OKLAHOMA STATE BUREAU OF NARCOTICS AND DANGEROUS DRUGS CONTROL RULES AND REGULATIONS TITLE 475



Director Donnie Anderson

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Chapter 1 - Administrative Operations

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Chapter 1 - Administrative Operations

Subchapter 1 - General Provisions

Section 475:1-1-1 Purpose

Section 475: 1-1-2 Definitions [NEW]

475:1-1-1. Purpose

The Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN) is authorized by Title 63 of the Oklahoma Statutes to enforce the Uniform Controlled Dangerous Substances Act (UCDSA) of the State of Oklahoma. The OBN also has the authority to investigate criminal offenses related to human trafficking and money laundering.

[Source: Amended at 29 Ok Reg 1311, eff 6-25-12]

475:1-1-2. **Definitions**

The following words and terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

"Agent" means a peace officer appointed by and who acts on behalf of the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or an authorized person who acts on behalf of or at the direction of a person who manufactures, distributes, dispenses, prescribes, administers or uses for scientific purposes controlled dangerous substances but does not include a common or contract carrier, public warehouser or employee thereof, or a person required to register under the Uniform Controlled Dangerous Substances Act. With regard to an authorized person who acts on behalf of or at the direction of a person who manufactures, distributes, dispenses, prescribes, administers, or uses for scientific purposes controlled dangerous substances, the term "agent" does not include contractors, subcontractors, or their employees.

"Applicant" means the person(s) seeking registration with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and includes all beneficial owners of any legal entity where ownership disclosure is a legal requirement or condition to any licensing or registration.

"Beneficial Owner" means the natural person(s) who ultimately own or control a legal entity, as well as the natural person(s) on whose behalf a business is conducted including those natural persons who exercise ultimate effective control over a legal entity or arrangement. No natural person or persons may perform any service in an attempt to become a beneficial owner that would otherwise violate, circumvent, bypass, or render meaningless, any statute of the State of Oklahoma or of the United States. This includes, but is not limited to, all natural persons:

- (A) Who contribute cash, property, or services to receive a membership or ownership interest in a legal entity;
- (B) Who becomes a member of the legal entity without acquiring a membership or ownership interest;
- (C) Who are managers of the legal entity;
- (D) Who have voting rights in the legal entity;
- (E) Who receive profits, losses, or distributions of the legal entity;
- (F) Who make capital contributions to the legal entity; or
- (G) Who receive capital interest from the legal entity.

"Registrant" means a person, persons, corporation or other entity who has been issued by the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control a registration pursuant to Section 2-302 of Title 63 of the Oklahoma Statutes and includes all beneficial owners of any legal entity where ownership disclosure is a legal requirement or condition to any licensing or registration.

Chapter 1 - Administrative Operations

Subchapter 3 - Open Records Act

Section 475:1-3-1 Open Records Act

475:1-3-1. Open Records Act

Title 51 Okl.St.Ann. § 24(A)(2) states: "Thus, it is the public policy of the State of Oklahoma that the people are vested with the inherent right to know and be fully informed about their government. The purpose of this act is to ensure and facilitate the public right of access to and review of government records so they may efficiently and intelligently exercise their inherent political power." Since § 24(A)(3) of the same title defines the OBN as a law enforcement agency, § 24(A)(8) specifies records must be made available to the public, if kept. In compliance with this act, the OBN has promulgated the following rules:

- (1) Information requests can be made and will be processed from 8:30 A.M. to 5:00 P.M. Monday through Friday (except for authorized holidays).
- (2) Information retrieval shall be conducted by OBN personnel to maintain the security of the agency.
- (3) A fee of \$0.20 per page will be assessed as direct costs of document reproduction, unless the request for information is such that requires an extensive use of OBN personnel to search the records, at which time \$0.50 per page will be charged. Payment can be made by money order, cashier's check or cash. Cash payment will not be accepted through the mail.
- (4) The supervisor of OBN's Communications and Records Section, OBN Attorney(s), the OBN Public Information Officer, or OBN Director designee shall be authorized to release the records.
- (5) The rules set out in this Chapter shall not alter any existing OBN policy about providing information to other state or law enforcement agencies.
- (6) The policy of this Section shall not alter any existing policy about how long records are retained by OBN and shall not change the existing policy regarding release of information about juveniles.

[**Source:** Amended at 24 Ok Reg 2735, eff 8-11-07]

Chapter 1 - Administrative Operations

Subchapter 5 - Administrative Actions

Section 475:1-5-1	Purpose
Section 475:1-5-2	Burden of proof
Section 475:1-5-3	Hearing officer
Section 475:1-5-4	Prehearing conference
Section 475:1-5-5	Prehearing ruling
Section 475:1-5-6	Submission and receipt of evidence
Section 475:1-5-7	Official transcript; index; corrections
Section 475:1-5-8	Proposed findings of fact and conclusions of law
Section 475:1-5-9	Report and record
Section 475:1-5-10	Final order
Section 475:1-5-11	Surrender of Registration in Lieu of Administrative Action
Section 475:1-5-12	Service in Administrative Proceedings [NEW]
Section 475:1-5-13	Request for Hearing and Default [NEW]
Section 475:1-5-14	Discovery in Administrative Proceedings [NEW]

475:1-5-1. Purpose

The rules of this Subchapter explain the administrative hearing process at the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control when said agency seeks to limit, condition, suspend, revoke or deny the renewal of an OBN registration and/or impose a fine.

[Source: Amended at 12 Ok Reg 2833, eff 7-15-95]

475:1-5-2. Burden of proof

At any hearing for the limitation, conditioning, denial of renewal application, suspension or revocation of a registration, or the assessing of a fine the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control shall have the burden of proving by clear and convincing evidence, except where statute has expressly provided for a different burden of proof, that the requirements for such registration are not satisfied pursuant to Title 63 O.S. §§ 2-302 through 2-304.

[Source: Amended at 12 Ok Reg 2833, eff 7-15-95; Amended at 18 Ok Reg 2217, eff 6-11-01]

475:1-5-3. Hearing officer

A hearing officer, designated by the Director, shall preside over the hearings. The functions of the hearing officer shall commence upon his/her designation and terminate upon the certification of the record to the Director. The presiding officer shall have the duty to conduct a fair hearing, to take all necessary action to avoid delay, and to maintain order. He/She shall have all powers necessary to these ends, including, but not limited to:

- (1) Arrange and change the date, time and place of hearings and prehearing conferences and issue notice thereof.
- (2) Hold conferences to settle, simplify or determine the issues in a hearing, or to consider other matters that may aid in the expeditious disposition of the hearing.
- (3) Require parties to state their position in writing with respect to the various issues in the hearing and to exchange such statements with all other parties.
- (4) Examine witnesses and direct witnesses to testify.
- (5) Receive, rule on, exclude or limit evidence.
- (6) Rule on procedural items pending before him/her.

[Source: Amended at 12 Ok Reg 2833, eff 7-15-95]

475:1-5-4. Prehearing conference

The hearing officer for a hearing on the limitation, conditioning, denial of a renewal application, suspension or revocation of a registration, and/or the assessment of a fine on his/her own motion or on the motion of any party for good cause shown, may direct all parties to appear at a specified time and place for a conference for:

- (1) The simplification of issues.
- (2) The possibility of obtaining stipulations, admission of facts and documents.
- (3) The possibility of limiting the number of expert witnesses.
- (4) The identification and, if practicable, the scheduling of all witnesses to be called.
- (5) The advance submission at the prehearing conferences of all documentary evidence and affidavits to be marked for identification.
- (6) Such other matters as may aid in the expeditious disposition of the hearing.

[Source: Amended at 12 Ok Reg 2833, eff 7-15-95]

475:1-5-5. Prehearing ruling

The hearing officer may have the prehearing conference described in 475:1-5-4 reported verbatim and shall make a ruling reciting the action taken at the conference, the agreements made by the parties, the schedule of witnesses, and a statement of the issues for hearing. Such ruling shall control the subsequent course of the hearing unless modified by a subsequent ruling.

[**Source:** Amended at 12 Ok Reg 2833, eff 7-15-95]

475:1-5-6. Submission and receipt of evidence

- (a) The hearing officer may allow evidence at a hearing or pre-hearing conference that is competent, relevant, material and not unduly repetitious.
- (b) Opinion testimony shall be admitted when the hearing officer is satisfied that the witness is properly qualified.
- (c) Authenticity of all documents submitted in advance shall be deemed admitted unless objection thereto is filed with the hearing officer, except that a party will be permitted to challenge such authenticity at a later time upon showing of good cause for failure to have filed such written objection.
- (d) Samples, if otherwise admissible into evidence, may be displayed at the hearing and may be described for purposes of the record or may be admitted into evidence as exhibits.
- (e) Where official notice is taken or is to be taken of a material fact not appearing in the evidence of record, any party, on timely request, shall be afforded opportunity to controvert such fact.
- (f) The hearing officer shall file as exhibits copies of the following documents:
 - (1) The order to show cause or notice of hearing.
 - (2) Any waiver of hearing.
 - (3) The prehearing ruling, if any.
 - (4) Any other document necessary to show the basis for the hearing.

[Source: Amended at 12 Ok Reg 2833, eff 7-15-95; Amended at 24 Ok Reg 2735, eff 8-11-07; Amended at 29 Ok Reg 1311, eff 6-25-12]

475:1-5-7. Official transcript; index; corrections

Testimony given at a hearing shall be recorded. The Director will make provision for a record of the testimony and for such copies of the transcript thereof as he/she requires for his/her own purposes. Any party desiring a copy of the testimony and exhibits taken at the hearing or of any part thereof shall be entitled to the same upon written request to the Office of General Counsel of the OBN and upon payment of the costs thereof. Any party desiring a stenographic record of the testimony, at their own expense, may provide the services of a licensed or certified shorthand reporter to obtain an official record of a hearing.

[Source: Amended at 24 Ok Reg 2735, eff 8-11-07]

475:1-5-8. Proposed findings of fact and conclusions of law

Any party to the hearing may file proposed findings of fact and conclusions of law within the time fixed by the hearing officer. Any party so filing shall also serve one copy of their proposed findings and conclusions upon each other party to the hearing.

[**Source:** Amended at 12 Ok Reg 2833, eff 7-15-95]

475:1-5-9. Report and record

- (a) As soon as practicable after the time for the parties to file proposed findings of fact and conclusions of law has expired, the hearing officer shall prepare a report containing the following:
 - (1) His/Her findings of fact and conclusions of law with the reasons therefor.
 - (2) His/Her recommendation.
- (b) The hearing officer shall certify to the Director the record, which shall contain the recording of the testimony, exhibits, the findings of fact and conclusions of law proposed by the parties, and his/her report. Upon receipt of the certified record, the Director shall cause one (1) copy of the report of the hearing officer to be delivered to each party to the hearing.
- (c) The hearing officer may announce his/her decision orally at the close of the hearing without requesting that the parties file proposed findings of fact and conclusions of law. The hearing officer shall prepare a written report containing his/her findings and recommendation to the Director in the same manner as above.

[**Source:** Amended at 12 Ok Reg 2833, eff 7-15-95]

475:1-5-10. Final order

- (a) As soon as practicable after the hearing officer has certified the record to the Director, as required in 475:1-5-9, the Director shall issue his/her order in the proceeding, which shall set forth the final rule or decision and the findings of fact and conclusions of law upon which the rule or decision is based. This order shall specify the date on which it shall take effect, which shall not be less than thirty (30) days from the date of the order unless the Director finds that emergency conditions exist necessitating an earlier effective date, in which event the Director shall specify in the order his/her findings as to such conditions. Any reportable action taken as the result of a Final Order from a hearing or an Agreed Order shall be reported to the National Practitioner Data Bank pursuant to 45 CFR §60.1 et seq.
- (b) Any respondent who fails to request a hearing or appear, after receipt of notice, may be determined to have waived the right to appear and present a defense. The Director may enter a default judgment against any party who fails to participate in an administrative hearing. A Final Order may be issued by the Director granting the relief requested by default.

[**Source:** Amended at 12 Ok Reg 2833, eff 7-15-95]

475:1-5-11. Surrender of Registration in Lieu of Administrative Action

- (a) Any registrant of the OBN may surrender the registration in lieu of or in addition to administrative action at any time before such action is taken. In such a case, the registrant will waive the right to reapply for an OBN registration for a period of six (6) months from the effective date of the surrender. In such case, the OBN Director may approve or deny any application from the registrant following this six (6) month period based on the impact issuing the requested registration may have on the general public safety. A surrender of an OBN registration made in lieu of further administrative action shall be reported to the National Practitioner Data Bank pursuant to 45 CFR §60.1 et seq, if required.
- (b) In the event a registration is revoked, suspended, or surrendered, either voluntarily or following administrative action, the registrant may not, at any time, utilize the registration of another individual and/or institution. Any effort to utilize the registration of another may be considered an unlawful dispensation, administration, distribution, and/or prescription of a controlled dangerous substance as set forth under Title 63 of the Oklahoma Statutes.

(c) For registered businesses, any owner, manager, board member, officer, legal counsel, or other specifically designated and disclosed representative may surrender the applicable registration on behalf of the registered business.

[Source: Added at 24 Ok Reg 2735, eff 8-11-07; Amended at 29 Ok Reg 1311, eff 6-25-12]

475:1-5-12. Service in administrative proceedings

- (a) Any written order or notice of hearing, other than an immediate suspension order, shall be primarily served by one of the following methods:
 - (1) Personal delivery to the respondent at the last known registered address provided to the Bureau or to the registered agent of the respondent or to the attorney of record of the respondent, in any manner authorized by the law of this State for the personal service of summons.
 - (2) Certified mail, return receipt requested, to the last known mailing address of the respondent or to the registered agent of the respondent or to the attorney of record of the respondent.
- (b) In addition to one of the above methods, the OBN may effectuate service by electronic mail to the respondent at the last known electronic mail address provided to the Bureau or by publication to the Bureau's public website or by publication to the public OBN Registrant Verification website.

 (c) Service shall be deemed effective either on the date of personal service or on the date of receipt of certified mail or if refused, on the date of refusal.
 - (1) Registrants are required to keep information current and up to date with the Bureau. If either primary method fails and service cannot be made following a diligent search, service shall also be deemed effective when the Bureau attempts at least one of the primary methods and effectuates service via both electronic mail and publication to one of the online sites above.
 - (2) Service of notice shall be reasonably calculated, under all circumstances, to apprise the interested parties of the pendency of the action and to afford them an opportunity to present their objections.
- (d) Service of subsequent pleadings, as prescribed herein, upon a respondent shall be deemed adequate upon mailing, by regular mail, postage prepaid, to the last known residential or business address of the party to be served or his or her representative of record or by electronic mail when the party has consented to service by electronic mail.

475:1-5-13. Request for hearing and default

- (a) A request for a hearing shall be submitted in writing, on a form prescribed by the OBN. This form is available at the Bureau's principal place of business located at 419 NE 38th Terrace, Oklahoma City, OK 73105 or online at www.obndd.ok.gov. Hearing requests may only be submitted in person or by mail to the Bureau's principal place of business. Hearing requests submitted other than in person or by mail on the prescribed form shall not be accepted. Hearing requests must be made within thirty (30) calendar days of the date of issuance of the written order, not inclusive of the day of issuance of the written order. Hearing requests made or postmarked after the deadline for requesting a hearing will not be granted. The Request for Hearing Form shall be addressed to the Oklahoma Bureau of Narcotics, Legal Division, 419 NE 38th Terrace, Oklahoma City, OK 73105.
- (b) Any respondent who fails to appear, after requesting a hearing, will be determined to have waived the right to appear and present a defense. All allegations of fact shall be deemed admitted and the written order providing notice of the violations shall become the Final Order by default. Notice of taking default shall not be required.

- (c) Respondents who are entities must appear in any administrative proceeding through an attorney licensed to practice law in the State of Oklahoma. Any timely request for hearing by an entity shall be accompanied by an Entry of Appearance by a licensed attorney of the State of Oklahoma. A template Entry of Appearance Form is available online at www.obndd.ok.gov for download but is not required to be used. If no attorney enters their appearance in the administrative proceeding within ten (10) business days following the request for hearing, the respondent will be determined to have waived the right to a hearing and present a defense. Any respondent who fails to appear, after requesting a hearing, will be determined to have waived the right to appear and present a defense. All allegations of fact shall be deemed admitted and the written order providing notice of the violations shall become the Final Order by default. Notice of taking default shall not be required.
- (d) Only the registrant or the registrant's legal representative may request a hearing on behalf of the registrant. For registered businesses, only the owner(s), manager(s), board member(s), officer(s), legal counsel(s), or other specifically designated and disclosed representative(s) may request a hearing on behalf of the registered business.

475:1-5-14. Discovery in administrative proceedings

- (a) Disclosure of Evidence by the Bureau.
 - (1) Upon written request of the respondent, the Bureau shall disclose the following:
 - (A) The name and addresses of witnesses which the prosecuting attorney intends to call at the hearing, together with a statement identifying which allegations of fact each witness may possess relevant knowledge.
 - (B) Any books, papers, documents, photographs, or tangible objects which the prosecuting attorney intends to use in the hearing.
 - (C) Administrative reports made for the enforcement of regulatory functions. The Bureau, in its discretion, may not include criminal investigative reports associated with the administrative action.
- (b) Disclosure of Evidence by the Respondent.
 - (1) Upon written request of the Bureau, the respondent shall disclose the following:
 - (A) The name and addresses of witnesses which the respondent intends to call at the hearing, together with a statement identifying which allegations of fact of which each witness may possess relevant knowledge.
 - (B) Any books, papers, documents, photographs, or tangible objects which the respondent intends to use in the hearing.
- (c) Continuing Duty to Disclose.
 - (1) If, prior to or during the hearing, a party discovers additional evidence or material previously requested or ordered, such party shall promptly notify the other party, and the hearing officer of the existence of the additional evidence or material.
 - (2) The hearing officer may determine what evidence is necessary and proper for the purposes of the proceeding.
- (d) Time of Discovery.
 - (1) Any request of motions for discovery may be made at any time after the respondent has filed a Request for Hearing, including an Entry of Appearance for any entity, in the case and requested a hearing provided that the Bureau may request discovery in the Order to Show Cause.

The hearing officer may specify the time, place, and manner of taking the discovery and may prescribe such terms and conditions as are just.

(2) All discovery shall be completed no less than three (3) business days prior to the scheduled hearing unless otherwise ordered by the hearing officer. Any exhibit or discovery not turned over shall not be admitted at the hearing without compelling reason. This provision does not apply to any hearing on immediate suspension resulting in revocation.

(e) Subpoenas:

- (1) The Bureau may require the furnishing of such information, the attendance of such witnesses, and the production of such books, records, papers or other objects as may be necessary and proper for the purposes of the proceeding or investigation. The Hearing Officer does not have authority to quash any subpoena or subpoena duces tecum issued by the Director.
- (2) The Bureau, or any party to a proceeding before it, may take the depositions of witnesses in the same manner as is provided by law for the taking of depositions in civil actions in courts of record.
 - (A) Witnesses must have knowledge of the facts necessary and proper for adjudication of the proceeding, or be designated as an expert witness, to be deposed. The hearing officer shall determine whether a witness is necessary and proper.
 - (B) Any requested depositions of Bureau personnel shall take place at an OBN designated location by non-video means unless the hearing officer finds a compelling reason to order otherwise. This shall be construed strictly to protect the health, safety, and welfare of Bureau personnel and their identities.
 - (C) Any witness, other than a named party, may testify in the administrative hearing via telephone or videoconference at the discretion of the hearing officer with notice provided to all parties at least three (3) business days prior to the scheduled hearing.
- (3) At the request of the respondent, or any other party, the hearing officer shall:
 - (A) Issue subpoenas for the attendance of witnesses with knowledge of facts necessary and proper for adjudication.
 - (B) Issue subpoenas duces tecum to compel the production of books, records, papers, or other things necessary and proper for adjudication.
 - (C) Quash a subpoena or subpoena duces tecum so issued with notice to all parties. The hearing officer may not quash a subpoena or subpoena duces tecum if any party objects. This does not limit the hearing officer's authority to exclude or deny requests for irrelevant, immaterial, or unduly repetitious evidence considering the scope of the administrative hearing and the seriousness of the violations.
 - (D) All witnesses and evidence sought must be necessary and proper for the purposes of the proceeding. The hearing officer shall determine what is necessary and proper and will receive, admit, limit, or exclude evidence accordingly. All evidence which is irrelevant, immaterial, or unduly repetitious may not be admitted.

(f) Regulation of Discovery:

(1) Upon motion of either party, the hearing officer may at any time order that specified disclosures be restricted or make any other protective order. If the hearing officer enters an order restricting specified disclosures, the entire text of the material restricted shall be sealed

and preserved in the records of the Bureau to be made available to the appellate court in the event of an appeal.

- (2) If at any time during the course of the proceedings it is brought to the attention of the hearing officer that a party has failed to comply with discovery, the court may order such party to permit the discovery or inspection, grant continuance, or it may enter such other order as it deems just under the circumstances including admission or denial of the evidence.
- (3) Any discovery order shall not include discovery of legal work product of either attorney which is deemed to include legal research or those portions of records, correspondence, reports, or memoranda which are only the opinions, theories, or conclusions of the attorney or the attorney's legal staff.

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 10 - Requirements for Registration

Section 475:10-1-1	Purpose
Section 475:10-1-2	Time and method of payment of registration fees
Section 475:10-1-3	Exemption from registration or payment of fees
Section 475:10-1-4	Separate registration
Section 475:10-1-5	Exemptions of agents and employees
Section 475:10-1-6	Exempted persons engaging in private activities
Section 475:10-1-7	Exemption of law enforcement officials
Section 475:10-1-8	Waiver of civil defense officials
Section 475:10-1-9	Application for registration pursuant to Title 63 Okl. St.Ann § 2-302
Section 475:10-1-10	Application notices for registration and re-registration
Section 475:10-1-11	Operational protocols
Section 475:10-1-12	Filing of application
Section 475:10-1-13	Acceptance for filing
Section 475:10-1-14	Additional information
Section 475:10-1-15	Amendments to and withdrawal of applications
Section 475:10-1-16	Inspection
Section 475:10-1-17	Applications for scientific research in Schedule I substances
Section 475:10-1-18	Certificate of registration form
Section 475:10-1-19	Surrender of certificate of registration
Section 475:10-1-20	Modification of registration
Section 475:10-1-21	Change of business address
Section 475:10-1-22	Termination of registration

Section 475:10-1-23 Special exempt persons -- Native American Church

Section 475:10-1-24 Ephedra/mahuang exemption

475:10-1-1. Purpose

The rules of this Chapter specify the requirements to be met in order to obtain an OBN registration; list exceptions to obtaining such a registration; explain requirements for a scientific research registration; and exempts the Native American Church from registration for possession of peyote.

475:10-1-2. Time and method of payment of registration fees

Registration and re-registration fees shall be paid at the time when the application for registration or re-registration is submitted for filing.

[Source: Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-3. Exemption from registration or payment of fees

- (a) The Director may exempt from payment of a fee for registration or re-registration any agency of the United States, the State of Oklahoma, or any political subdivision or agency thereof, which is authorized to purchase controlled dangerous substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct scientific research, institutional instructional activities, or analytical laboratory activities with such substances or any combination thereof, in the course of official duties (e.g., city, county, state, or governmental institutions duly licensed by appropriate state agencies). A fee exemption must be requested at the time of application submission. If a fee exemption is not requested at the time of application submission, and payment is submitted with the application, no refund shall be given.
- (b) The Director may exempt from registration the following persons:
 - (1) Any official, employee, or officer of any agency of the United States, State of Oklahoma, or political subdivision or agency thereof, who is authorized to purchase controlled dangerous substances, to obtain such substances from official stocks, to dispense or administer such substances, to conduct scientific research, institutional instructional activities, or analytical laboratory activities with such substances, to possess such substances or any combination thereof, in the course of his/her official duties or employment.
 - (2) Such persons shall be deemed agents of their respective agencies, provided that their professional handling of controlled dangerous substances are confined to the agency of their specific place of official duties or employment [e.g., practitioners limited to practice with such official agency, pharmacies, or drug departments limited to dispensing of controlled dangerous substances to inpatients only of their respective institutions, registered nurses, and others as defined in 63 Okl.St.Ann. § 2-302].

[Source: Amended at 12 Ok Reg 2835, eff 7-15-95; Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-4. Separate registration

(a) Every person or entity who engages in, or who proposes to engage in, more than one group of independent activities shall obtain a separate registration for each group of activities, except as provided by this subsection. Any person or entity, when registered to engage in the group of activities described in each paragraph of this subsection, shall be authorized to engage in the coincident activities described in that subparagraph without obtaining a registration to engage in such coincident activities; provided that, unless specifically exempted, the registrant complies with

all requirements and duties prescribed by law for persons or entities registered to engage in such coincident activities.

- (1) A person or entity registered to manufacture any controlled dangerous substance or basic class of controlled dangerous substances shall be authorized to distribute that substance or class, but is not authorized to distribute any substance or class which the registrant is not registered to manufacture.
- (2) A person or entity registered to manufacture any controlled dangerous substance listed in Schedules I through V shall be authorized to conduct chemical analysis and preclinical research (including quality control analysis) with narcotic and non-narcotic controlled dangerous substances listed in those schedules which the registrant is authorized to manufacture.
- (3) A registrant authorized to conduct analytical laboratory activities with controlled dangerous substances shall be authorized to manufacture such substances for analytical or instructional purposes, to distribute such substances to other registrants authorized to conduct analytical laboratory activities, institutional instructional activities, or scientific research with such substances and to persons or entities exempted from registration provided such distribution is made in conformance with state law.
- (4) A person registered or authorized to conduct scientific research with controlled dangerous substances listed in Schedules I through V shall be authorized to conduct analytical laboratory activities with controlled dangerous substances listed in those schedules in which he/she is authorized to conduct scientific research, to manufacture such substances if and to the extent that such manufacturing is set forth in the protocol filed with the application for registration, to distribute such substances to other persons or entities registered or authorized to conduct analytical laboratory activities, institutional instructional activities, or scientific research with such substances, and to persons or entities exempted from registration provided such distribution is made in conformance with state law, and to conduct instructional activities with controlled dangerous substances.
- (5) Physicians, dentists, podiatrists, veterinarians, optometrists and other qualified persons who are authorized to carry on their respective activities under the laws of the State of Oklahoma and who are registered with the OBN to dispense, prescribe, and/or administer controlled dangerous substances shall be authorized to conduct instructional activities with those substances. Practitioners authorized to administer and/or dispense controlled dangerous substances are authorized to order the controlled dangerous substances for dispensation and administration.
- (6) Trainers or handlers of a canine controlled dangerous substance detector who, in the ordinary course of their profession, desire to possess any controlled dangerous substance for training said canine.
- (7) A single registration to engage in any group of independent activities may include one or more controlled dangerous substances listed in the schedules authorized in that group of independent activities. A person registered to conduct scientific research with controlled dangerous substances listed in Schedule I may conduct scientific research with any substance listed in Schedule I for which the registrant has filed and had approved a scientific research protocol.
- (b) The following locations shall not be deemed to be principal places where controlled dangerous substances are manufactured, distributed, dispensed, and/or prescribed:
 - (1) A warehouse where controlled dangerous substances are stored by or on behalf of a registered person, unless such substances are distributed directly from such warehouse to

registered locations, other than the registered location from which the substances were delivered, or to persons registrant, but not used as a distribution point, does not require a separate registration. The warehouse location shall be included on the registration application but may be fee exempt at the discretion of the Director. If a warehouse location is added at any later time after the application has been submitted, the registrant shall notify OBN of such location within one (1) business day. Warehouse locations shall meet all applicable state and local laws and have the same physical security requirements as specified in Chapter 20 of this Title.

- (2) An office used by agents of a registrant where sales of controlled dangerous substances are solicited, made, or supervised but which neither contain such substances (other than substances for display purposes or lawful distribution as samples only) nor serves as a distribution point for filling sales orders.
- (3) An office used by a practitioner (who is registered at another location) where controlled dangerous substances are prescribed but neither administered nor otherwise dispensed as a regular part of the professional practice of the practitioner at such office, and where no supplies of controlled dangerous substances are maintained.
- (c) No more than one medical marijuana manufacturing registration for growing medical marijuana shall be issued per location. Location is the entire real property identified by the parcel identification number and any corresponding address on file with the County Assessor. A registrant or applicant may, in writing, request that the OBN waive the above requirement, by submitting on a form provided by the OBN for OBN approval. The OBN may in its discretion and on a case- by-case basis, approve the waiver if it finds that the safeguard proposed by the registrant meets the goals of the security requirements. Registrant grow operations must be clearly separate and distinct from other registrant grow operations. Approved waivers expire at the same time as the underlying registration. The approved waiver shall be displayed in a conspicuous manner near the associated Certificate of Registration.

[**Source:** Amended at 12 Ok Reg 2835, eff 7-15-95]

475:10-1-5. Exemptions of agents and employees

The following persons shall not be required to register and may lawfully possess controlled dangerous substances in the performance of their official duties under the provisions of the Act:

- (1) An agent, or employee thereof, of any registered manufacturer, distributor, dispenser and/or user for scientific purposes of any controlled dangerous substances if such agent is acting in the usual course of his/her business or employment.
- (2) An individual physician who is a resident or staff physician of a licensed or otherwise-authorized hospital shall not be required to register in order to administer, prescribe, or dispense controlled dangerous substances in the usual course of his/her professional practice, while acting within the scope of his/her employment in the hospital, provided that:
 - (A) Such resident or staff physician is authorized to carry on the respective activities under the laws of the State of Oklahoma by their appropriate State of Oklahoma licensing board.
 - (B) The hospital by whom he/she is employed has verified that the individual physician is so licensed by the appropriate State of Oklahoma licensing board.

- (C) Such administering, prescribing, and/or dispensing is confined solely to inpatients or outpatients of the hospital by which the individual physician is employed.
- (D) All prescriptions and records relating to controlled dangerous substances administered, dispensed, or prescribed to inpatients or outpatients shall reflect the designated specific internal hospital code number given to each resident or staff physician so authorized by the hospital pursuant to 475:25-1-18 and Title 21 Code of Federal Regulations, § 1301.22(C)(5) and (6).
- (3)(2) Interns or residents of teaching hospitals shall not be required to register and may administer, dispense, and/or prescribe controlled dangerous substances in accordance with paragraph (2) of this Section, provided that:
 - (A) All prescriptions issued by such interns <u>or residents</u> for outpatients shall be countersigned by a physician licensed by the physician's appropriate State of Oklahoma licensing board and shall bear such physician's personal designated hospital code number.
 - (B) Such intern <u>or resident</u> is so authorized by the hospital and is acting only within the scope of his/her employment within the teaching hospital.
- (4)(3) An individual physician, dentist, podiatrist, or veterinarian, as defined in 63 Okl.St.Ann. § 2-101, who is a resident or foreign-trained, whose practice is, for any reason, limited solely to federal, state, or local government institutions, shall dispense, administer and/or prescribe controlled dangerous substances under the authority of the license of the institutional hospital by whom he/she is employed in lieu of being registered himself/herself, provided that:
 - (A) Such dispensing, administering, and/or prescribing is done in the usual course of his/her professional practice.
 - (B) Such individual practitioner is authorized to carry on the respective activities under the laws of the State of Oklahoma by the appropriate State of Oklahoma licensing board.
 - (C) The hospital or other institution by which he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, and/or prescribe drugs within the jurisdiction.
 - (D) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution.
 - (E) Records relating to controlled dangerous substances that are prescribed by such residents, foreign-trained physicians, or physicians limited to federal, state, or local government institutions, shall be kept pursuant to Title 21 Code of Federal Regulations §1304.04 and 475:25-1-18.
- (5)(4) An individual practitioner, as defined in (4)(3) of this Section, who is limited solely to federal, state, or local government institutional practice, may obtain individual fee-exempt registration in the event that such institution by which he/she is employed does not maintain a hospital as defined by the appropriate State of Oklahoma licensing authority and the institution is not so registered with the OBN.
 - (A) Such limited practitioners shall be required to maintain records of all controlled dangerous substances administered, dispensed, and prescribed by such practitioner.

- (B) Such limited practitioners shall be authorized to dispense, administer, and/or prescribe controlled dangerous substances in the course of their professional practice only within such institution as designated by their appropriate State of Oklahoma licensing boards.
- (C) Prior to being authorized to dispense, administer, and/or prescribe controlled dangerous substances at any new or additional location, such limited practitioners shall be required to report to the OBN each change of location or addition of institutional employment.
- (D) Such limited practitioners shall be held individually responsible for safeguards, record keeping, inventories, transferring, and disposing of controlled dangerous substances in accordance with this Chapter.

[Source: Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-6. Exempted persons engaging in private activities

If any person exempted by this Chapter also engages, or proposes to engage, as a private individual in any activities for which registration is required, such official shall obtain a registration for such private activities.

475:10-1-7. Exemption of law enforcement officials

- (a) The requirement of registration is waived for any officer or employee of any federal, state, or any political subdivision or agency thereof, who is engaged in the enforcement of federal, state or local law relating to controlled dangerous substances and is duly authorized to possess controlled dangerous substances in the course of his/her official duties, excluding law enforcement canine handlers/trainers; provided that law enforcement agencies maintaining analytical laboratories must obtain annual registration as otherwise provided in this Section.
- (b) Any exempted official may, when acting in the course of his/her official duties, possess any controlled dangerous substance and distribute any such substance to any other official who is also exempted by (a) of this Section and acting in the course of his/her official duties.
- (c) Any official engaged in drug education where possession of controlled dangerous substances is necessary shall obtain authorization for such possession from the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

[**Source:** Amended at 12 Ok Reg 2835, eff 7-15-95]

475:10-1-8. Waiver of civil defense officials

The requirement of registration is waived for any official of a civil defense or disaster relief organization who, in the course of his/her official duties, is authorized to maintain and distribute controlled dangerous substances held for emergency use.

475:10-1-9. Application for registration pursuant to Title 63 Okl. St.Ann § 2-302

- (a) Any person or entity who is required to be registered and who is not so registered may apply for registration at any time unless otherwise provided in this Title. No person or entity required to be registered shall engage in any activity for which registration is required until the application for registration is granted and a Certificate of Registration is issued by the Director to such person or entity.
- (b) After any person or entity is first registered, the person or entity shall thereafter be required to be registered no later than the first day of November of each year.

- (c) Any person or entity who fails to register shall be in violation of the Uniform Controlled Dangerous Substances Act and subject to penalties as provided therein.
- (d) Applications for registration of new principal places of business and new personal registration requests received after July 1st of each year will, if accepted for registration, be registered for the forthcoming registration period and, therefore, will not be required to pay the registration fee for the remaining four (4) months of the registration period in which the application is made.
- (e) A thirty (30) day grace period from the registration expiration date may be given before a registration is inactivated.
- (f) All medical marijuana applicants and registrants, and all medical facilities required to register under 63 O.S. § 2-302(C), shall disclose to OBN all beneficial owners and all other entities or natural persons that have an ownership interest in the business.

[Source: Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-10. Application notices for registration and re-registration

- (a) Any person or entity required to be registered under Title 63 may register by contacting the OBN to obtain the registration application, downloading the registration application on the official OBN website, or applying on the official OBN website.
- (b) Any person or entity desiring to professionally handle controlled dangerous substances for the purpose of canine drug detector handling and/or training, manufacturing, distributing, conducting scientific research, or performing analytical laboratory activities of controlled dangerous substances listed in the Uniform Controlled Dangerous Substances Act, Schedules I through V, shall apply for registration as follows:
 - (1) A canine drug detector handler/trainer or scientific researcher shall be registered with the OBN as an individual.
 - (2) Applicants for scientific research, analytical laboratory activities, or institutional instructional activities shall attach one (1) copy of the proposed operational protocol to the application.
 - (3) A detailed description, diagram, and/or photographs of all security measures proposed for the safe storage of all controlled dangerous substances shall be attached to the application.
- (c) Any person or entity licensed by the appropriate State of Oklahoma licensing authority who desires to professionally handle controlled dangerous substances in their practice of medicine, retail pharmacy, hospital, teaching institution, or institutional drug department shall apply for registration.
- (d) Registrants will be notified by renewal notice approximately ninety (90) days before the expiration date of October 31 of each year; if any registrant does not receive such notice within thirty (30) days prior to the expiration date of the registration, the registrant must give notice of such omission and request such notice either by personal contact with, or in writing to, the OBN. It shall be the registrant's responsibility to maintain a valid registration.
- (e) Each application shall include all information called for in the application, unless the item is not applicable, in which case this fact shall be indicated, and the application with comments shall be required to be returned to the OBN. The address of the registrant shall be the business address. A post office box will not be considered a sufficient business address. If the business address contains no physical street address, then a PO Box or route number may be listed, however, directions to the registrant's business location must be included with the application.

(f) Each application, attachment, or other document filed as a part of any application shall be signed by the applicant or by an officer or official of the applicant. Those applications with questions left unanswered or without proper signature will not be accepted.

[**Source:** Amended at 12 Ok Reg 2835, eff 7-15-95; Amended at 24 Ok Reg 2736, eff 8-11-07; Amended at 29 Ok Reg 1312, eff 6-25-12; Amended at 30 Ok Reg 544, eff 5-13-13]

475:10-1-11. Operational protocols

- (a) An operational protocol to conduct scientific research, analytical laboratory activities, or institutional instructional activities with controlled dangerous substances listed in Schedules I through V shall be in the following form and contain the following information where applicable:
 - (1) Scientific research, analytical laboratory activities, or institutional instructional activities.
 - (A) Name, business address, and if any, the Federal Drug Enforcement Administration (DEA) registration number.
 - (B) Institutional affiliation, if any.
 - (C) Qualifications, including an academic vita and an appropriate bibliography (listing publications).
 - (i) Applicants shall be required affirmatively to establish (by documentation or suitable references or other appropriate means) their good moral character and high ethical professional standing.
 - (ii) Applicants for scientific research shall possess at least an earned bachelor's degree in natural science, medicine, or other appropriate field from institution(s) accredited by bodies recognized by the designated authority of the University of Oklahoma Health Sciences Center.
 - (iii) Applicants for scientific research proposing studies involving human subjects should minimally possess an earned doctorate in medicine or natural sciences or other appropriate field from accredited institution(s).
 - (iv) Applicants for analytical laboratory activities who propose studies involving chemical analysis or other chemical, physical, or biological scientific activities with Schedule I-V substances shall be required to have satisfactorily completed a minimum of thirty-two (32) semester hours, or the equivalent, of acceptable courses in chemistry, with one (1) or more accredited courses in analytical chemistry.
 - (v) Institutional instructional activities or institutions of higher learning requesting registration of an agent of such institution shall be an institution accredited by the Oklahoma State Regents for Higher Education, or such agent of an institution shall be required to have satisfactorily completed a minimum of thirty-two (32) semester hours, or their equivalent, of acceptable courses in chemistry from an institution(s) accredited by bodies recognized by the United States Department of Education or the United States Department of Health and Human Services.
 - (vi) All said applicants shall further be required to document at least one (1) year of recent suitable, professional experience for the activities to be undertaken for a Schedule I registration. This may consist of formal participation in established and recognized analytical laboratory analysis of controlled dangerous substances, research programs, institutional

instructional activities, or other evidence of appropriate background approved by the Director (post-doctoral training, applicable laboratory experience, etc.).

- (2) Research project.
 - (A) Title of project.
 - (B) Statement of purpose.
 - (C) Name of controlled dangerous substance or substances involved and the amount of each substance for use.
 - (D) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.
 - (E) Location where the research will be conducted.
 - (F) Statement of the security provisions for storing the controlled dangerous substances and for dispensing the controlled dangerous substances in order to prevent diversion.
 - (G) If the researcher or investigator desires to manufacture any controlled dangerous substances listed in this part, a statement of the quantity to be manufactured and the sources of the chemicals to be used.
- (3) Authority.
 - (A) Institutional approval.
 - (B) Approval of Institutional Review Board.
 - (C) Indication of an approval for new DEA registration number if additional registration is required by DEA.
 - (D) Indication of an approved funded grant (number), if any.
- (4) Adequate environment and facilities. All said applicants shall be required to establish that they have access to and beneficial use of an institutional (or other) environment appropriate to the type of activities contemplated, and that they possess the necessary facilities (inclusive of proper laboratory facilities and equipment, etc.). This requirement shall be interpreted as requiring that overall environment, facilities, and equipment meet generally recognized standards for the activities proposed.
- (5) Confidentiality of research subjects.
 - (A) Any registrant under the Uniform Controlled Dangerous Substances Act who intends to maintain the confidentiality of those persons who are the subjects of such research shall, pursuant to Title 63 Okl.St.Ann. § 2-106, upon registration or within a reasonable time thereafter, submit to the Director a separate request for each research project involving controlled dangerous substances, which shall contain the following:
 - (i) The researcher's registration number with the OBN and/or DEA registration number(s) for that project.
 - (ii) The location of the research project.
 - (iii) A general description of the research or a copy of the research protocol as required in this Chapter.
 - (iv) A specific request to withhold the names and/or any identifying characteristics of the research subjects.
 - (v) The reasons supporting the request.

- (B) Within thirty (30) days from the receipt of the request, the Director shall issue a letter, either granting confidentiality, requesting additional information, or denying confidentiality, in which case the reasons for the denial shall be included. A grant of confidentiality shall be limited solely to the specific research project indicated in the request.
- (b) Within thirty (30) days after the date of completion of the research project, the researcher shall so notify the Director.

[**Source:** Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-12. Filing of application

- (a) All applications for registration shall be submitted for filing with the OBN and shall be accompanied by the appropriate registration fee and any required attachments.
- (b) Any person or entity required to obtain more than one registration <u>mayshall</u> submit all applications in one (1) <u>package individually</u>. Each application must be complete and should not refer to any accompanying application for required information.

475:10-1-13. Acceptance for filing

- (a) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this Chapter will not generally be accepted for filing. A defective application will be rejected and returned to the applicant with a statement of the reason for not accepting the application for filing. A defective application shall be corrected and re-submitted for filing prior to acceptance of application.
- (b) Accepting an application for filing does not preclude any subsequent request for additional information and has no bearing on whether the application will be granted.
- (c) All information requested within the application, as well as any requests for additional or supplemental information, are deemed material information for purposes of the application and enforcement of the Uniform Controlled Dangerous Substances Act.

475:10-1-14. Additional information

The Director may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Director in granting or denying the application and may result in an application being rejected as incomplete.

475:10-1-15. Amendments to and withdrawal of applications

- (a) An application may be amended or withdrawn without permission of the Director at any time before the date on which the applicant receives an order to show cause why the registration should not be denied, revoked or suspended pursuant to Title 63 Okl.St.Ann. § 2-305. An application may be amended with permission of the Director at any time where good cause is shown by the applicant or where the amendment is in the public interest.
- (b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application shall be deemed to be a withdrawal of the application.

- (c) If an application is withdrawn after the application and payment have been submitted, no refund shall be given.
- (d) For registered businesses, any owner, manager, board member, officer, legal counsel, or other specifically designated and disclosed representative may withdraw the application on behalf of the business.

[**Source:** Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-16. Inspection

The Director, his or her agents, as well as specifically designated or assigned state, county and municipal officers whose duty it is to enforce the laws of this State relating to controlled dangerous substances may inspect, or cause to be inspected, the establishment of an applicant or registrant pursuant to this Title and the provisions of Title 63 of the Oklahoma Statutes.

[Source: Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-17. Applications for scientific research in Schedule I substances

- (a) In the case of an application to conduct scientific research with controlled dangerous substances listed in Schedule I, the Director may process the application and protocol and forward a copy of each to an independent expert selected by the Director within seven (7) days after receipt. The independent expert shall promptly advise the Director concerning the qualification of the applicant.
- (b) An applicant whose protocol is defective shall be notified by the Director within seven (7) days after receipt of such protocol from the independent expert, and he/she shall be required to correct the existing defects before consideration shall be given to his/her submission.
- (c) After the independent expert finds that the applicant is qualified and competent and the protocol meritorious, the Director shall be notified. The Director shall issue a Certificate of Registration within ten (10) days after receipt of this notification unless he/she determines that the application should be denied pursuant to the Uniform Controlled Dangerous Substances Act or OAC 475.
- (d) If the independent expert finds that the protocol is not meritorious and/or the applicant is not qualified or competent, said designated authority shall notify the Director. The Director shall notify the applicant of said findings and his/her final decision, after which time the applicant may submit written request to the Director within thirty (30) days for a hearing to show cause why the application should not be denied.
- (e) Except, Schedule I medical marijuana researchers shall submit the documentation, with their application, as required by 63 O.S. §427.19 et seq and 63 O.S. § 427.20 et seq.

[Source: Amended at 24 Ok Reg 2736, eff 8-11-07; Amended at 33 Ok Reg 1766, eff 9-11-16]

475:10-1-18. Certificate of registration form

(a) The Certificate of Registration shall contain the name, business address, and registration number of the registrant, the schedules of controlled dangerous substances which the registrant is authorized to handle, any limitation or condition placed on the registration, and the expiration date of the registration. The registrant shall maintain the Certificate of Registration at the registered location, displayed in a conspicuous manner, and shall permit inspection of the Certificate by a peace officer or agency official in the enforcement of laws relating to controlled dangerous substances.

(b) Medical marijuana manufacturers shall post a sign at the entrance of the medical marijuana manufacturing location. The sign shall include, at a minimum, business name, business address, contact phone number, and OBN registration number. This information may be placed on other existing signs of a similar nature if otherwise allowed by law.

475:10-1-19. Surrender of certificate of registration [REVOKED]

- (a) Upon the revocation, suspension, or retirement of the registrant's Certificate of Registration, the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control shall require that the registrant immediately deliver the assigned Certificate of Registration to an officer of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and shall further require the registrant to surrender, destroy, or provide the security deemed necessary by the Director for all stocks of controlled dangerous substances in control of the registrant.
- (b) In the event of limitation of a registrant's authority to handle controlled dangerous substances ordered by the Director or the authorized appropriate State of Oklahoma professional licensing board which may limit the registrant's professional services regarding controlled dangerous substances, the registrant shall be issued a new Certificate of Registration. No fee shall be required to be paid for the new Certificate of Registration.

[Source: Amended at 12 Ok Reg 2835, eff 7-15-95]

475:10-1-20. Modification of registration

- (a) Any registrant may apply to modify the registration to authorize the handling of additional controlled dangerous substances by submitting a letter of request to the Registration Division of the OBN. The letterrequest shall contain the registrant's name, address, state and federal registration numbers as printed on the registrant's State of Oklahoma and Federal Certificates of Registration, the substances and/or schedules to be added to the registration, and shall be signed certified by the registrant. If the registrant is seeking to handle additional controlled dangerous substances listed in Schedule I of the Uniform Controlled Dangerous Substances Act for the purpose of analytical laboratory activities, scientific research, or institutional instructional activities, the registrant shall attach one (1) copy of the protocol describing each anticipated activity involved with the additional substances or, in the event of institutional instructional activities, a statement describing the nature, extent, and duration of such institutional instructional activity, as appropriate. No fee shall be required to be paid for the modification.

 (b) Change of name or ownership shall require a new registration for all businesses. Notice shall be submitted in writing on a form prescribed by OBN at least fourteen (14) days prior to the proposed change.
- (1) A change of ownership occurs when:
 - (A) Any new beneficial owner, not previously recorded on the registration, is added to the business; or
 - (B) A change in the form of ownership occurs (for example, from a sole proprietor ownership to a partnership, limited liability company, or corporation).
 - (2) For publicly traded corporations, a routine sale of stock is not a change of ownership. (Note: a publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange. Publicly traded corporations do not include any entity engaged in activities involving federally prohibited substances.)

- (3) A change to the registered business name as a result of government entities making changes to the name or to correct typographical errors does not require a new registration.
- (c) Any change in the existing ownership percentage of a registered business shall be reported to the OBN within one (1) business day, if ownership disclosure is a legal requirement or condition to any licensing or registration.
- (d) OBN registrations are only valid for the individual or entity to which the registration is issued including all beneficial owners of a registered entity or business. An OBN registration shall never be utilized by another individual or entity unless specifically authorized to do so by this Title or the Uniform Controlled Dangerous Substances Act. This provision shall be strictly construed to guard against theft and diversion of controlled dangerous substances.

[Source: Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-21. Change to registrant details

The registrant shall notify the Registration Division of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, in writing, sent via U.S. certified mail, return receipt requested, or through the registrant's online account, within fourteen (14) calendar daysone (1) business day of any change to information on the current registration. This includes, but is not limited to, changes in contact information, ownership information, or changes to the registered premises where physical security controls are impacted such as the addition of, expansion of, or destruction of structures on the registered premises.

[Source: Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-22. Termination of registration

- (a) The registration of any person or entity shall terminate if and when such registrant dies, ceases legal existence, or discontinues business or professional practice including, but not limited to, full retirement. Any registrant who discontinues business or professional practice and/or no longer holds a valid Oklahoma license of the profession or occupation shall notify the Director within fourteen (14) calendar days OBN within one (1) business day of such fact.
- (b) Pursuant to 63 O.S. § 2-302(L), failure to maintain an active, valid professional or occupational license, will result in automatic termination of the OBN registration.
- (c) For registered businesses, any owner, manager, board member, officer, legal counsel, or other specifically designated and disclosed representative may terminate or discontinue the applicable OBN registration on behalf of the registered business.

[Source: Amended at 12 Ok Reg 2835, eff 7-15-95; Amended at 29 Ok Reg 1312, eff 6-25-12]

475:10-1-23. Special exempt persons -- Native American Church

The listing of mescaline as a controlled dangerous substance in Schedule I of the Uniform Controlled Dangerous Substances Act does not apply to the non-drug use of the peyote cactus in bona-fide religious ceremonies of the Native American Church, and members of the Native American Church so using the peyote cactus are exempt from registration with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control. Any person who produces peyote cactus for, or distributes the peyote cactus to, the Native American Church of the State of Oklahoma, however, is required to obtain registration annually as a distributor and to comply with all other requirements of the Uniform Controlled Dangerous Substances Act and OAC 475.

475:10-1-24. Ephedra/mahuang exemption

Products meeting the following criteria are exempt from application of Sections 2-210, 2-322, and 2-402 of the Uniform Controlled Dangerous Substances Act [O.S. Title 63, §§ 2-210, 2-322, 2-402]:

- (1) Dietary supplements containing naturally occurring ephedrine alkaloids, provided that all of the following conditions are met:
- (A) the alkaloids are contained in an unadulterated naturally occurring organic material; and,
- (B) the product contains no hydrochloride or sulfate salts of ephedrine alkaloids; and,
 - (C) the product contains, per dosage unit or serving, not more than 25 milligrams of ephedrine alkaloids; and,
 - (D) the product is packaged with a prominent label securely affixed to each package that states the amount in milligrams of ephedrine alkaloids in a serving or dosage unit; the amount of food product or dietary supplement that constitutes a serving or dosage unit; the maximum recommended dosage unit of ephedrine alkaloids for a healthy adult; and that improper use of the product may be hazardous to a person's health; and,
 - (E) the product is labeled and marketed as "ephedra" or "mahuang" and not as "ephedrine." It shall be acceptable to include descriptions of the ephedra alkaloids such as "contains 25 mg. of naturally occurring ephedrine alkaloids." And,
- (2) In the course of selling, offering for sale, or otherwise distributing a product described in section 10-1-24 (A), a person shall not advertise or represent in any manner that the product causes euphoria, ecstasy, a "buzz", or "high", or an altered mental state, heightens sexual performance, or because it contains ephedrine alkaloids, increases muscle mass.

[Source: Added at 18 Ok Reg 2217, eff 6-11-01; Amended at 19 Ok Reg 1197, eff 5-13-02]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 15 - Imminent Danger Suspension

Section 475:15-1-1	Purpose
Section 475:15-1-2	Immediate suspension of registration
Section 475:15-1-3	Hearing following immediate suspension

475:15-1-1. Purpose

The rules of this Chapter govern the immediate suspension of a controlled dangerous substances registration pending the final outcome of an administrative proceeding.

[**Source:** Added at 12 Ok Reg 2839, eff 7-15-95]

475:15-1-2. Immediate suspension of registration

If the Director finds there is imminent danger to the public health or safety, he/she may immediately suspend any registration—simultaneously with the institution of show cause proceedings.

- (1) **Method**. The registrant shall be notified of such suspension through an imminent danger letterimmediate suspension order identifying an imminent danger to the public health or safety signed by the Director.
- (2) Notice and surrender of controlled dangerous substances. The imminent danger letterimmediate suspension order shall be personally served on the registrant by an Agent of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control at which time the registrant shall be required to surrender to the Agent all controlled dangerous substances in his/her possession. In the event the registrant cannot be located by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Agent, the Agent shall deliver the imminent danger letterimmediate suspension order to the address listed on the registrant's most current registration applicationregistered address on file with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control at which time the Agent shall take possession of all controlled dangerous substances located at such address.
- (3) **Additional violations**. Where there is a reasonable belief that a registrant has committed a new violation of OBN's rules or applicable law while serving a term of probation with OBN, the registrant's OBN registration may be immediately suspended—until a hearing can be had, which shall be within fourteen (14) calendar days, unless otherwise agreed to by the parties.

[Source: Added at 12 Ok Reg 2839, eff 7-15-95; Amended at 29 Ok Reg 1317, eff 6-25-12]

475:15-1-3. Hearing following immediate suspension

A show cause hearing shall be held within fourteen (14) calendar days, unless waived by the parties, following the suspension of a registration suspended without a hearing. An immediate suspension order takes effect upon the Director's signature and shall be governed by the administrative proceeding process outlined by the Uniform Controlled Dangerous Substances Act. Failure to comply with the immediate suspension order may result in administrative penalties not to exceed Ten Thousand Dollars (\$10,000.00) per day of noncompliance. If the registrant makes a timely request for hearing, the Director shall serve formal notice of a hearing to be held within thirty (30) days of the formal notice, unless waived by the parties.

[Source: Added at 12 Ok Reg 2839, eff 7-15-95; Amended at 29 Ok Reg 1317, eff 6-25-12]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 20 - Security Requirements for Registrants

Section 475:20-1-1	Purpose
Section 475:20-1-2	General security requirements
Section 475:20-1-3	Physical security controls for nonpractitioners; storage areas
Section 475:20-1-4	Physical security controls for nonpractitioners; manufacturing areas
Section 475:20-1-5	Other security controls for nonpractitioner registrants
Section 475:20-1-6	Physical security controls for practitioners
Section 475:20-1-7	Physical security controls for drug canine handlers
Section 475:20-1-8	Other security controls for registrants

475:20-1-1. Purpose

The rules of this Chapter mandate the security requirements for OBN registrants and other individuals in possession of controlled dangerous substances.

475:20-1-2. General security requirements

- (a) All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled dangerous substances. In order to determine whether a registrant has provided effective controls against diversion, the Director shall require adherence to the security requirements as set forth generally in the Uniform Controlled Dangerous Substances Act, and specifically by this Chapter, as standards for the physical security controls and operating procedures necessary to prevent diversion. Materials and construction which will provide a structural equivalent to the physical security controls set forth in 475:20-1-4 and 475:20-1-6 may be used in lieu of the materials and construction described in those Sections.
- (b) Substantial compliance with the standards set forth in 475:20-1-3 through 475:20-1-7 may be deemed sufficient by the Director after evaluation of the overall security system and needs of the applicant or registrant. In evaluating the overall security system of a registrant or applicant, the Director may consider any of the following factors as he/she may deem relevant to the need for strict compliance with security requirements:
 - (1) The type of activity conducted (e.g., processing of bulk chemicals, preparing dosage forms, packaging, labeling, cooperative buying, etc.).
 - (2) The type and form of controlled dangerous substances handled (e.g., bulk liquids or dosage units, usable or non- usable powders).
 - (3) The quantity of controlled dangerous substances handled.
- (4) The location of the premises and the relationship such location bears on security needs.
 - (5) The type of building construction comprising the facility and the general characteristics of the building(s).
 - (6) The type of vault, safe, and secure enclosures or other storage system (e.g., automatic storage and retrieval system) used.
 - (7) The type of closures on vaults, safes and secure enclosures.
 - (8) The adequacy of key control systems and/or combination lock control systems.
 - (9) The adequacy of electric detection and alarm systems, if any, including use of supervised transmittal lines and standby power sources.
 - (10) The extent of unsupervised public access to the facility, including the presence and characteristics of perimeter fencing, if any.
- (11) The adequacy of supervision over employees having access to manufacturing and storage areas.
 - (12) The procedures for handling business guests, visitors, maintenance personnel and non-employee service personnel.
- (13) The availability of local police protection or of the registrant's or applicant's security personnel.
 - (14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution and disposition of controlled dangerous substances in its operations.
- (c) When physical security controls become inadequate as a result of a controlled dangerous substance being transferred to a different schedule, or as a result of a non-controlled dangerous

substance being listed on any schedule, or as a result of a significant increase in the quantity of controlled dangerous substances in the possession of the registrant during normal business operations, the physical security controls shall be expanded and extended accordingly. A registrant may adjust physical security controls within the requirements set forth in 475:20-1-3 through 475:20-1-7 when the need for such controls, as determined by the Director, decreases as a result of a controlled dangerous substance being transferred to a different schedule, or as a result of a controlled dangerous substance being moved from control, or as a result of a significant decrease in the quantity of controlled dangerous substances in the possession of the registrant during normal business operations.

(d) Any registrant or applicant desiring to determine whether a proposed security system substantially complies with, or is the structural equivalent of, the requirements set forth in 475:20-1-3 through 475:20-1-7, may submit any plans, blueprints, sketches, or other materials regarding the proposed security system to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

475:20-1-3. Physical security controls for nonpractitioners; storage areas

- (a) Physical security controls for nonpractitioners and storage areas shall comply with Title 21 Code of Federal Regulations §1301.72., except physical security controls for medical marijuana retailers shall, at a minimum, meet the following requirements for each retail storage area:
- (b) Physical security controls for all medical marijuana businesses (dispensaries, growers, processors, etc.) shall, at a minimum, meet the following requirements for each medical marijuana storage area:
 - (1) Each registered premise shall have a security alarm system which upon unauthorized entry shall transmit a signal directly to a central station protection agency or a local or state police agency, each having a legal duty to respond, or to a 24-hour control station operated by the registrant, or to such other source of protection as the Director may approve.
 - (2) All retailcontrolled dangerous substance storage areas shall be equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. If door hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination, keyless entry, or key lock type and;
 - (A) In the case of key locks, shall require key control which limits access to a limited number of employees, or;
 - (B) In the case of multiple-position combination or keyless entry systems, the system shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination.
 - (3) The <u>retailcontrolled dangerous substance</u> storage areas shall be accessible only to an absolute minimum number of authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through a controlled dangerous substance storage area, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.) All finished, processed, or packaged medical marijuana must be stored in a secure, locked
- (c) All finished, processed, or packaged medical marijuana must be stored in a secure, locked storage area, such as a closet, cabinet, safe, or vault, and in such a manner as to prevent diversion,

theft, or loss. All safes and cabinets must be made of substantially constructed steel. If the safe or cabinet weighs less than 750 pounds, it must be bolted or cemented to the floor in such a way that it cannot be removed. Hinges and locks on the cabinets and safes must meet the requirements set forth in subsection (b) of this section.

475:20-1-4. Physical security controls for nonpractitioners; manufacturing areas

- (a) Physical security controls for nonpractitioners and manufacturing areas shall be in compliance with Title 21 Code of Federal Regulations §1301.73., except physical security controls for medical marijuana commercial growers, processors, packagers, and manufacturers shall, at a minimum, meet the following requirements:
- (b) Physical security controls for medical marijuana commercial growers, processors, packagers, and manufacturers shall, at a minimum, meet the following requirements:
 - (1) All in-process medical marijuana shall be returned to the storage area at the termination of the process. If the process is not terminated at the end of a workday (except where a continuous process or other normal manufacturing operation should not be interrupted), the processing area or tanks, vessels, bins or bulk containers containing medical marijuana shall be securely locked, with adequate security for the area or building.
 - (2) Each building shall require a security alarm system, that upon unauthorized entry, shall transmit a signal directly to a central station protection company, or local or state police agency that has a legal duty to respond, or a 24-hour control station operated by the registrant, or to such other source of protection as the Director may approve.
 - (3) Each building shall be equipped with self-closing, self-locking doors constructed of substantial material commensurate with the type of building construction, provided, however, a door which is kept closed and locked at all times when not in use and when in use is kept under direct observation of a responsible employee or agent of the registrant is permitted in lieu of a self-closing, self-locking door. Doors may be sliding or hinged. If doors hinges are mounted on the outside, such hinges shall be sealed, welded or otherwise constructed to inhibit removal. Locking devices for such doors shall be either of the multiple-position combination, keyless entry, or key lock type and;
 - (A) In the case of key locks, shall require key control which limits access to a limited number of employees, or;
 - (B) In the case of multiple-position combination or keyless entry systems, the system shall be limited to a minimum number of employees and can be changed upon termination of employment of an employee having knowledge of the combination.
 - (4) Any outdoor or greenhouse facilities shall provide adequate security measures for the area or building including the following:
 - (A) The entire outdoor or greenhouse facility shall be surrounded by a fence and entry gates. Acceptable fencing shall be a metal chain link fence with a wire diameter at least nine (9) gauge or larger, or another similarly secure material or wood. The fence shall measure at least eight (8) feet from the ground to the top of the fence. The fence may be at least six (6) feet of acceptable fencing with a top guard of fencing wire with sharp edges or points, such as barbed wire, to enhance the overall height of the fence to the minimum of eight (8) feet. All support posts shall be steel and securely anchored.
 - (B) All entry gates shall measure at least eight (8) feet from the ground to the top of the entry gate and shall be constructed of acceptable fencing. The entry gate may be at least six (6) feet of acceptable fencing with a top guard of fencing wire with sharp edges or points,

- such as barbed wire, to enhance the overall height of the entry gate to the minimum of eight (8) feet. All entry gates shall be kept closed and securely locked at all times when not in use and when in use shall be kept under direct observation of a responsible employee or agent of the registrant.
- (C) The fence and entry gates shall be in good repair and obscure the outdoor or greenhouse facility so that it is not easily viewed from outside the fence or entry gates.
- (5) The medical marijuana commercial growing, processing, packaging, and manufacturing areas shall be accessible only to an absolute minimum number of authorized employees. When it is necessary for employee maintenance personnel, nonemployee maintenance personnel, business guests, or visitors to be present in or pass through areas where controlled dangerous substances are present, the registrant shall provide for adequate observation of the area by an employee specifically authorized in writing.
- (6) A registrant may, in writing, request that the OBN waive one or more of the security requirements described in subsection (4) of this rule, by submitting on a form provided by the OBN a security waiver request for OBN approval. The OBN may in its discretion and on a case-by-case basis, approve the security waiver if it finds that the alternative safeguard proposed by the registrant meets the goals of the above security requirements. Approved security waivers expire at the same time as the underlying registration. The registrants request for a waiver shall include:
 - (A) The specific portion(s) of subsection (4) that is requested to be waived;
 - (B) The reason for the waiver; and,
 - (C) A description of an alternative safeguard the registrant will implement in lieu of the requirement that is the subject of the waiver.

[Source: Amended at 37 Ok Reg 2020, eff 9-11-20]

475:20-1-5. Other security controls for nonpractitioner registrants

- (a) Before distributing a controlled dangerous substance to any person whom the registrant does not know to be registered to possess the controlled dangerous substance, the registrant shall make a good-faith inquiry either with the OBN orand with the Federal Drug Enforcement Administration, or when applicable, the Oklahoma Medical Marijuana Authority, to determine that the person is registered to possess the controlled dangerous substance.
- (b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled dangerous substances. The registrant shall inform the OBN of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.
- (c) All registrants shall notify the OBN of any theft or significant loss of any controlled dangerous substances upon discovery of such theft or loss. Notification shall be made in writing and shall contain a list of the substances stolen or diverted by their trade name, quantities, descriptions, amount lost or stolen, and any cost code marks utilized. Thefts must be reported whether or not the controlled dangerous substances are subsequently recovered and/or the responsible parties are identified and action taken against them.
- (d) No person acting as an agent of a registered controlled dangerous substances manufacturer or distributor (i.e., detailman, salesman, etc.) shall distribute samples of controlled dangerous substances to a practitioner without first having been registered (no fee required) with the OBN.

- (1) To register with the OBN to distribute samples of controlled dangerous substances a form must be completed and submitted to the Registration Division. Such forms may be obtained through the OBN website or by calling the Registration Division.
- (2) A new form shall be completed and submitted to the Registration Division each time the list of items to be distributed changes.
- (3) A copy of the form submitted to the OBN shall be retained by the distributor.
- (4) The practitioner receiving the samples shall keep a record each time he/she receives or distributes samples of controlled dangerous substances.
- (e) When shipping controlled dangerous substances, a registrant is responsible for selecting common or contract carriers which provide adequate security to guard against in-transit losses. When storing controlled dangerous substances in a public warehouse, a registrant is responsible for selecting a warehouseman who will provide adequate security to guard against storage losses; wherever possible, the registrant shall store controlled dangerous substances in a public warehouse which complies with the requirements set forth in this Chapter. In addition, the registrant shall employ precautions (e.g., assuring that shipping containers do not indicate that contents are controlled dangerous substances except in the case of medical marijuana) to guard against storage or in-transit losses and comply with all current Federal regulations, except medical marijuana transit shall comply with rules set forth in OAC 310:681-3by the OMMA. Reporting the loss of in-transit shipments is the responsibility of the registrant shipping the controlled dangerous substances.
- (f) When distributing controlled dangerous substances through agents (e.g., detailmen), a registrant is responsible for providing and requiring adequate security to guard against theft and diversion while the controlled dangerous substances are being stored or handled by the agent(s).
- (g) No registrant shall knowingly employ, as an agent or employee, any person who will have access to controlled dangerous substances if such person has been convicted, pled guilty, or nolo contendere, or otherwise ordered to complete a period of probation or supervision for a misdemeanor or felony relating to any controlled dangerous substances as defined by the Uniform Controlled Dangerous Substances Act in this state, any other state, or the United States, or any person convicted, pled guilty, or nolo contendere, or otherwise ordered to complete a period of probation or supervision for any felony of this state, any other state, or the United States, unless, after full review of the circumstances, the Director waives this requirement in writing with respect to each person on a case-by-case basis. Except Schedule I medical marijuana registrants, employees, and agents shall be subject to the criminal history requirements pursuant to Title 63 Okl.St.Ann. §420A et seq., unless, after full review of the circumstances, the Director waives this requirement in writing with respect to each person on a case-by-case basis.
- (h) The registrant shall immediately notify OBN and seek authorization to employ any individual as specified above.

[Source: Amended at 12 Ok Reg 2841, eff 7-15-95; Amended at 24 Ok Reg 2737, eff 8-11-07; Amended at 29 Ok Reg 1317, eff 6-25-12; Amended at 31 Ok Reg 2110, eff 9-12-14]

475:20-1-6. Physical security controls for practitioners

Physical security controls for practitioners shall be as follows:

- (1) Controlled dangerous substances listed in Schedule I shall be stored in a securely locked, substantially constructed cabinet.
- (2) Controlled dangerous substances listed in Schedules II, III, IV and V shall be stored in a securely locked, substantially constructed cabinet. However, pharmacies and

institutional practitioners may disperse such substances throughout the stock of non-controlled dangerous substances in such a manner as to obstruct the theft or diversion of the controlled dangerous substance.

475:20-1-7. Physical security controls for drug canine handlers

Physical security controls for drug canine handlers shall be as follows:

- (1) Controlled dangerous substances stored at a registration location shall be in a securely locked, substantially constructed cabinet and/or may be stored in a safe deposit box maintained by a financial institution.
- (2) Controlled dangerous substances transported in a vehicle must be maintained in a locked container inside the vehicle.

[**Source:** Amended at 29 Ok Reg 1317, eff 6-25-12]

475:20-1-8. Other security controls for registrants

- (a) All registrants shall immediately notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of any theft or significant loss of any state or federal registration certificates, D.E.A. Form 222 order blanks, prescription blanks or other materials used in purchasing, distributing, prescribing or transferring controlled dangerous substances.
- (b) All registrants shall immediately notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control orand the local law enforcement agency having jurisdiction of any information the registrant receives concerning any violations of the Oklahoma Controlled Dangerous Substances Act and/or federal statutes and regulations related to controlled dangerous substances.
- (c) All registrants shall ensure that every person, with access to controlled dangerous substances, keep and maintain a valid government-issued photo identification card on their person at all times when on the registered premises.
- (d) All registrants shall notify the OBN within one (1) business day of the discovery of any charge, arrest, or conviction of any beneficial owner, agent, employee, contractor, or subcontractor.

[Source: Amended at 12 Ok Reg 2841, eff 7-15-95; Amended at 29 Ok Reg 1317, eff 6-25-12]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 25 - Records and Reports of Registrants

Section 475:25-1-1	Purpose
Section 475:25-1-2	General information
Section 475:25-1-3	Persons required to keep records and file reports
Section 475:25-1-4	Maintenance of records and inventories
Section 475:25-1-5	General requirements for inventories
Section 475:25-1-6	Initial inventory date [Revoked]
Section 475:25-1-7	Biennial inventory date
Section 475:25-1-8	Inventory date for newly-controlled dangerous substances
Section 475:25-1-9	Inventories of manufacturers
Section 475:25-1-10	Inventories of distributors
Section 475:25-1-11	Accounting requirements
Section 475:25-1-12	Inventories of scientific analyst
Section 475:25-1-13	General requirements for continuing records
Section 475:25-1-14	Records for manufacturers
Section 475:25-1-15	Records for distributors
Section 475:25-1-16	Records of scientific researchers
Section 475:25-1-17	Records of scientific analyst
Section 475:25-1-18	Records of medical institutions
Section 475:25-1-19	Order forms
Section 475:25-1-20	Reports for Manufacturers and Distributors

475:25-1-1. Purpose

The rules of this Chapter list and describe the types of records that must be maintained regarding the lawful possession of controlled dangerous substances, and also state how long said records must be available for inspection.

475:25-1-2. General information

Registrants shall be required to maintain records, reports, and inventory in accordance with this Chapter and pursuant to Title 21 Code of Federal Regulations, and Title 63 Okl.St.Ann. §2-307, except Schedule I medical marijuana registrants shall be required to maintain readily-retrievable inventory tracking, records, and reports in the format set forth in OAC 310:681-5-6by the OMMA.

475:25-1-3. Persons required to keep records and file reports

- (a) Each registrant shall maintain the readily-retrievable records and inventories and shall file the reports required by this Chapter, except as exempted by this Section. Any registrant who is authorized to conduct other activities without being registered to conduct those activities pursuant to 475:10-1-7 shall maintain the records and inventories and shall file the reports required for persons registered to conduct such activities. This latter requirement should not be construed as requiring stocks of controlled dangerous substances being used in various activities under one registration to be stored separately, nor that separate records are required for each activity. The intent of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN) is to permit the registrant to keep one set of records which are adapted by the registrant to account for controlled dangerous substances used in any activity. Also, the Director does not wish to require separate stocks of the same substance to be purchased and stored for separate activities. Otherwise, there is no advantage gained by permitting several activities under one registration. Thus, when a researcher manufactures a controlled dangerous substance, he/she must keep a record of the quantity manufactured; when he/she distributes a quantity of the item, he/she must use and keep invoices or order forms as required by Title 21 Code of Federal Regulations, to document the transfer. When substances are used in chemical analysis, he/she need not keep a record of this because such record would not be required of him/her under a registration to do chemical analysis. All of these records may be maintained in one consolidated record system. Similarly, the researcher may store all of his/her controlled dangerous substances in one place and every two (2) years take inventory of all items on hand, regardless of whether the substances were manufactured by him/her, purchased domestically by him/her, or whether the substances will be administered to subjects, distributed to other researchers, or destroyed during chemical analysis. This may be accomplished by keeping a log for administering similar to that kept for dispensing.
- (b) A registered individual practitioner is required to keep readily-retrievable records with respect to all controlled dangerous substances listed in Schedules II through V which he/she prescribes, administers, or dispenses in the lawful course of his/her professional practice. Practitioners shall keep a suitable book, file, or record in which information pertaining to controlled dangerous substances dispensed by the practitioner shall be preserved for a period of at least two (2) years and be available to designated law enforcement officers for their inspection and copying. These records will be maintained separate and apart from all other records.
- (c) A registered individual practitioner is required to maintain patient records for any individual receiving controlled dangerous substances whether by prescribing, administering, or dispensing. Such record will contain as a minimum the patient's full legal name, date of birth, residence

address, last physician seen and when, chief complaint, and notations of date, amount, and type of controlled dangerous substance for each occasion the patient receives a controlled dangerous substance, and diagnostic and medical procedure reports. Such records should contain additional identifying information when possible, including, but not limited to, social security number or driver's license number, telephone number, next-of-kin, and general physical description of the patient. This includes authorization of refills and the number of refills authorized on the original prescription.

(d) A registered person using any controlled dangerous substance in preclinical research or in teaching at a registered establishment which maintains records with respect to such substances is not required to keep records, unless so ordered by the Director for cause, if he/she notifies the OBN of the name, address, and registration number of the establishment maintaining such records. (e) Schedule I medical marijuana registrants shall be required to maintain readily-retrievable, onsite, inventory tracking, records, and reports in the format set forth by the OMMA.

[Source: Amended at 12 Ok Reg 2843, eff 7-15-95; Amended at 24 Ok Reg 2739, eff 8-11-07]

475:25-1-4. Maintenance of records and inventories

- (a) Every inventory and other record required to be kept by the Uniform Controlled Dangerous Substances Act and this Chapter shall be kept by the registrant for at least two (2) years from the date of such inventory or record. Schedule I medical marijuana inventory and records shall be kept for at least seven (7) years from the date of such inventory or record. Every inventory and other record required to be kept shall be available for inspecting and copying by authorized peace officers or officers of agencies specifically directed to enforce the State of Oklahoma or the United States controlled dangerous substances laws, pursuant to and in the manner prescribed by Title 63 Okl.St.Ann. § 2-502, and if applicable, Title 21 Code of Federal Regulations § 1304.04, and this Chapter.
- (b) Each registered manufacturer and distributor shall maintain inventories and records of controlled substances as follows:
 - (1) Inventories and records of controlled dangerous substances listed in Schedules I and II shall be maintained separately from all other records of the registrant.
 - (2) Inventories and records of controlled dangerous substances listed in Schedules III, IV, and V shall be maintained separately from all other records of the registrant as of November 1, 1990.
- (c) Each registered individual practitioner required to keep records and institutional practitioners required to keep records shall maintain inventories and records of controlled dangerous substances in the manner prescribed in (b) of this Section.
- (d) Each registered pharmacy shall maintain the inventories and records of controlled dangerous substances as follows:
 - (1) Inventories, records, invoices, and purchase records of all controlled dangerous substances listed in Schedules I and II shall be maintained separately from all other records of the pharmacy, and prescriptions for such substances shall be maintained in a separate prescription file and be readily retrievable.
 - (2) Inventories, records, invoices, and purchase records of controlled dangerous substances listed in Schedules III, IV, and V shall be maintained separately from all other records of the pharmacy and be readily retrievable. Prescriptions for such substances shall be maintained in separate prescription files for controlled dangerous substances listed in

Schedules III, IV, and V and shall be readily retrievable from the other prescription records of the pharmacy.

[Source: Amended at 12 Ok Reg 2843, eff 7-15-95; Amended at 24 Ok Reg 2739, eff 8-11-07]

475:25-1-5. General requirements for inventories

- (a) Each inventory shall contain a complete accurate record of all controlled dangerous substances on hand on the date the inventory is taken. Controlled dangerous substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, substances stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.
- (b) A separate inventory shall be made by a registrant for each registered location. In the event controlled dangerous substances in the possession or under the control of the registrant are at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. Each inventory for a registered location shall be kept at the registered location.
- (c) A separate inventory shall be made by a registrant for each independent activity for which he/she is registered.
- (d) A registrant may take an inventory on a date that is within four (4) days of this biennial inventory date pursuant to 475:25-1-7 if he/she notifies in advance the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of the date on which he/she will take the inventory. A registrant may take an inventory either as of the opening of business or as of the close of business on the inventory date. The registrant shall indicate on the inventory records whether the inventory is taken as of the opening or as of the close of business and the date the inventory is taken. The inventory shall be signed by the person taking said inventory.
- (e) An inventory must be maintained in a written, typewritten or printed form. An inventory taken by use of an oral recording device must be promptly transcribed.
- (f) Schedule I medical marijuana registrants shall take an inventory and maintain the inventory pursuant to the format set forth by the OMMA.

475:25-1-6. Initial inventory date [REVOKED]

[Source: Revoked at 24 Ok Reg 2739, eff 8-11-07]

475:25-1-7. Biennial inventory date

Every two (2) years following the date on which the initial inventory is taken by a registrant, the registrant shall take a new inventory of all stocks of controlled dangerous substances on hand. The biennial inventory may be taken:

- (1) on the day of the year on which the initial inventory was taken; or
- (2) on the registrant's regular general physical inventory date, as long as the date chosen does not exceed two (2) years from the last inventory date.

[Source: Amended at 29 Ok Reg 1319, eff 6-25-12]

475:25-1-8. Inventory date for newly-controlled dangerous substances

Every registrant required to keep records who possesses a substance which has been added to any schedule of controlled dangerous substances shall take an inventory of all stocks of the

newly-scheduled substance on hand. Thereafter, such substances shall be included in each inventory made by the registrant pursuant to 475:25-1-7.

475:25-1-9. Inventories of manufacturers

Except for Schedule I medical marijuana registrants, inventories of manufacturers of controlled dangerous substances shall conform to Title 21 Code of Federal Regulations, §1304.11. <u>Schedule I medical marijuana registrants required to register pursuant to Title 63 Okla.St.Ann §2-302 shall report in the format set forth by the OMMA.</u>

[Source: Amended at 29 Ok Reg 1319, eff 6-25-12]

475:25-1-10. Inventories of distributors

Except for Schedule I medical marijuana registrants, each person registered or otherwise authorized to distribute controlled dangerous substances shall include in his/her inventory the same information required of a manufacturer pursuant to Title 21 Code of Federal Regulations, §1304.11. Schedule I medical marijuana registrants required to register pursuant to Title 63 Okla.St.Ann §2-302 shall report in the format set forth by the OMMA.

[Source: Amended at 29 Ok Reg 1319, eff 6-25-12]

475:25-1-11. Accounting requirements

In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the registrant shall make an accurate count or measure of all controlled dangerous substances in schedules I, II, III, IV, or V.

[Source: Amended at 12 Ok Reg 2843, eff 7-15-95; Amended at 24 Ok Reg 2739, eff 8-11-07]

475:25-1-12. Inventories of scientific analyst

Inventories of each person registered or otherwise authorized to conduct scientific analysis with controlled dangerous substances shall conform to Title 21 Code of Federal Regulations, §1304.11. [Source: Amended at 29 Ok Reg 1319, eff 6-25-12]

475:25-1-13. General requirements for continuing records

- (a) Every registrant required to keep records shall maintain on a current basis a complete and accurate record of each such substance manufactured, received, sold, delivered or otherwise disposed of by him/her, except that no registrant shall be required to maintain a perpetual inventory.
- (b) Separate records shall be maintained by a registrant for each registered location or except as otherwise provided independent activity for which he/she is registered.
- (c) In recording dates of receipt, distribution or other transfers, the date on which the controlled dangerous substances are actually received, distributed or otherwise transferred shall be used as the date of receipt or distribution of any documents of transfer (e.g., invoices or packing slips).

 [Source: Amended at 12 Ok Reg 2843, eff 7-15-95; Amended at 24 Ok Reg 2739, eff 8-11-07]

475:25-1-14. Records for manufacturers

Except for Schedule I medical marijuana registrants, records for manufacturers of controlled dangerous substances shall conform to Title 21 Code of Federal Regulations, §1304.22.

475:25-1-15. Records for distributors

Each person registered or otherwise authorized to distribute controlled dangerous substances, except for Schedule I medical marijuana registrants, shall maintain records with the following information for each controlled dangerous substance:

- (1) The name of the substance.
- (2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- (3) The number of commercial containers of each such finished form received from other persons, including the date and number of containers in each receipt and the name, address and Federal Drug Enforcement Administration registration number of the person from whom the containers were received.
- (4) The number of commercial containers of each such finished form imported directly by the person, including the date of, the number of commercial containers in, and the import permit or declaration number for each importation.
- (5) The number of commercial containers of each such finished form distributed to other persons, including the date and number of containers in each distribution and the name, address, and Federal Drug Enforcement Administration registration number of the person to whom the containers were distributed.
- (6) The number of commercial containers of each such finished form exported directly by the person, including the date of, the number of commercial containers in, and the export permit or declaration number for each exportation.
- (7) The number of units or volume of finished forms and/or commercial containers distributed or disposed of in any other manner by the person (e.g., by distribution as complimentary samples or by destruction), including the date and manner of distribution or disposal, the name, address, Federal Drug Enforcement Administration registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed.

475:25-1-16. Records of scientific researchers

Each person registered or otherwise authorized to conduct scientific research with controlled dangerous substances and required to keep records shall maintain records with the following information for each controlled dangerous substance:

- (1) The name of the substance.
- (2) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- (3) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, address, and, if applicable, Federal Drug Enforcement Administration registration number of the person from whom the containers were received.
- (4) The number of units or volume of such finished forms and/or commercial containers disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in the finished form disposed.

475:25-1-17. Records of analytical laboratory activities

- (a) Each person registered or otherwise authorized to conduct analytical laboratory activities with controlled dangerous substances shall maintain records with the following information to the extent known and reasonably ascertainable by him/her for each controlled dangerous substance:
 - (1) The name of the substance.
 - (2) The form or forms in which the substance is received, imported, or manufactured by the registrant (e.g., powder, granulation, tablet, capsule, or solution) and the concentration of the substance in such form (e.g., C.P., U.S.P., N.D., 10-milligram tablet or 10-milligram concentration per milli-liter).
 - (3) The total number of the forms received, imported, or manufactured (e.g., 100 tablets, 30 1-milliliter vials, or 10 grams of powder), including the date and quantity of each receipt, importation or manufacture, and the name, address, and Federal Drug Enforcement Administration registration number, if any, of the person from whom the substance was received.
 - (4) The quantity distributed or destroyed in any manner by the registrant (except quantities used in chemical analysis or other laboratory work), including the date and manner of distribution or destruction and the name, address, and Federal Drug Enforcement Administration registration number, if any, of each person to whom the substance was distributed.
- (b) Records relating to known or suspected controlled dangerous substances received as evidentiary material for analysis are not required under (a) of this Section.
- (c) Each person registered to conduct analytical laboratory activities of samples of suspected controlled dangerous substances shall maintain records containing the following information (to the extent known and reasonably ascertainable by him/her):
 - (1) Laboratory identification number.
 - (2) Date the sample was received.
 - (3) Purported contents and actual identification.
 - (4) Quantity received.
 - (5) Form of sample (i.e., powder, liquid, tablets, etc.).
 - (6) Description of sample.
 - (7) Quantity utilized in analysis.
 - (8) Disposition of sample.
 - (9) Street price, if known.
 - (10) Method shipment is received.
 - (11) Each laboratory shall submit to the OBN a quarterly report containing at least the following information:
 - (A) Actual content of drug analyzed.
 - (B) Alleged content of drug analyzed.
 - (C) Description of sample.
 - (D) Origin of sample.
 - (E) Street price, if known.
- (d) Qualitative and quantitative analysis may be conducted of samples.
 - (1) Security of standards and samples, including Schedule I medical marijuana, shall be in accordance with 475:20-1-6 and 475:20-1-7, with the exception that all standards and samples must be treated as Schedules I and II.

- (2) Any unused portion of a submitted sample shall be disposed of in accordance with 475:35-1-4.
- (3) All controlled dangerous substances distributed to drug canine handler registrants and scientific research registrants shall be analyzed quantitatively, and a record of such analysis shall be maintained prior to distribution. Oklahoma State Bureau of Investigation has discretion to refuse to distribute any controlled dangerous substances. Each such registrant shall receive a copy of the quantitative analysis.

[Source: Amended at 12 Ok Reg 2843, eff 7-15-95]

475:25-1-18. Records of medical institutions

Each registered medical institution licensed by the Oklahoma State Department of Health or the Oklahoma State Department of Human Services as a hospital or otherwise authorized to professionally handle controlled dangerous substances shall maintain records with the following information for each controlled dangerous substance:

- (1) Each such registered or otherwise authorized hospital shall issue a specific internal code number for each resident or staff practitioner required within the scope of his or her employment to administer, dispense or prescribe controlled dangerous substances within the hospital. The code number shall consist of numbers, letters, or a combination thereof, and shall be a suffix to the hospital's Federal Drug Enforcement Administration registration number, preceded by a hyphen (e.g., AB1234567-12 or AB1234567-A12).
 - (A) If the hospital has a graduate intern training program authorized by the Oklahoma State Board of Medical Licensure and Supervision, the hospital may authorize such interns, required within the scope of his or her employment, to administer, dispense or prescribe controlled dangerous substances within the hospital, in accordance with 475:10-1-5.
 - (B) A current list of the internal code numbers of each hospital and the corresponding authorized individual resident, staff practitioner or intern shall be kept by the hospital pharmacist and will be made available at all times to other registrants and properly designated law enforcement agencies upon request, for the purpose of verifying the prescribing individual practitioner.
- (2) Controlled dangerous substances records for accountability in a registered medical institution are required for all substances listed in Schedules II through V of the Oklahoma Uniform Controlled Dangerous Substances Act. These records shall include and provide at least:
 - (A) The number of doses of controlled dangerous substances purchased.
- (B) The number of doses dispensed to individual patients or distributed to nursing stations.
 - (C) The number of doses administered.
 - (D) A biennial physical inventory and reconciliation of any discrepancies.
- (3) Where a controlled dangerous substance is not dispensed to an individual patient, the following are required:
- (A) Controlled dangerous substances records for those substances in Schedules II through V.
 - (B) Distribution of a controlled dangerous substance to a nursing station shall not exceed twenty-five (25) doses per container.

- (C) A distribution record for each multiple of twenty-five (25) or fewer doses shall be used to account for delivery to a nursing station. The record shall include the name and dose of the controlled dangerous substance, quantity, date, location of the nursing station, and names of the person from the pharmacy or drug department distributing and the person on the nursing station receiving the substance.
- (D) A proof-of-use record to account for all doses of a substance administered, including the name of the substance, dose administered, time administered, name of the patient and signature of the person who administered the dose.
- (4) A controlled dangerous substance maintained at a nursing station shall be stored in a securely-locked cabinet or medication cart accessible only to persons responsible for administration or distribution of the substance.
- (5) Completed controlled dangerous substances records shall be maintained or controlled by the pharmacy or drug department official for two (2) years.
- (6) When a dose is destroyed, a witness shall countersign on the proper accountability record, record the disposition, and explain the destruction of the dose.
- (7) The patient's chart shall constitute the medication record.

[Source: Amended at 12 Ok Reg 2843, eff 7-15-95]

475:25-1-19. Order forms

Procedures governing the issuance, use and preservation of order forms regarding controlled dangerous substances shall be maintained pursuant to Title 21 Code of Federal Regulations §1305 in accordance with Title 63 Okl.St.Ann. §2-308.

475:25-1-20. Reports for manufacturers and distributors

- (a) Except Schedule I medical marijuana registrants, manufacturers required to register pursuant to Title 63 Okla.St.Ann §2-302 shall provide the following data on every sale of any controlled dangerous substance in Schedules I, II, III, IV, and V.
 - (1) The manufacturer's or distributor's name, address, phone number, DEA registration number and controlled dangerous substance registration number issued by the Bureau;
 - (2) The name, address and DEA registration number of the entity to whom the controlled dangerous substance was sold;
 - (3) The date of the sale of the controlled dangerous substance
 - (4) The name and National Drug Code of the controlled dangerous substance sold; and
 - (5) The number of containers and the strength and quantity of controlled dangerous substances in each container sold.
- (b) Except for Schedule I medical marijuana registrants, distributors required to register pursuant to Title 63 Okla.St.Ann §2-302 shall provide the following data on every sale of any controlled dangerous substance in Schedules I, II, III, IV, and V.
 - (1) The manufacturer's or distributor's name, address, phone number, DEA registration number and controlled dangerous substance registration number issued by the Bureau;
 - (2) The name, address and DEA registration number of the entity to whom the controlled dangerous substance was sold;
 - (3) The date of the sale of the controlled dangerous substance
 - (4) The name and National Drug Code of the controlled dangerous substance sold; and

- (5) The number of containers and the strength and quantity of controlled dangerous substances in each container sold.
- (c) Schedule I medical marijuana registrants required to register pursuant to Title 63 Okla.St.Ann §2-302 shall report in the format set forth in OAC 310:681-5-6by the OMMA or as required by the Director.
- (d) Registrants shall maintain at the registered location a readily-retrievable, on-site, employment record for all employees or agents, or contract(s) with identifying information of each independent contractor or subcontractor, of the registrant that have access to controlled dangerous substances which include, at a minimum, the name, date of birth, address, phone number, hire date, and title/duties.

[Source: New at 37 Ok Reg 2022, eff 9-11-20]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control

Chapter 30 - Labeling Requirements

Section 475:30-1-1	Purpose
Section 475:30-1-2	Persons entitled to issue prescriptions
Section 475:30-1-3	Purpose of issuance of prescriptions
Section 475:30-1-4	Manner of issuance of prescriptions
Section 475:30-1-5	Dispensing of narcotic drugs during scientific research
Section 475:30-1-6	Requirements of prescriptions for controlled dangerous substances listed in Schedule II
Section 475:30-1-7	Partial filling of Schedule II prescriptions
Section 475:30-1-8	Labeling of substances for institutionalized persons [Revoked]
Section 475:30-1-9	Filling of emergency prescriptions [Revoked]
Section 475:30-1-10	Requirements of prescriptions for controlled dangerous substances listed in Schedules III and IV
Section 475:30-1-11	Refilling of prescriptions
Section 475:30-1-12	Partial filling of Schedules III, IV and V prescriptions
Section 475:30-1-13	Requirements of prescriptions for controlled dangerous substances listed in Schedule V
Section 475:30-1-14	Dispensing, prescribing, administering or distributing without prescription
Section 475:30-1-15	Identification requirement

475:30-1-1. Purpose

The rules of this Chapter describe the procedures to be followed for issuance of a valid prescription, and the information required to be placed on labels for controlled dangerous substances. Labeling for Schedule I medical marijuana shall be in accordance with OAC 310:681-7-1.

475:30-1-2. Persons entitled to issue prescriptions

Only a registered individual practitioner may issue a prescription for a Schedule II, III, IV and V controlled dangerous substance. Except as otherwise prohibited by law or rule, an individual practitioner, an authorized employee of the practitioner, or an authorized employee of the facility at which the practitioner works may communicate by telephone an oral prescription for any controlled dangerous substance in Schedules III, IV or V being prescribed by the individual practitioner. It remains the responsibility of the practitioner to guard against the diversion of CDS by employees authorized by him/her to call in such prescriptions.

[Source: Amended at 12 Ok Reg 2847, eff 7-15-95; Amended at 24 Ok Reg 2741, eff 8-11-07; Amended at 37 Ok Reg 2023, eff 9-11-2020]

475:30-1-3. Purpose of issuance of prescriptions

- (a) A prescription for a controlled dangerous substance to be effective must be issued for a legitimate medical purpose by a registered or otherwise authorized individual practitioner acting in the usual course of his/her professional practice. The responsibility for the proper prescribing and dispensing of controlled dangerous substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription, as the filling of a prescription is not incumbent on the pharmacy. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of Title 63 Okl.St.Ann. §§ 2-309 and 2-312, and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled dangerous substances.
- (b) A prescription may not be issued in order for a registered or otherwise authorized individual practitioner to obtain controlled dangerous substances to stock or re-supply his/her office or medical bag for the purpose of general dispensing to patients. Such orders for stock or re-supply must be made by invoice for schedules III, IV, and V, or by DEA-222 order form for schedules I and II.
- (c) A prescription may not be issued for the dispensing of a controlled dangerous substance listed in any schedule to a drug dependent person for the sole purpose of continuing his/her dependence upon such drugs. This prohibition applies to the use of gradually diminished doses for the purpose of tapering the person's dependence. This section does not apply to a properly licensed and registered narcotic treatment program.
- (d) A practitioner may not distribute, dispense, sell, give, prescribe or administer any controlled substances in Schedules I through V for the practitioner's personal use, or for an immediate family member. Provided that this paragraph shall not apply to family members outside the second degree of consanguinity or affinity. Provided further that this paragraph shall not apply to medical emergencies when no other medical doctor is available to respond to the emergency.

475:30-1-4. Manner of issuance of prescriptions

- (a) The practitioner shall sign a prescription in the same manner he/she would sign a check or legal document and shall also type, stamp, or print the practitioner's name on the face of each prescription. Where an oral order is not permitted or an electronic prescription is not utilized, prescriptions shall be written with ink. All written prescriptions shall be manually signed by the practitioner. The prescriptions may be prepared by an agent for the signature of a practitioner, but the prescribing practitioner is responsible in the event the prescription does not conform in all essential respects to the Uniform Controlled Dangerous Substances Act and this Chapter.
- (b) A resident or staff practitioner, an intern of a teaching hospital, or a limited institutional practitioner of a federal, state, or local government hospital or institution, practitioner exempted from registration or registered in fee-exempt status with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN), shall include on all prescriptions issued by him/her the hospital or institutional Federal Drug Enforcement Administration (DEA) registration number with the special internal code number assigned by the hospital or other institution; or include on all prescriptions he/she issues his/her personal DEA registration number. Such prescriptions issued by interns of a teaching hospital, if for outpatients, must be countersigned by a practitioner licensed by the practitioner's appropriate State of Oklahoma licensing board.
- (c) A practitioner must state on a prescription for any controlled dangerous substance the name, address, and DEA registration number of the practitioner; the date of delivery of the prescription; the name, dosage, and strength per dosage unit of the controlled dangerous substance; the name and address of the patient, or if it is a veterinary prescription, the species of the animal and the name and address of the owner; the directions for use and any cautionary statements required; and if allowable, the number of times to be refilled.
 - (1) The face of a prescription must not be materially altered; if an error is made in filling out the prescription, a new prescription must be issued by the prescribing practitioner.
 - (A) A pharmacist may add to the prescription the patient's address or age, the prescribing practitioner's DEA registration number, or the generic drug name if used.
 - (B) After confirming with the prescribing practitioner, the pharmacist may add information indicating the strength, whether tablet or capsule form, and whether it is compounded if such additions would not materially alter the prescription.
 - (C) If omitted, the directions (Sig) or the quantity, may be added by the pharmacist after confirming with the prescribing practitioner.
 - (D) Documentation of contacting the prescribing practitioner will be noted on the back of the prescription regarding (B) and (C) above.
 - (2) A prescription for a controlled dangerous substance in Schedule II becomes invalid thirty (30) days after the earliest date on which a pharmacy may fill the prescription, with day one (1) of the thirty (30) day period being the first day after the earliest date on which a pharmacy may fill the prescription. After issuing an initial prescription pursuant to Section 2-309I of Title 63, an individual practitioner may issue one (1) subsequent prescription for an immediate-release opioid drug in Schedule II in a quantity not to exceed seven (7) days if:
 - (A) The subsequent prescription is due to a major surgical procedure and/or "confined to home" status as defined in 42 U.S.C. 1395n(a);
 - (B) The practitioner provides the subsequent prescription on the same day as the initial prescription;

- (C) The practitioner provides written instruction on the subsequent prescription indicating the earliest date on which the prescription may be filled (i.e. "do not fill until" date); and,
- (D) The subsequent prescription is dispensed no more than five (5) days after the "do not fill until" date indicated on the prescription.
- (3) Each scheduled drug shall be written on a single prescription form, and no other prescriptions (controlled or non-controlled) shall be written on the same prescription form.
- (d) Upon receiving an oral prescription, the pharmacist must reduce the oral prescription to the form specified in (c) of this Section, including the typewritten name of the prescribing practitioner. The pharmacist filling any prescription for any controlled dangerous substance must enter the date of filling and handwrite the initials of the pharmacist on the prescription. If the practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that the oral authorization came from a registered practitioner.
- (e) Upon receiving an oral prescription, the pharmacist may use a computer printout label if the label meets all requirements for a prescription as set out by the Uniform Controlled Dangerous Substances Act and this Chapter. On computer labeling for oral prescriptions, it is not necessary that the DEA registration number be on the label used as an oral prescription, but it must be recorded on the document prepared by the pharmacist.
- (f) Written prescriptions may be transmitted by a practitioner to a dispensing pharmacy by facsimile. In such cases, the prescribing practitioner shall print "FAXED" on the face of the prescription, and the facsimile received must be on non-fading standard paper. Thermographic paper is not acceptable for any prescriptions for drugs in any Schedule.
 - (1) For drugs in Schedules III, IV, and V, a facsimile of a written, signed prescription transmitted directly by the prescribing practitioner to the pharmacy can serve as an original prescription.
 - (2) For drugs in Schedule II, the original written prescription must still be presented and verified against the facsimile at the time the substance is actually dispensed and the original document must be properly annotated and retained for filing subject to the exceptions listed in (3) below.
 - (3) Exception to (2): A facsimile copy of a prescription for a Schedule II drug when sent by facsimile by the prescribing practitioner:
 - (A) To a Home Infusion Pharmacy.
 - (B) When the prescription is for a patient in a Long Term Care Facility (LTCF).
 - (C) When the prescription is for a patient in a Hospice program certified by Medicare under Title XVIII or licensed by the state.
 - (D) If the facsimile is sent from a LTCF or hospice instead of the prescribing practitioner's office, the original must be presented at the time any controlled dangerous substance is dispensed.
- (g) The pharmacist still bears the responsibility for ensuring that prescriptions for controlled dangerous substances have been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his/her professional practice. This responsibility applies equally to an order transmitted by facsimile. Measures to be considered in authenticating prescriptions sent by facsimile equipment would include maintenance of a practitioner's facsimile number reference file, verification of the telephone number of the originating facsimile equipment, and/or telephone verification with the practitioner's office that the prescription was both written by the practitioner and transmitted by the practitioner or the practitioner's agent.

(h) Electronic prescriptions are permitted as provided by 21 CFR §§ 1311 et. seq. [Source: Amended at 12 Ok Reg 2847, eff 7-15-95; Amended at 22 Ok Reg 2683, eff 7-25-05; Amended at 24 Ok Reg 2741, eff 8-11-07; Amended at 29 Ok Reg 1320, eff 6-25-12; Amended at 30 Ok Reg 545, eff 5-13-13; Amended at 37 Ok Reg 2023, eff 9-11-20]

475:30-1-5. Dispensing of narcotic drugs during scientific research

- (a) The administering or dispensing directly (but not prescribing) of narcotic drugs in any schedule to a narcotic drug dependent person for the purpose of continuing his/her dependence upon such drugs in the course of conducting an authorized clinical scientific research in the development of a narcotic addict rehabilitation program shall be deemed to be within the meaning of the term "in the course of his/her professional practice or research"; PROVIDED that approval is obtained prior to the initiation of such a program by submission of a protocol submitted to the OBN and the State of Oklahoma Department of Mental Health and Substance Abuse Services. It will be reviewed by the State of Oklahoma Department of Mental Health and Substance Abuse Services for scientific merit and qualifications and by the OBN for controlled dangerous substance requirements as provided by the Uniform Controlled Dangerous Substances Act and this Chapter.

 (b) Nothing in this Title shall prohibit a physician who is not specifically registered to conduct a
- narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms, when necessary, while arrangements are being made for referral for treatment. Not more than one (1) day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three (3) days and may not be renewed or extended.

475:30-1-6. Requirements of prescriptions for controlled dangerous substances listed in Schedule II

- (a) A pharmacy may dispense directly a controlled dangerous substance listed in Schedule II which is a prescription drug as determined under the Uniform Controlled Dangerous Substances Act, only pursuant to a prescription or as otherwise provided for in this Title.
- (b) A registered individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedule II in the course of his/her professional practice without a prescription, subject to 475:30-1-5.
- (c) An institutional physician limited in practice by the individual's appropriate Oklahoma state licensing board, other than those registered in a fee-exempt status with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, may administer or dispense directly (but not prescribe) a controlled dangerous substance listed in Schedule II, only pursuant to a prescription signed by the "Limited Institutional Practitioner's" supervising chief medical practitioner or to an order for medication made by an individual supervising chief medical practitioner which is dispensed for immediate administration to the ultimate user.
- (d) In case of an emergency situation, as defined by the Oklahoma State Board of Pharmacy pursuant to Title 63 Okl.St.Ann. §2-309, and Title 21 Code of Federal Regulations, §1306.11, the pharmacist of a registered or otherwise authorized pharmacy may dispense a controlled dangerous substance listed in Schedule II upon receiving oral authorization of a prescribing registered individual; PROVIDED that:
 - (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a prescription signed by the prescribing registered individual practitioner).

- (2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in Title 63 Okl.St.Ann. §2-309 and OAC 475, except for the signature of the prescribing registered individual practitioner.
- (3) If the prescribing registered individual practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that oral authorization came from a registered individual practitioner, which may include a callback to the prescribing registered individual practitioner, using his/her phone number as listed in the telephone directory and/or good faith effort to ensure his/her identity.
- (4) In emergency situations, reasonable effort must be made to determine the identity of the person picking up the prescription if that person is not known to the pharmacist.
- (5) Within seventy-two (72) hours after authorizing an emergency oral prescription, the prescribing registered individual practitioner shall cause a prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of Title 63 Okl.St.Ann. §2-309(F), the prescription shall have written on its face "Authorization for Emergency Dispensing", and the date of the oral order. The prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the 72-hour period. Upon receipt, the dispensing pharmacist shall attach this prescription to the oral emergency prescription which had earlier been reduced to writing. The pharmacy shall notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control if the prescribing registered individual practitioner fails to deliver to him/her a prescription; failure of the pharmacy to do so shall void the authority conferred by this paragraph to dispense without a prescription of a prescribing registered individual practitioner.

[Source: Amended at 12 Ok Reg 2847, eff 7-15-95; Amended at 29 Ok Reg 1320, eff 6-25-12; Amended at 30 Ok Reg 545, eff 5-13-13; Amended 37 Ok Reg 2024, eff 9-11-20]

475:30-1-7. Partial filling of Schedule II prescriptions

- (a) The partial filling of a prescription for a controlled dangerous substance listed in Schedule II is permissible if the pharmacy is unable to supply the full quantity called for on the prescription, or where the partial fill is requested by the patient or the practitioner that wrote the prescription. A notation of the quantity supplied on the face of the prescription (or written record of the emergency oral prescription) is required. Except as otherwise prohibited by law or rule, if the remaining portion of the prescription is going to be filled, it shall be filled not later than thirty (30) days after the earliest date on which a pharmacy may fill the prescription; however, in the case of emergency oral prescriptions, the remaining portion of a partially filled prescription shall be filled not later than seventy-two (72) hours after the earliest date on which a pharmacy may fill the prescription.
- (b) For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. Prior to any subsequent partial filling, the pharmacist is to determine that the additional partial filling is necessary. The total quantity of Schedule II controlled dangerous substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in a LTCF or patients with a medical diagnosis documenting a terminal illness shall be valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

[Source: Amended at 12 Ok Reg 2847, eff 7-15-95; Amended at 24 Ok Reg 2741, eff 8-11-07; Amended at 37 Ok Reg 2025, eff 9-11-20]

475:30-1-8. Labeling of substances for institutionalized persons [REVOKED]

[**Source:** Revoked at 24 Ok Reg 1741, eff 8-11-07]

475:30-1-9. Filling of emergency prescriptions [REVOKED]

[**Source:** Revoked at 24 Ok Reg 1741, eff 8-11-07]

475:30-1-10. Requirements of prescriptions for controlled dangerous substances listed in Schedules III and IV

- (a) A pharmacy may dispense controlled dangerous substances listed in Schedules III or IV only pursuant to either a prescription signed by a registered or otherwise authorized individual practitioner, except as otherwise prohibited by law or rule, an oral prescription made by a prescribing registered or otherwise authorized individual practitioner and promptly reduced to writing by the pharmacist, containing all the information required by Title 63 Okl.St.Ann.§ § 2-309 and 2-314, and this Chapter, or pursuant to an electronic prescription in compliance with the terms of 21 CFR §§ 1311 et. seq. Computer labels meeting these requirements are acceptable.
- (b) A registered or otherwise authorized individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedule III or IV in the course of his/her professional practice without a prescription, subject to 475:30-1-5.
- (c) An institutional practitioner limited in practice by the individual's appropriate State of Oklahoma professional licensing board, other than those registered as fee-exempt by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, may administer or dispense directly (but not prescribe) a controlled dangerous substance listed in Schedule III or IV pursuant to a prescription signed by the "Limited Institutional Practitioner's" supervising chief medical practitioner, or, except as otherwise prohibited by law or rule, pursuant to oral prescription made by the "Limited Institutional Practitioner's" supervising chief medical practitioner and promptly reduced to writing by the pharmacist containing all information required by 475:30-1-4, except for the signature of the "Limited Institutional Practitioner's" supervising chief medical practitioner or pursuant to an order for medication made by an individual supervising chief medical practitioner which is dispensed for immediate administration to the ultimate user, subject to 475:30-1-5.

[Source: Amended at 12 Ok Reg 2847, eff 7-15-95; Amended at 29 Ok Reg 1320, eff 6-25-12; Amended at 37 Ok Reg 2025, eff 9-11-20]

475:30-1-11. Refilling of prescriptions

- (a) The refilling of a prescription for a controlled dangerous substance listed in Schedule II is prohibited.
- (b) Except as prohibited by law or rule, an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled dangerous substance provided the following conditions are met:
 - (1) Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;
 - (2) The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be

filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;

- (3) The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse; and,
- (4) The individual practitioner complies fully with all other applicable requirements.
- (c) No prescription for a controlled dangerous substance in Schedules III or IV shall be filled or refilled more than six (6) months after the date such prescription was issued, and no such prescription authorized to be refilled may be refilled more than five (5) times. Each refilling of a prescription shall be maintained by the pharmacy, which indicated by the number of the prescription the following information: the name and dosage form of the controlled dangerous substance; the date of each refilling; the quantity dispensed; the identity or initials of the dispensing pharmacist in each refilling; and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription, he/she shall be deemed to have dispensed a refill for the full face amount of the prescription. Additional quantities of controlled dangerous substances listed in Schedule III or IV may only be authorized by a prescribing practitioner through issuance of a new and separate prescription. Refills shall not be obtained at the same time as the initial filling of the prescription and only one (1) refill shall be obtained at any one time. A new prescription for a specific controlled dangerous substance voids any existing refills or other prescriptions for the same drug.
- (d) A pharmacy registrant may elect to use an automated data processing system to maintain prescription files; however, if such a system is used, there must also be written files kept which meet the requirements of Title 59 Okl.St.Ann. § 353.20, OAC 535:15-3-21 and 21 CFR § 1306.22. [Source: Amended at 12 Ok Reg 2847, eff 7-15-95; Amended at 29 Ok Reg 1320, eff 6-25-12; Amended at 31 Ok Reg 332, eff 12-3-13 (emergency); Amended at 31 Ok Reg 2111, eff 9-12-14]

475:30-1-12. Partial filling of Schedules III, IV and V prescriptions

The partial filling of a prescription for a controlled dangerous substance listed in Schedules III, IV, or V is permissible; PROVIDED that:

- (1) Each partial filling is recorded in the same manner as a refilling.
- (2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.
- (3) No dispensing occurs six (6) months after the date on which the prescription was issued.

[Source: Amended at 31 Ok Reg 332, eff 12-3-13 (emergency); Amended at 31 Ok Reg 2111, eff 9-12-14]

475:30-1-13. Requirements of prescriptions for controlled dangerous substances listed in Schedule V

(a) A pharmacist of a registered or otherwise authorized pharmacy may dispense directly a controlled dangerous substance listed in Schedule V pursuant to a prescription as required for controlled dangerous substances listed in Schedules III and IV. A prescription for a controlled dangerous substance listed in Schedule V may be refilled only the number of times expressly authorized by the prescribing registered individual practitioner on the face of the prescription, and such prescription may not be refilled more than six (6) months after the date of issuance. If no such authorization is given, the prescription may not be refilled. A pharmacist dispensing such substance pursuant to a prescription shall label the substance and file the prescription.

- (b) A registered individual practitioner may administer or dispense directly a controlled dangerous substance listed in Schedule V, in the course of his/her professional practice, without a prescription.
- (c) An institutional physician limited in practice by the individual's appropriate State of Oklahoma professional licensing board, other than those registered as fee-exempt with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, may administer or dispense directly (but not prescribe) a controlled dangerous substance listed in Schedule V only pursuant to a written prescription signed by the "Limited Institutional Practitioner's" supervising chief medical practitioner, or pursuant to an oral prescription made by a "Limited Institutional Practitioner's" supervising chief medical practitioner and promptly reduced to writing by the pharmacist (containing all information required in 475:30-1-4, except for the signature of the "Limited Institutional Practitioner's" supervising practitioner), or pursuant to an order for medication made by a "Limited Institutional Practitioner's" supervising chief medical practitioner which is dispensed for immediate administration to the ultimate user.

[**Source:** Amended at 12 Ok Reg 2847, eff 7-15-95]

475:30-1-14. Dispensing, prescribing, administering, or distributing without prescription

A controlled dangerous substance listed in Schedule V which is not a prescription drug as determined by the Oklahoma State Board of Pharmacy and/or the Federal Food and Drug Administration, may be dispensed by a pharmacy without a prescription to a purchaser at retail level; PROVIDED that:

- (1) Such dispensing is made only by a pharmacist that has been licensed by the Oklahoma State Board of Pharmacy to dispense controlled dangerous substances and not by a non-pharmacist employee, even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his/her professional and legal responsibilities set forth in this Section, the actual cash, credit transaction or delivery may be completed by a non-pharmacist).
- (2) No person shall dispense, prescribe, administer or distribute to any one person, for the use of any one person or animal, any preparation(s) included in Title 63 Okl.St.Ann. § 2-313(B)(1), when the dispensing, prescribing, administering or distributing person knows, or can by reasonable diligence ascertain, that such dispensing, prescribing, administering or distributing will provide the person to whom or for whose use, or the owner of the animal for the use of which, such preparation is prescribed, administered, dispensed or distributed, within any forty-eight (48) consecutive hours, with more than 320 milligrams of opium, or more than 40 milligrams of morphine or any of its salts, or more than 160 milligrams of codeine or any of its salts, or will provide such person or the owner of such animal, within forty-eight (48) consecutive hours, more than one preparation exempted by Title 63 Okl.St.Ann. § 2-313.
- (3) Except as otherwise authorized by the Act, OAC 475:30-1-14 shall not apply to the following cases:
 - (A) Prescribing, administering, dispensing or selling at retail not more than one of any of the following medicinal preparations that contain in thirty (30) milliliters or if a solid or semi-solid preparation, in one (1) avoirdupois ounce:
 - (i) Not more than one hundred sixty (160) milligrams of opium.
 - (ii) Not more than twenty (20) milligrams of morphine or any of its salts.
 - (iii) Not more than eighty (80) milligrams of codeine or any of its salts.

- (B) Prescribing, administering, dispensing or selling at retail of liniments, ointments and other preparations that are susceptible of external use only and that contain narcotic drugs in such combinations as to prevent their being readily extracted from such liniments, ointments or preparations, except that this shall apply to all liniments, ointments and other preparations that contain coca leaves in any quantity or combination.
- (C) Any compound, mixture or preparation which contains not more than one drachma of paregoric per thirty (30) milliliters.
- (D) The labeling requirements set forth in this Chapter shall not apply to medicinal preparations excepted by Title 63 Okl.St.Ann. § 2-313, and OAC 475.
- (4) The medicinal preparation or the liniment, ointment or other preparation susceptible of external use only, prescribed, administered, dispensed or distributed shall contain, in addition to the narcotic drug therein, some drug or drugs conferring upon it medicinal qualities other than those possessed by the narcotic drug alone. Such preparation shall be prescribed, administered, dispensed and distributed in good faith as a medicine and not for the purpose of evading the provisions of the Uniform Controlled Dangerous Substances Act and this Chapter.
- (5) The pharmacy, through its agent who is duly licensed by the Oklahoma State Board of Pharmacy, shall not dispense to persons under eighteen (18) years of age.
- (6) A bound record book for dispensing controlled dangerous substances under this Section is maintained by the pharmacy, which book shall contain the name and address of the purchaser, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser (the book shall be maintained in accordance with the record-keeping requirements of 475:25-1-4).
- (7) The pharmacy agent dispensing controlled dangerous substances listed in Schedule V shall, pursuant to Title 63 Okl.St.Ann. § 2-314(B), affix to the package a label showing the prescription number, if any, the date dispensed, the purchaser's name, the name of the prescribing physician, if any, name and address of the pharmacy, if the patient or ultimate user is an animal, the name of the owner of the animal and the words "for veterinary use only".

[Source: Amended at 24 Ok Reg 1741, eff 8-11-07; Amended 37 Ok Reg 2025, eff 9-11-20]

475:30-1-15. Identification requirement

Pharmacists are required to obtain valid identification as required by Title 63 § 2-309C if they are unsure of the identity of a person picking up a prescription for any controlled dangerous substance.

[Source: Amended at 24 Ok Reg 1741, eff 8-11-07; Amended at 29 Ok Reg 1320, eff 6-25-12]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 35 - Transfer and Disposal of Controlled Dangerous Drugs

Section 475:35-1-1	Purpose
Section 475:35-1-2	Distribution by a registered practitioner or pharmacy to another registered practitioner or pharmacy
Section 475:35-1-3	Distribution upon discontinuance or transfer of business
Section 475:35-1-4	Procedure for disposing of controlled dangerous substances
Section 475:35-1-5	Procedure for disposing of controlled dangerous substances in bankruptcy proceeding

475:35-1-1. Purpose

The rules of this Chapter describe the methods of acceptable transfer of controlled dangerous substances other than by prescription.

475:35-1-2. Distribution by a registered practitioner or pharmacy to another registered practitioner or pharmacy

- (a) A practitioner or pharmacy who is registered to dispense a controlled dangerous substance may distribute (without being registered to distribute) a quantity of such substance to another registered practitioner or pharmacy for the purpose of general dispensing by the practitioner or pharmacy to his/her or its patients; PROVIDED that:
 - (1) The practitioner or pharmacy to whom the controlled dangerous substance is to be distributed is registered under the Uniform Controlled Dangerous Substances Act to dispense that controlled dangerous substance.
 - (2) The distribution is recorded by the distributing practitioner or pharmacy and by the receiving practitioner or pharmacy in accordance with Chapter 25 of this Title. If the substance is listed in Schedule I or II, an order form is used, as required by Title 21 Code of Federal Regulations, §1305, and pursuant to Title 63 Okl.St.Ann. §2-308.
 - (3) The total number of dosage units of all controlled dangerous substances distributed by the practitioner pursuant to this Section during the 12-month period in which the practitioner or pharmacy is registered to dispense does not exceed five percent (5%) of the total number of dosage units of all controlled dangerous substances distributed and dispensed by the practitioner during the 12-month period.
- (b) If, at any time during the 12-month period during which the practitioner or pharmacy is registered to dispense, the practitioner or pharmacy has reason to believe that the total number of dosage units of all controlled dangerous substances which will be distributed by him/her pursuant to this Section will exceed five percent (5%) of the total number of dosage units of all controlled dangerous substances distributed and dispensed by him/her during the 12-month period, the practitioner or pharmacy shall obtain a registration to distribute controlled dangerous substances.

[Source: Amended at 12 Ok Reg 2851, eff 7-15-95; Amended 37 Ok Reg 2027, eff 9-11-20]

475:35-1-3. Distribution upon discontinuance or transfer of business

- (a) Any registrant desiring to discontinue business activities altogether or with respect to controlled dangerous substances (without transferring such business activities to another person) shall return for cancellation of his/her Certificate of Registrationnotify the OBN. Any controlled dangerous substances in his/her possession shall be disposed of in accordance with Title 21 Code of Federal Regulations, part 1317. Schedule I medical marijuana shall be disposed pursuant to standards set forth in 63 Okla.St.Ann. §429.
- (b) Any registrant desiring to discontinue business activities altogether or with respect to controlled dangerous substances (by transferring such business activities to another person) shall submit in person or by registered or certified mail, return receipt requested, to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN) at least fourteen (14) days in advance of the date of the proposed transfer (unless the Director waives this time limitation in individual instances), the following information:
 - (1) The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor).

- (2) The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee).
- (3) Whether the business activities will be continued at the location registered by the person discontinuing the business or moved to another location (if the latter, the address of the new location should be listed).
- (4) Whether the registrant-transferor has a quota to manufacture or procure any controlled dangerous substance listed in Schedule I or II (if so, the basic class or classes of the substance should be indicated).
- (5) The date on which the transfer of controlled dangerous substances will occur.
- (c) Unless the registrant-transferor is informed by the OBN, before the date on which the transfer was stated to occur, that the transfer may not occur, the registrant-transferor may distribute (without being registered to distribute) controlled dangerous substances in his/her possession to the registrant-transferee in accordance with the following:
 - (1) On the date of transfer of the controlled dangerous substances, a complete inventory of all controlled dangerous substances being transferred shall be taken in accordance with 475:25-1-5 through 475:25-1-12, and OMMA rules where applicable. This inventory shall serve as the final inventory of the registrant-transferor and the initial inventory of the registrant-transferee, and a copy of the inventory shall be included in the records of each person. It shall be necessary to file a copy of the inventory with the OBN unless waived by the Director. Except for Schedule I medical marijuana, transfers of any substances listed in Schedule I or II require the use of order forms in accordance with Title 21 Code of Federal Regulations, § 1305.
 - (2) On the date of transfer of the controlled dangerous substances, all records required to be kept by the registrant-transferor with reference to the controlled dangerous substances being transferred, pursuant to this Chapter and Title 21 Code of Federal Regulations, § 1304, or OAC 310:681-5-60MMA rules where applicable, shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.
- (d) OBN registrations are non-transferable and cannot be purchased, sold, or otherwise given to or utilized by any other person. The transferee must have a unique, active OBN registration prior to the transfer occurring. The transferor cannot transfer the OBN registration with the controlled dangerous substances and cannot transfer controlled dangerous substances to anyone lacking an active OBN registration. Change of name or ownership require a new OBN registration for all businesses. For any proposed transfer of controlled dangerous substances, the registrant-transferor shall remain in full control of all controlled dangerous substances unless and until the registrant-transferee's new OBN registration is approved and activated; after which, the registrant-transferor's OBN registration shall be inactivated.

[Source: Amended at 24 Ok Reg 2745, eff 8-11-07; Amended at 33 Ok Reg 1766, eff 9-11-16]

475:35-1-4. Procedure for disposing of controlled dangerous substances

Any registrant in possession of any controlled dangerous substances and desiring or required to dispose of such substances shall do so according to the provisions of Title 63 Okl.St.Ann. §2-315 and Title 21 of the Code of Federal Regulations, part 1317, except Schedule I medical marijuana shall be disposed pursuant to standards set forth in 63 Okla.St.Ann. §429.

[Source: Amended at 33 Ok Reg 1766, eff 9-11-16; Amended 37 Ok Reg 2027, eff 9-11-20]

475:35-1-5. Procedure for disposing of controlled dangerous substances in bankruptcy proceeding

At no time shall a representative who is not duly registered with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control be in possession of any controlled dangerous substances awarded out of a bankruptcy proceeding.

[**Source:** Amended at 24 Ok Reg 2745, eff 8-11-07]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 40 - Enforcement and Administrative Inspections

Section 475:40-1-1	Purpose
Section 475:40-1-2	Authority to make inspections
Section 475:40-1-3	Entry

475:40-1-1. Purpose

The rules of this Chapter set out the authority for administrative inspections of OBN registrants to validate compliance with rules and statutes.

475:40-1-2. Authority to make inspections

Administrative inspections of OBN registrants shall include, but not be limited to, the following:

- (1) Inspecting, copying, and verifying the correctness of records, reports, or other documents required to be kept or made, including, but not limited to, inventory, patient records, and other records required to be kept pursuant to the Uniform Controlled Dangerous Substances Act, this Title, the Code of Federal Regulations governing controlled dangerous substances, or OAC 310:681-5-60MMA; order form records required to be kept pursuant to Title 63 Okl.St.Ann. § 2-308 and other applicable state statutes and rules; prescriptions and distribution records required to be kept pursuant to Title 63 Okl.St.Ann. § 2-307 and other applicable state statutes and rules; shipping records identifying the name of each carrier used; and the date and quantity of each storage.
- (2) Inspecting within reasonable limits and in a reasonable manner all pertinent equipment, finished and unfinished controlled dangerous substances, and other substances or materials, containers, and labeling found at the controlled premises relating to the Uniform Controlled Dangerous Substances Act and this Title.
- (3) Making a physical inventory of all controlled dangerous substances on hand at the premises.
- (4) Collecting samples of controlled dangerous substances or precursors (in the event any samples are collected during an inspection, the peace officer or officer so authorized shall issue a receipt for such samples to the owner, operator or agent in charge of the premises).
- (5) Inspecting within reasonable limits and in a reasonable manner records containing the contact information all employees, agents, contractors, or subcontractors to include the name, address, and phone number of each.

[Source: Amended at 24 Ok Reg 2746, eff 8-11-07]

475:40-1-3. Entry

A peace officer of the State of Oklahoma, upon stating his/her purpose and presenting to the owner, operator or agent in charge of the premises to be inspected his/her appropriate credentials, shall have the right to enter such premises and conduct inspections at reasonable times and in a reasonable manner.

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 45 - Oklahoma Control Reporting Requirements

Section 475:45-1-1	Purpose
Section 475:45-1-2	Required reporting of certain information
Section 475:45-1-3	Method of reporting
Section 475:45-1-4	Waiver of electronic submissions
Section 475:45-1-5	Time limit for reporting
Section 475:45-1-6	Failure to report

475:45-1-1. Purpose

The rules of this Chapter delineate the requirement of pharmacies or dispensing (but not administering) practitioners to report certain information upon filling any prescription for any controlled dangerous substance in schedules II, III, IV or V.

[Source: Added at 18 Ok Reg 2218, eff 6-11-01; Amended at 24 Ok Reg 2747, eff 8-11-07; Amended at 29 Ok Reg 1323, eff 6-25-12]

475:45-1-2. Required reporting of certain information

- (a) Every pharmacy or dispensing practitioner filling any Schedule II, III, IV, or V prescriptions must report the following information to a central repository maintained by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (OBN). The information must include, but not be limited to, the following:
 - (1) Recipient's name;
 - (2) Recipient's address;
 - (3) Recipient's date of birth;
 - (4) Recipient's identification number;
 - (5) National Drug Code number of the substance dispensed;
 - (6) Date of the dispensation;
 - (7) Quantity of the substance dispensed;
 - (8) Prescriber's U.S. Drug Enforcement Administration registration number;
 - (9) Dispenser's U.S. Drug Enforcement Administration registration number and location; and
 - (10) Other information as required by the most recent version of the American Society for Automation in Pharmacy's (ASAP) Telecommunications Format for Controlled Substances.
- (b) The term 'recipient' is also intended to include reporting the required information concerning the recipient's agent as defined by 63 O.S. § 2-309B.
- (c) Dispensations of controlled dangerous substances for veterinary use shall report, to the central repository, the owner information as the recipient.

[Source: Added at 18 Ok Reg 2218, eff 6-11-01; Amended at 24 Ok Reg 2747, eff 8-11-07; Amended at 29 Ok Reg 1323, eff 6-25-12; Amended at 33 Ok Reg 1768, eff 9-11-16; Amended 37 Ok Reg 2028, eff 9-11-20]

475:45-1-3. Method of reporting

Each pharmacy or dispensing practitioner must transmit the information required in 475:45-1-2 in the following manner: on an electronic device which is compatible with the receiving device of the central repository.

[Source: Added at 18 Ok Reg 2218, eff 6-11-01; Amended at 24 Ok Reg 2747, eff 8-11-07; Amended at 29 Ok Reg 1323, eff 6-25-12]

475:45-1-4. Waiver of electronic submissions

(a) The Director of the OBN may waive the requirement to submit prescription data in an electronic format, and allow a pharmacy filling a prescription of a Schedule II, III, IV, or V controlled dangerous substance to submit prescription data in a paper format if the dispenser has an appropriate hardship.

- (b) A formal request for this waiver must be made in writing to the OBN and must clearly state
- (1) the nature and extent of the hardship; and, (2) a proposed time-line for the waiver.
- (c) Any such hardship granted by the Director of OBN will be reviewed every thirty (30) days following the granting of a waiver to determine whether or not the hardship will be extended.

[Source: Added at 18 Ok Reg 2218, eff 6-11-01; Amended at 24 Ok Reg 2747, eff 8-11-07; Amended at 29 Ok Reg 1323, eff 6-25-12]

475:45-1-5. Time limit for reporting

The information required by this section must be reported to the central repository within five (5) minutes of the time that the controlled dangerous substance was dispensed.

[Source: Added at 18 Ok Reg 2218, eff 6-11-01; Amended at 24 Ok Reg 2747, eff 8-11-07; Amended at 29 Ok Reg 1323, eff 6-25-12]

475:45-1-6. Failure to report

Failure to accurately report the required information, or correct inaccuracies within reported information, according to the rules set forth in this Chapter may result in administrative action against the registration of the pharmacy or dispensing practitioner, including, but not limited to, fines not to exceed TwoFive Thousand Dollars (\$2000)(\$5000) per violation.

[Source: Added at 18 Ok Reg 2218, eff 6-11-01; Amended at 24 Ok Reg 2747, eff 8-11-07]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 50 - Animal Control Officers

Section 475:50-1-1	Purpose
Section 475:50-1-2	Qualifications for Registration/ Required Training
Section 475:50-1-3	Exempt from Fees
Section 475:50-1-4	Special Conditions on Ordering Controlled Substances
Section 475:50-1-5	Special conditions for animal control officers storing controlled dangerous substances
Section 475:50-1-6	Special conditions for animal control officers transporting controlled dangerous substances
Section 475:50-1-7	Readily retrievable records for animal control officers
Section 475:50-1-8	Inspections

475:50-1-1. Purpose

- (a) The purpose of this section of Title 475 is to make it possible for animal control officers to register with the Oklahoma Bureau of Narcotics and Dangerous Drugs Control (OBNDDC), pursuant to Oklahoma State Statute, Title 63,§ 2-302. This legislation was enacted to allow professional animal control officers who are employed by cities, counties, or the state, within Oklahoma, to be able to obtain, possess, and administer controlled dangerous substances that are consistent with a formulary established by OBNDDC, in the performance of their official duties as animal control officers, including, but not limited to, the tranquilization, sedation, and humane euthanasia of animals.
- (b) The term "animal control officer" includes animal control officers and their supervisors or managers who, through their supervisory or managerial duties, are responsible for the supervision and/or management of the officer and the shelter or field services program in which the officer is employed.

[Source: Added at 24 Ok Reg 2747, eff 8-11-07; Amended at 30 Ok Reg 548, eff 5-13-13]

475:50-1-2. Qualifications for Registration/Required Training

Only animal control officers who are employed by a government entity (i.e., city, county, state, or federal) may apply for OBNDDC registration. Furthermore, as a necessary condition for registration, officers will have completed a certification course, meeting the curriculum established by the Oklahoma Animal Control Association, or equivalent curriculum that is approved by the OBNDDC Director. This training will include, among other things, the following:

- (1) Rules and regulations covering animal control officers pertaining to controlled dangerous substances;
- (2) Guarding against the diversion of controlled dangerous substances;
- (3) The Uniform Controlled Dangerous Substances Act (Title 63 Oklahoma Statutes); and,
- (4) Rules for storing and transporting controlled dangerous substances.

[Source: Added at 24 Ok Reg 2747, eff 8-11-07; Amended at 30 Ok Reg 548, eff 5-13-13]

475:50-1-3. Exempt from Fees

Government-employed animal control officers shall be exempted from any fees required for OBNDDC registration. No other animal control officers will be allowed to register to possess controlled substances.

[**Source:** Added at 24 Ok Reg 2747, eff 8-11-07]

475:50-1-4. Special Conditions on Ordering Controlled Substances

(a) Animal control officers, although allowed to order controlled substances, shall only be permitted to do so on official city, county, state, or federal purchase orders or through credit card transactions on government-issued credit cards, and all orders shall be shipped only to the city, county, state, or federal facility. Under no circumstances shall an animal control officer be allowed to order controlled dangerous substances and cause them to be shipped to a residence, post office box (unless exempted by OBNDDC), or any other location except the official government location. The animal control officer ordering controlled substances shall not also be the direct receiver of

the controlled substances, but shall arrange to have the controlled substances delivered to their supervisor or other person in their chain of command.

(b) Animal control officers are subject to any other restrictions, procedures, or policies established by their employing cities, counties, or the state that are not in direct conflict with the state law statute or OBNDDC regulations.

[Source: Added at 24 Ok Reg 2747, eff 8-11-07; Amended at 29 Ok Reg 1324, eff 6-25-12]

475:50-1-5. Special conditions for animal control officers storing controlled dangerous substances

Animal control officers shall only store controlled dangerous substances at the animal control facility and in accordance with all OBNDDC and DEA requirements regarding security.

[Source: Added at 24 Ok Reg 2747, eff 8-11-07]

475:50-1-6. Special conditions for animal control officers transporting controlled dangerous substances

Animal control officers, by the nature of their duties, must have access to controlled dangerous substances in the field. Therefore, animal control officers may transport controlled dangerous substances as long as the controlled dangerous substances are maintained in a secure location within the vehicle and in a locked box meeting specifications set forth by OBNDDC.

[**Source:** Added at 24 Ok Reg 2747, eff 8-11-07]

475:50-1-7. Readily retrievable records for animal control officers

Animal control officers must maintain thorough and readily retrievable records at their official place of business of all controlled dangerous drugs inventory and dispensations in accordance with Oklahoma Administrative Code, Title 475.

[**Source:** Added at 24 Ok Reg 2747, eff 8-11-07]

475:50-1-8. Inspections

OBNDDC or its designees has the right to inspect all records, inventory and check all controlled dangerous substances on hand, and require any special conditions as deemed necessary by OBNDDC in order to ensure public safety and prevent the potential diversion of controlled dangerous substances.

[**Source:** Added at 24 Ok Reg 2747, eff 8-11-07]

Title 475 - Oklahoma State Bureau of Narcotics and Dangerous Drugs Control Chapter 55 - Pseudoephedrine Control

Section 475:55-1-1	Purpose
Section 475:55-1-2	Characteristics of exempt pseudoephedrine products [Revoked]
Section 475:55-1-3	Pharmacy requirements
Section 475:55-1-4	[Reserved]
Section 475:55-1-5	Electronic Reporting
Section 475:55-1-6	Special registration for distribution centers
Section 475:55-1-7	Lawful possession of Schedule V pseudoephedrine
Section 475:55-1-8	Records and invoices [Revoked]
Section 475:55-1-9	Labeling
Section 475:55-1-10	Prescriptions
Section 475:55-1-11	Distributor and Warehouse Storage of Schedule V Pseudoephedrine Products
Section 475:55-1-12	Criteria for exemption

475:55-1-1. Purpose

- (a) 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.
- (b) 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.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05]

475:55-1-2. Characteristics of exempt pseudoephedrine products [REVOKED]

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05; Amended at 29 Ok Reg 1324, eff 6-25-12; Revoked at 30 Ok Reg 548, eff 5-13-13]

475:55-1-3. Pharmacy requirements

- (a) 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.
- (b) Pharmacies that sell, distribute or otherwise deliver Schedule V pseudoephedrine substances must post a sign, provided by the Oklahoma Bureau of Narcotics, in a conspicuous area in or around the pharmacy, to inform persons obtaining pseudoephedrine about the provisions of the Oklahoma Methamphetamine Offender Registry Act, 63 O.S. §2-701, that prohibit any person who, after November 1, 2010, that has been convicted, pled guilty or no contest, or otherwise on that date was serving any sentence for a methamphetamine related offense, from purchasing or possessing a product containing any amount of pseudoephedrine. Alternatively, the above notification may be presented to the purchaser by electronic means. A purchaser must attest, by signature, in written or electronic form, that they are not subject to the Oklahoma Methamphetamine Offender Registry Act, as summarized above, prior to purchase of any pseudoephedrine products. The pharmacy must maintain those signatures for a period of two (2) years from the date of signature.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05; Amended at 31 Ok Reg 211, eff 10-29-13 (emergency); Amended at 31 Ok Reg 2112, eff 9-12-14]

475:55-1-4. [RESERVED]

[**Source:** Reserved at 22 Ok Reg 2685, eff 7-25-05]

475:55-1-5. Electronic Reporting

Pharmacists or other authorized persons who sell Schedule V pseudoephedrine products shall exercise reasonable care in assuring that the purchaser has not exceeded the three and six-tenths (3.6) gram limit per day, the seven and two-tenths (7.2) gram limit for a thirty (30) day period or the sixty (60) gram limit for a twelve (12) month period. The pharmacist or other authorized person must utilize the real-time electronic pseudoephedrine tracking system as set forth pursuant to 63 O.S. §2-341 and the Methamphetamine Registry as set forth pursuant to 63 O.S. §2-701. The following provisions are necessary for compliance with this system:

- (1) All pseudoephedrine transactions regulated by Oklahoma law must be approved through submitting the request to the electronic log and Methamphetamine Registry;
- (2) Pseudoephedrine products regulated by Oklahoma law will only be sold to customers who present a valid form of identification and who attest that they are not subject to the Oklahoma Methamphetamine Offender Registry Act;
- (3) The customer information must be the same as that on the presented identification, and shall include the following information (fields that are required for submitting information as required by Oklahoma law):
 - (A) Pharmacy identification;
 - (B) Identification number;
 - (C) Last name;
 - (D) First name;
 - (E) Purchase quantity (in grams);
- (F) Initials of the pharmacist or other authorized person conducting the transaction:
 - (G) Product name;
 - (H) Form of pseudoephedrine if it is liquid or gel-caps;
 - (I) Customer's street address;
 - (J) Customer's current city, state, and zip code; and
 - (K) Date of birth.
- (4) If at any time a pharmacist or other authorized person discovers that the electronic log is unavailable or that the information submitted to the electronic log is inaccurate, the authorized person may continue regulated transactions for twenty-four (24) hours, provided that all sales are manually recorded. The authorized person shall suspend all sales if the reporting problem is not corrected within twenty-four (24) hours of discovery. Regulated sales may be resumed only when the reporting problem is corrected and all manually recorded sales are correctly submitted to the electronic log.

[Source: Reserved at 22 Ok Reg 2685, eff 7-25-05; Added at 24 Ok Reg 601, eff 12-21-06 through 7-14-07 (emergency)¹; Added at 24 Ok Reg 2749, eff 8-11-07; Amended at 29 Ok Reg 1324, eff

6-25-12; Amended at 30 Ok Reg 548, eff 5-13-13; Amended at 31 Ok Reg 211, eff 10-29-13 (emergency); Amended at 31 Ok Reg 2112, eff 9-12-14]

EDITOR'S NOTE: ¹This emergency action expired before being superseded by a permanent action. Upon expiration of an emergency action enacting a new Section, the Section is no longer effective. Therefore, on 7-15-07 (after the 7-14-07 expiration of the emergency action), Section 475:55-1-5 reverted back to its previous reserved status, and remained as such until added by permanent action on 8-11-07.

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.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05]

475:55-1-7. Lawful possession of Schedule V pseudoephedrine

- (a) 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 pharmacy 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.
- (b) 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.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05; Amended at 24 Ok Reg 2749, eff 8-11-07]

475:55-1-8. Records and invoices [REVOKED]

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05; Amended at 24 Ok Reg 2749, eff 8-11-07]

475:55-1-9. Labeling

Schedule V pseudoephedrine products shall be exempt from the labeling requirements of 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.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05; Amended at 24 Ok Reg 2749, eff 8-11-07]

475:55-1-10. Prescriptions

The threshold limits set forth in Oklahoma Statutes, Title 63 §2-212 shall not apply to Schedule V pseudoephedrine products that are dispensed pursuant to a valid prescription.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05; Amended at 24 Ok Reg 2749, eff 8-11-07; Amended at 30 Ok Reg 548, eff 5-13-13]

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.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05]

475:55-1-12. Criteria for exemption

(a) 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.
- (b) 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.

[Source: Added at 22 Ok Reg 1030, eff 6-16-05 (emergency); Added at 22 Ok Reg 2685, eff 7-25-05]