Criteria for exemption

[Authority: 63 O.S., 2-212, 2-301]

**475:55-1-1. Purpose.**

The Oklahoma Bureau of Narcotics and Dangerous Drugs Control has been granted statutory authority by 63 O.S., 2-301 to “promulgate rules and regulations relating to the registration and control of the manufacture, distribution, dispensing, prescribing, administering or use for scientific purposes of controlled dangerous substances within this state.” Furthermore, 63 O.S., 2-212 authorizes the Oklahoma Bureau of Narcotics and Dangerous Drugs Control to promulgate rules specifically for Schedule V pseudoephedrine products. These statutes, as well as the entire Oklahoma Uniform Controlled Dangerous Substances Act, O.S. 63 Chapter 2, and the Oklahoma Administrative Code Title 475, are used as guiding authorities for the specific points of these rules and regulations.

The rules of this Chapter specify the requirements for pseudoephedrine control in Oklahoma. Included in this Chapter are characteristics of exempt pseudoephedrine products, pharmacy requirements, dispensing pseudoephedrine products, thirty-day requirement, special registration for distribution centers, lawful possession of Schedule V pseudoephedrine products, records and invoices, labeling, prescriptions, distributor and warehouse storage of Schedule V pseudoephedrine, and criteria for exemption.

[Authority: 63 O.S., 2-212, 2-301; OAC: 475: 1-1-1]

**475:55-1-2. Characteristics of exempt pseudoephedrine products.**

All products that are either: (1) soft gelatin liquid-filled capsules; or, (2) liquid preparations, are exempt from Schedule V. Conversely, all solid dosage forms of medications, including powders, that contain any quantity of pseudoephedrine are

classified as Schedule V controlled dangerous substances and are subject to the rules of this section.

The term “gel capsule,” as specified in O.S. Title 63, means any soft gelatin liquid-filled capsule that contains a liquid suspension, which, in the case of pseudoephedrine, is suspended in a matrix of glycerin, polyethylene glycol, and propylene glycol, along with other liquid substances. Regardless of the product manufacturers’ labeling, a gelatin-covered solid does not constitute a “gel capsule” under this provision.

The term “active ingredient,” as specified in O.S. Title 63, shall include the matrix of glycerin, polyethylene glycol, and propylene glycol that is found in liquid capsules.

Nothing in this section shall exempt from Schedule V status any liquid preparation that is found in an illegal laboratory, is associated with an illegal laboratory, or is in any form other than that manufactured and sold by a registered manufacturer for medicinal purposes.

Products containing pseudoephedrine that are dispensed pursuant to a valid prescription by a registrant are exempt from classification as Schedule V. As such, these are not restricted to the limitations of five (5) refills within a six (6) month period – instead, they are regulated the same as any non-scheduled prescription drug. Any product that is dispensed by prescription must be kept in a container that is supplied by the pharmacy and must be labeled in a manner consistent with any other prescription.

[Authority: 63 O.S., 2-212, 2-301]

**475:55-1-3. Pharmacy requirements.**

Schedule V pseudoephedrine substances may be sold only in licensed pharmacies that are registered with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control. These substances, as a special class of Schedule V controlled substances, shall be kept in a locked environment (shelving unit, safe, cabinet, etc.) that is within view of the pharmacy, or behind the pharmacy counter. As specified in 63 OS, 2-303 (1), 2-304 (A)-4, and OAC 475:20-1-2, the pharmacist and those with access to pseudoephedrine products will have an affirmative duty to guard against the theft and diversion of these products.

[Authority: 63 O.S., 2-212, 2-301; 2-302, 2-303, 2-304 (A)-4; OAC 475-20-1-1 through 1-8]

**475:55-1-4. Reserved**

**475:55-1-5. Reserved**

**475:55-1-6. Special registration for distribution centers.**

Wholesale distribution centers located in Oklahoma that are engaged in interstate business to states in which Schedule V pseudoephedrine products may be sold legally can apply for and be granted a limited Schedule V pseudoephedrine pharmacy distributor license from the Oklahoma Bureau of Narcotics and Dangerous Drugs Control. Eligibility for this registration shall be subject to the applicant's meeting the following conditions:

- (1) Applicant is actively engaged in the interstate sale of grocery or pharmaceutical items;
- (2) Applicant's sales are not limited to pseudoephedrine items alone, or to pseudoephedrine items in conjunction with other items associated with the illegal manufacture of methamphetamine or other controlled drugs;
- (3) Applicant does not have a history of association with the diversion of pseudoephedrine, or of having failed to guard against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs;
- (4) Applicant provides a list of customers, and they do not have a history of association with the diversion of pseudoephedrine, or of having failed to guard against the diversion of pseudoephedrine or other products used in manufacturing illegal drugs;
- (5) Applicant meets the security conditions determined by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control in 475:20 of this code. However, the security for pseudoephedrine shall be less restrictive than for other pharmaceutical Schedule V controlled drugs and shall be held to a level commensurate with the nature of wholesale distribution;
- (6) Other conditions, as determined on a case-by-case basis by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control.

[Authority: 63 O.S., 2-212, 2-301, 2-302; OAC 475:10, 475:20]

**455:55-1-7. Lawful possession of Schedule V pseudoephedrine**

The following persons are allowed to lawfully possess Schedule V pseudoephedrine while in the course of legitimate business:

- (1) Any Schedule V pseudoephedrine-only limited pharmaceutical distributor, or its agents, licensed by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
- (2) Any wholesale drug distributor, or its agents, licensed by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
- (3) Any manufacturer of controlled drugs, or its agents, licensed by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control;
- (4) A pharmacist licensed by the Oklahoma State Board of Pharmacy; and,
- (5) A physician, certified registered nurse anesthetist, advance practice nurse, physician's assistant, or other person, registered with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control who is allowed to possess and dispense controlled drugs.

These individuals will be required to guard against the diversion of controlled

drugs and are subject to the rules and regulations pertaining to registrants handling, reporting, dispensing controlled dangerous drugs, and submission to inspections by peace officers as set forth in 63 O.S. and OAC 475.

[Authority: 63 O.S., 2-212, 2-301, 2-302, 2-303, 2-304, 2-305, 2-502; OAC 475]

**475:55-1-8. Records and invoices.**

Any distributor or retailer of Schedule V pseudoephedrine products must keep readily retrievable records, as specified in 475:25-1-3 (b), and invoices pertaining to the receipt and sale of the substance. These records do not have to be kept separate from other records, if and only if such records can be produced within a reasonable period of time (no more than 2 days) as requested by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control or other persons legally authorized to request these records. All records must be kept for a minimum of two (2) years.

[Authority: 63 O.S., 2-212, 2-301, 2-307; OAC 475:25-1-3]

**475:55-1-9. Labeling.**

Schedule V pseudoephedrine products shall be exempt from the labeling requirements for other prescriptions or other Schedule V controlled drugs. Pseudoephedrine products that are obtained pursuant to a valid prescription and exempt from Schedule V classification must have an attached pharmacy label consistent with other non-scheduled drugs obtained by prescription.

[Authority: 63 O.S., 2-212, 2-301, 2-314; OAC 475:45]

**475:55-1-10. Prescriptions.**

The nine (9) gram per month threshold limit shall not apply to Schedule V pseudoephedrine products that are dispensed for a valid prescription.

[Authority: 63 O.S., 2-212, 2-301, 475:30]

**475:55-1-11. Distributor and Warehouse Storage of Schedule V Pseudoephedrine Products.**

Scheduled pseudoephedrine products shall be stored in a locked area that is monitored; however, they will not be required to be kept in a special locked cage. Pharmaceutical distributors and warehouses are responsible for establishing security measures to guard against diversion as specified in Chapter 20 of this code.

[Authority: 63 O.S., 2-212, 2-301, 2-303; OAC 475:20]

**475:55-1-12. Criteria for exemption.**

Any person may request an exemption or conditional exemption of Schedule V classification for a specific product. The decision of whether to grant an exemption shall be made by the Director of the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, who will take the following into consideration:

- (1) Ease with which the product can be converted to methamphetamine;
- (2) Ease with which pseudoephedrine is extracted from the substance and whether it forms an emulsion, salt, or other form;
- (3) Whether the product contains a “molecular lock” that renders it incapable of being converted into methamphetamine;
- (4) Presence of other ingredients that render the product less likely to be used in the manufacture of methamphetamine; and,
- (5) Any pertinent data that can be used to determine the risks of the substance being used in the illegal manufacture of methamphetamine or any other controlled substance.

The burden of proof for exemption shall be upon the person requesting the exemption. The petitioner shall provide the Oklahoma Bureau of Narcotics and Dangerous Drugs Control with evidence that the product has been formulated in such a way as to serve as an effective general deterrent to the conversion of pseudoephedrine into methamphetamine. Such evidence shall include the furnishing of a valid scientific study, conducted by a professional laboratory and evincing professional quality chemical analysis, which is in accordance with uniform parameters set forth in writing by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. This report shall include documentable and reviewable data and a clear delineation of methodology.

[Authority: 63 O.S., 2-212 (C), 2-301, 2-302, 2-303, 2-304; 75 O.S., 302]