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- (1) The name, full business address, and telephone number;
  - (2) All trade or business names used by the manufacturer applicant;
  - (3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;
  - (4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);
  - (5) The name(s) of the owner and/or operator of the manufacturer applicant; and
  - (6) Any other information the Board deems necessary to protect the public health.

[Source: Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09]

#### **535:20-5-4. Minimum qualifications**

(a) All packagers must conform to the federal Good Manufacturing Practices GMPA, and/or any other applicable federal, state or local laws and regulations.

(b) The minimum qualifications for packagers shall be the same as those set forth in 535:25 and this Chapter for applicants and registrants.

(c) The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacturer of drugs or devices:

- (1) Any convictions of the applicant under any federal, state, or local laws relating to drug samples, manufacturer, wholesale or retail drug distribution, or distribution of controlled substances;
- (2) Any felony convictions of the applicant under federal, state, or local laws;
- (3) The applicant's past experience in the manufacture or distribution of drugs, including controlled substances;
- (4) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;
- (5) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;
- (6) Compliance with licensing requirements under previously granted licenses, if any;
- (7) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,
- (8) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(d) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

[Source: Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09]

#### **535:20-5-5. Personnel**

Personnel employed in packaging shall have sufficient education, training and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

[Source: Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-01-01; Amended at 26 Ok Reg 2296, eff 7-1-09]

### **535:20-5-6. Minimum requirements for storage, handling, maintenance and records**

The following decimal sections shall describe the minimum requirements for the storage and handing of drugs, and for the establishment and maintenance of drug records by packagers and their officers, agents, representatives, and employees.

[Source: Added at 9 Ok Reg 2145, eff 6-11-92; Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 26 Ok Reg 2296, eff 7-1-09]

#### **535:20-5-6.1. Facility requirements**

(a) All packagers of drugs shall conform to U. S. Food and Drug Administration (FDA) Current Good Manufacturing Practice Regulations (CGMP).

(b) All packagers shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(c) Each facility at which drugs are packaged, stored, warehoused, handled, held, offered, marketed, or displayed shall:

- (1) Be licensed by the Board;
- (2) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- (3) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;
- (4) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
- (5) Be maintained in a clean and orderly condition; and,
- (6) Be free from infestation by insects, rodents, birds, or vermin of any kind.

[Source: Added at 26 Ok Reg 2276, eff 7-1-09]

#### **535:20-5-6.2. Multiple Licensing**

(a) A packager facility shall not be in a facility where a retail pharmacy is located.

(b) The packager facility shall be located apart and separate from any retail pharmacy, licensed by the Board of Pharmacy, as set forth in this Title and 535:25-3-5.

[Source: Added at 26 Ok Reg 2296, eff 7-1-09]

#### **535:20-5-6.3. Security**

(a) Each facility used for packaging shall be secure from unauthorized entry.

- (1) Access from outside the premises shall be kept to a minimum and be well-controlled.
- (2) The outside perimeter of the premises shall be well-lighted.
- (3) Entry into areas where drugs are held shall be limited to authorized personnel.

(b) All facilities shall be equipped with an alarm system to detect entry after hours.

(c) All packagers shall establish and maintain controls and systems that protect



















(iii) if a publicly traded corporation, the information in (c)(1)(C)(i) and (c)(1)(C)(ii) above are not required for corporate officers. A publicly traded corporation shall provide information regarding the operator of the licenses; and as required in (c)(1)(D) below the designated manager information.

(D) Names of designated managers (operators of the wholesaler applicant), their Social Security numbers and date of birth;

(E) Applicant's and designated managers' fingerprints,

(F) Criminal background check information for the applicants and designated managers as required by rule;

(G) A surety bond of not less than \$10,000, or if located in another state which requires a surety bond, documentation of such bond;

(H) A copy of the license from the resident (home) state where the wholesaler is located; and,

(2) Renewal applications for both in- and out-of-state wholesale distributors, chain pharmacy warehouses and repackagers that ship into Oklahoma shall include those things listed in 535:20-7-4. If such has previously been provided to the Board and has not changed then the applicant can use a Board renewal application.

(3) Any other information the Board deems necessary to protect the public health.

(d) The Board may use an outside agency, such as the National Association of Boards of Pharmacy (NABP) Verified-Accredited Wholesale Distributors (VAWD), to accredit wholesale distributors and repackagers. The Board may exempt wholesalers accredited by VAWD from some provisions of Subparagraphs (c) (1) of this section.

(e) Logistics providers that receive prescription drugs from original sponsors or manufacturers, deliver the drug products in commerce at the direction of the original sponsor or manufacturer, and do not purchase, sell, trade, or take title to any prescription drug are exempt from the provisions in (c) (1) of this section.

[Source: Amended at 9 Ok Reg 2145, eff 6-11-92; Amended at 18 Ok

Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

### **535:20-7-5. Minimum qualifications**

(a) The Board shall consider, at a minimum, the following factors in determining the eligibility for, and renewal of licensure of persons who engage in wholesale distribution of drugs or devices:

(1) Any findings by the Board that the applicant has violated or been disciplined by a regulatory agency in any state for violating any federal, state, or local laws relating to drug distribution;

(2) Any criminal convictions of the applicant under federal, state, or local laws;

(3) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device manufacturing or distribution;

(4) Suspension, sanction, or revocation by federal, state, or local government against any license currently or previously held by the applicant or any of its owners for violations of state or federal laws regarding drugs or devices;

- (5) Compliance with licensing requirements under previously granted licenses;
- (6) Compliance with requirements to maintain and/or make available to the Board or to federal, state, or local law enforcement officials those records required to be maintained by wholesale drug distributors; and,
- (7) Any registrant who has no record of wholesaler distributions during routine inspection may have their subsequent renewal application referred to the Board for review and possible approval or disapproval, and such review may require registrant appearance before the Board.
- (8) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

[Source: Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906 eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

### **535:20-7-6. Personnel**

(a) Personnel employed in wholesale distribution shall have education, training and/or experience sufficient so that they may perform assigned functions related to compliance with state licensing requirements.

(b) The Board shall as required in 353.18(B), at a minimum, consider those qualifications listed in 535:20-7-5 for personnel employed in wholesale distribution.

(c) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications. Also known as responsible persons list.

(d) Each person issued a wholesaler license, initial or renewal, whether in or out-of-state, must designate, in writing, on a form required by the Board a person to serve as the designated manager of the wholesale distributor for each location licensed.

[Source: Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

### **535:20-7-7. Minimum requirements for the storage, handling, transport, and shipment of drugs and/or devices and establishment and maintenance of drug records**

The following describe the requirements for the storage, handling, transport and shipment of drugs or devices, and for the establishment and maintenance of wholesale distribution records, and requirement for wholesale distributor's officers, agents, representatives, and employees

[Source: Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

#### **535:20-7-7.1. Facility requirements**

(a) All wholesalers of prescription drugs shall conform the Prescription Drug Marketing Act of 1988 (21 USC 363) and applicable rules for the storage and handling of prescription drugs.

(b) All wholesalers of prescription drugs shall conform to the Oklahoma Pharmacy Act and the rules of this Title, and be licensed by the Board.

- (c) All facilities at which drugs are received, stored, warehoused, handled, held, offered, marketed, displayed, or transported from shall:
- (1) be of suitable construction to ensure that all drugs and devices in the facilities are maintained in accordance with labeling of such drugs, or in compliance with official compendium standards such as USP/NF;
  - (2) be of suitable size and construction to facilitate cleaning, maintenance, and proper wholesale distribution operations;
  - (3) have adequate storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;
  - (4) have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, otherwise unfit for distribution, or that are in immediate or sealed, secondary containers that have been opened;
  - (5) be maintained in a clean and orderly condition; and,
  - (6) be free from infestation of any kind.
- (d) Each wholesaler shall be in a commercial location and not a personal dwelling or residence.
- (e) Wholesale distributors involved in the distribution of controlled substances shall be duly registered with the Drug Enforcement Administration (DEA) and the Oklahoma Bureau of Narcotics, if required, and shall be in compliance with all applicable laws and rules for the storage, handling, transport, shipment and distribution of controlled substances.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

### **535:20-7-7.2. Multiple Licensing**

- (a) A wholesale facility shall not be located in a facility where a retail pharmacy is located.
- (b) The wholesale facility shall be located apart and separate from any retail pharmacy, licensed by the Board of Pharmacy, as set forth in this Title and 535:25-3-5.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

### **535:20-7-7.3. Security and anti-counterfeiting**

- (a) All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
- (1) Access from outside the premises shall be kept to a minimum and be well-controlled.
  - (2) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
- (b) All facilities shall be equipped with an alarm system to detect entry after hours.
- (c) All facilities shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(d) All wholesalers shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:

(1) The wholesaler must not ship the customer's order if the order is confirmed as suspicious;

(2) Each wholesaler shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,

(3) Wholesalers shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.

(e) If a wholesaler has reason to believe, based on the totality of the facts and circumstance, that any drug purchased is counterfeit, suspected of being counterfeit, mis-branded, or adulterated, the purchasing wholesaler must authenticate the pedigree.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 27 Ok Reg 2261, eff 7-11-10]

#### **535:20-7-7.4. Storage**

All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(1) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official compendium such as USP/NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs.

(3) Packaging of the drugs should be in accordance with an official compendium such as USP/NF and identify any compromise in the integrity of the drugs due to tampering or adverse storage conditions.

(4) Controlled dangerous substance (CDS) drugs should be isolated from non-CDS drugs and stored in a secure area in accordance with federal and state CDS security requirements and standards.

[Source: Amended at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

#### **535:20-7-7.5. Examination of materials**

(a) Upon receipt, each shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting or suspected of being counterfeit, or other damage to the contents.

(b) The drugs found to be unacceptable under paragraph (a) should be quarantined from the rest of stock until the drugs are determined to be fit for human use.

(c) Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that there is no delivery of drugs that have been damaged in storage or held

under improper conditions.

(d) The recordkeeping requirement in this Title for wholesale drug distributors shall be followed for all incoming and outgoing prescription drugs.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

#### **535:20-7-7.6. Drug returns, and returned, damaged, and outdated drugs**

(a) Wholesale distributors shall receive prescription drug returns or exchanges from a pharmacy, chain pharmacy warehouse, or other persons authorized by law to administer and dispense such drugs, pursuant to the terms and conditions of the agreement between the wholesale distributor and the pharmacy, chain pharmacy warehouse or other persons authorized by law to administer and dispense such drugs including the returns of expired, damaged, and recalled pharmaceutical product to either the manufacturer, the wholesaler, or a third party returns processor, and such returns shall not be subject to the pedigree requirement.

(b) If, the returns described in (a) appear to be a suspicious, unusual or excessive quantity of drugs, such wholesale distributor shall report such returns to the Board.

(c) Wholesale distributors shall be held accountable for administering their return process and ensuring that the aspects of this operation are secure, and do not permit the entry of adulterated, misbranded, and/or counterfeit drugs.

(d) Any drug returned to a manufacturer or wholesale distributor shall be kept under proper conditions for storage, handling, transport, and shipment.

(e) When drugs are adulterated, misbranded, counterfeited, or suspected of being counterfeit, notice shall be provided to the Board, FDA and manufacturer or wholesale distributor from which it was acquired within three (3) business days.

(f) Contraband, counterfeit, or suspected to be counterfeit drugs, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the Board and/or FDA.

(g) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity.

(h) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to prescription drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

(i) The recordkeeping requirements for wholesale prescription drug distributors in 535:20-7-7.7 shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated prescription drugs.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2911, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

#### **535:20-7-7.7. Recordkeeping; including pedigree requirement**

(a) Wholesale distributors shall establish and maintain complete inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs and devices.

(b) After January 1, 2011, each person who is engaged in wholesale distribution of

prescription drugs, (including repackagers of the finished form of the prescription drug) whether located in or out-of-state, must maintain and provide a pedigree record developed in accordance with standards and requirements of the Board, for all drugs received, distributed, sold and/or offered for sale outside of the normal distribution channel, or that leave or have ever left the normal distribution channel and shall before each wholesale distribution of such drug provide a pedigree to the person who receives such prescription drug.

(1) A statement or record in written or electronic form shall be used to record each distribution of any given drug, from the sale by a manufacturer through acquisition and sale by any wholesaler distributor, packager and/or repackager.

(2) The pedigree shall include, but not be limited to, the following information for each transaction:

(A) The source of the drug(s), including the name and principal address of the seller;

(B) The name of the drug and the national drug code (NDC) number, the amount of the drug, the date of the purchase, quantity (container size, number of containers), and lot number(s) of the drug;

(C) The business name and address of each owner of the drug, its shipping information, including the name and address of the facility of each person certifying delivery or receipt of the drug;

(D) A certification that the information contained therein is true and accurate under penalty of perjury.

(3) The wholesale distributor must conduct due diligence in verifying pedigrees.

(4) The pedigree or electronic record requirements do not apply to compressed medical gases (medical gas suppliers and medical gas distributors, etc.)

(5) The pedigree or electronic record requirements do not apply to drugs labeled for veterinarian use.

(c) Wholesale distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution, or other disposition of all drugs and devices. Such records shall include the dates of receipt and distribution or other disposition of the drugs and devices. Inventories and records shall be maintained and made available for inspection and photocopying for a period of two (2) years following their creation date.

(1) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period.

(2) Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(d) Each wholesale distributor should maintain an ongoing list of persons with whom they do business.

[Source: Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08; Amended at 26 Ok Reg 2296, eff 7-1-09]

### **535:20-7-7.8. Written policies and procedures**

(a) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, transport, shipping and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories and implementing and maintaining a continuous quality improvement system. Such written policies and procedures shall be available for inspection.

(b) Wholesale drug distributors shall include in their written policies and procedures the following:

(1) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(2) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(A) Action initiated at the request of the Food and drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

(B) Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or

(C) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(3) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(4) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed.

(A) This procedure shall provide for written documentation of the disposition of outdated prescription drugs.

(B) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(5) A procedure for identifying, investigating, and reporting significant drug inventory discrepancies involving counterfeit, suspected of being counterfeit, contraband, or suspected of being contraband; and for reporting of such discrepancies to the Board and to the appropriate federal agency upon discovery of such discrepancies shall be the same as in 535:20-7-7.6.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

### **535:20-7-7.10. Compliance with federal, state and local laws**

(a) Wholesale drug distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(b) Wholesale drug distributors shall permit the Board of Pharmacy and authorized

federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures, and to confiscate records to the extent authorized by law or rules.

(c) Wholesale drug distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulations.

[Source: Added at 18 Ok Reg 2749, eff 7-1-01; Amended at 24 Ok Reg 2906, eff 8-1-07 (emergency); Amended at 25 Ok Reg 1976, eff 7-1-08]

### **535:20-7-8. Compressed medical gases**

Wholesalers of multiple products that include medical gases shall comply with the requirements in 535:20-9 for medical gas distributors.

[Source: Revoked at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-01-01]

### **535:20-7-9. Violations and penalties**

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in Title 59, Oklahoma Statutes, Section 353, et seq.

(b) Rules of conduct, violations of the rules of conduct and other requirements of wholesalers and all applicants can be found in this Title and in 535:25.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-01-01]

#### **535:20-7-9.1. Prohibited Conduct**

The following shall be considered prohibited conduct and be a violation of these rules:

(1) Engaging in the wholesale distribution of drugs

(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate pedigree and/or failure to authenticate a pedigree, when required;

(B) and destroying, altering, concealing, or failing to maintain complete and accurate pedigree concerning any drug in their possession, when required;

(C) and having possession of drug pedigree documents required by the board and failing to authenticate the matters contained in the documents as required, and nevertheless distributing or attempting to further distribute drugs;

(D) with intent to defraud or deceive, falsely swearing or certifying that they have authenticated any documents related to the wholesale distribution of drugs;

(E) and forging, counterfeiting, or falsely creating any pedigree, falsely representing any factual matter contained on any pedigree, or knowingly omitting to record material information required to be recorded in a pedigree;

(F) and knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, in wholesale distribution; or,

(G) and selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the

person receives the drug(s) in a wholesale distribution.

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a prescription drug or the commission of any other act with respect to a prescription drug that results in the prescription drug being misbranded.

(5) Any violation of the rules of registrant conduct in 535:25:9 is prohibited conduct.

(6) Failing to maintain suspicious order monitoring records in a suspicious order monitoring program; and failing to notify the Board, within ten (10) days, of confirmed suspicious orders.

[Source: Added at 24 Ok Reg 2906, eff 8-1-07 (emergency); Added at 25 Ok Reg 1976, eff 7-1-08; Amended at 27 Ok Reg 2261, eff 7-11-10]

## **SUBCHAPTER 9. MEDICAL GAS SUPPLIERS AND DISTRIBUTORS**

Section

535:20-9-1. Purpose

535:20-9-2. Definitions

535:20-9-3. Medical gas suppliers

535:20-9-4. Medical gas distributors

535:20-9-5. Violations and penalties

[Source: Codified 6-25-93]

### **535:20-9-1. Purpose**

This subchapter is to establish rules specific to medical gases due to the fact that its labeling, packaging, distribution and handling is unique.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93]

### **535:20-9-2. Definitions**

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

“**Drug order**” means a prescription drug order issued by a licensed medical practitioner for medical gas.

“**Medical gas**” means those gases and liquid oxygen upon which the manufacturer or distributor has, in compliance with federal law and regulations, placed one of several cautions, such as: "RX Only" that replaces "Caution - Federal Law prohibits dispensing without prescription".

“**Medical gas distributor**” means a person licensed to distribute medical gases on drug orders and to suppliers or other entities licensed to use, administer, or distribute medical gases.

“**Medical gas supplier**” means a person licensed to supply medical gases only on drug orders.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04]

### **535:20-9-3. Medical gas suppliers**

(a) **Licensing requirement.** Before conducting interstate and/or intrastate

transactions in Oklahoma, a medical gas supplier shall register annually with the Board of Pharmacy.

(1) A medical gas supplier permit is only valid for the name, ownership and location listed on the permit. Changes of name, ownership or location shall require a new medical gas supplier permit.

(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas supplier permit. A medical gas supplier permit entitles the permit holder to store and supply medical gas (prescription drugs) at the licensed location.

(b) Permits shall be issued only to those medical gas suppliers who satisfy the provisions of:

(1) Title 59, O.S., Section 353.18 (B)(1)(2) et seq.,

(2) All medical gas supplier applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.

(3) Applicants shall be registered with the federal Food and Drug Administration (FDA) and meet the federal requirements to handle medical gas.

(4) The Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or,

(5) Any other applicable federal, state, or local laws and regulations.

(c) **Minimum required information for licensure.** The minimum required information for medical gas supplier licensure shall be as follows, Medical gas supplier applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

(1) The name, full business address, and telephone number;

(2) All trade or business names used by the manufacturer applicant;

(3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;

(4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the manufacturer applicant; and

(6) Any other information the Board deems necessary to protect the public health.

(d) **Minimum qualifications.** Medical gas suppliers must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(1) Medical gas suppliers must conform to all applicable federal, state or local laws and regulations.

(2) The minimum qualifications shall be the same as those set forth in 535:25 and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in the supplying of medical gases:

(A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;

(B) Any felony convictions of the applicant under federal, state, or local laws;

- (C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;
- (D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;
- (E) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;
- (F) Compliance with licensing requirements under previously granted licenses, if any;
- (G) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,
- (H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

(e) **Personnel.** Personnel employed by medical gas suppliers shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

(f) **Minimum requirements for storage, handling, and records.** Medical gas suppliers must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

(1) The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.

(A) All medical gas suppliers of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.

(B) All medical gas suppliers shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(C) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

- (i) Be licensed by the Board;
- (ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- (iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment and security conditions;
- (iv) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
- (v) Be maintained in a clean and orderly condition; and,

(vi) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Medical gases housed by a medical gas supplier shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(g) **Prescription requirement.** Medical gas suppliers shall not supply medical gas without a drug order. Drug orders may be issued for institutional or licensed medical practitioner office use as well as to a patient.

(1) An original or copy of a prescription drug order must be kept at the licensed location supplying the medical gas.

(2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.

(h) **Minimum requirements for storage, handling, and records for medical gas.**

The following shall describe the minimum requirements for the storage and handling of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas suppliers and their officers, agents, representatives, and employees.

(1) **Security.** Each facility used for medical gases shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well-controlled.

(B) The outside perimeter of the premises shall be well-lighted.

(C) Entry into areas where drugs are held shall be limited to authorized personnel.

(D) All medical gas suppliers shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All medical gas suppliers shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:

(i) The medical gas supplier must not ship the customer's order if the order is confirmed as suspicious;

(ii) Each medical gas supplier shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,

(iii) Medical gas suppliers shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.

(2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(A) If no storage requirements are established for a drug, the drug may be held at "controlled" room temperature, as defined in an official

compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.

(C) The recordkeeping requirement in this Chapter for medical gas suppliers shall be followed for all stored drugs.

(3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.

(4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas supplier shall consider, among other things:

(i) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(B) The recordkeeping requirements for medical gas suppliers in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

(5) **Recordkeeping.** Medical gas suppliers shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized

official of a federal, state, or local law enforcement agency.

(C) Each medical gas supplier should maintain an ongoing list of persons with whom they do business.

**(6) Written policies and procedures.** Medical gas suppliers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas suppliers shall include in their written policies and procedures the following:

(i) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(I) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

(II) Voluntary action by the medical gas supplier to remove defective or potentially defective drugs from the market; or

(II) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(B) A procedure to ensure that medical gas suppliers prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(i) This procedure shall provide for written documentation of the disposition of outdated drugs.

(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

**(7) Responsible persons.** Medical gas suppliers shall establish and maintain lists of officers, directors, managers and other persons in charge of drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

**(8) Compliance with federal, state and local laws.** Medical gas suppliers shall operate in compliance with applicable federal, state, and local laws and regulations.

(A) Medical gas suppliers shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(B) Medical gas suppliers that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with

all applicable state, local and DEA regulation.

(9) **Salvaging and reprocessing.** Medical gas suppliers shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-11-10]

#### **535:20-9-4. Medical gas distributors**

(a) **Licensing requirement.** Before conducting interstate and or intrastate transactions in Oklahoma, a medical gas distributor shall register annually with the Board of Pharmacy.

(1) A medical gas distributor permit is only valid for the name, ownership and location listed on the permit. Changes of name, ownership or location shall require a new medical gas distributor permit.

(2) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. manager, contact person, phone, etc.)

(3) Each location shall possess a medical gas distributor permit. Medical gas distributor permit entitles the permit holder to store and distribute medical gas (prescription drugs) at the licensed location.

(b) Permits shall be issued only to those medical gas distributors who satisfy the provisions of:

(1) Title 59, O.S., Section 353.18 (B)(1)(2) et seq.,

(2) All medical gas distributor applicants must meet the requirements under the Oklahoma Pharmacy Act, this Title and the rules in 535:25 for applicants.

(3) Applicants shall be registered with the federal Food and Drug Administration (FDA) and meet the federal requirements to handle and wholesale medical gas.

(4) The Prescription Drug Marketing Act (PDMA, 21 U.S.C., Sec. 331 et seq.); and/or,

(5) Any other applicable federal, state, or local laws and regulations.

(c) **Minimum required information for licensure.** The minimum required information for medical gas distributors licensure shall be as follows, Medical gas distributor applicants must submit a satisfactorily completed application together with the required fee annually. This application shall include, at least, the following:

(1) The name, full business address, and telephone number;

(2) All trade or business names used by the manufacturer applicant;

(3) Address, telephone numbers, and the names of contact persons for the manufacturing facility;

(4) The type of ownership or operation (e.g., partnership, corporation, or sole proprietorship);

(5) The name(s) of the owner and/or operator of the manufacturer applicant; and

(6) Any other information the Board deems necessary to protect the public health.

(d) **Minimum qualifications.** Medical gas distributors must conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(1) Medical gas distributors must conform to all applicable federal, state or

local laws and regulations.

(2) The minimum qualifications shall be the same as those set forth in 535:25 and this Chapter. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in medical gas distribution:

(A) Any convictions of the applicant under any federal, state, or local laws relating to drugs, drug samples, manufacture, packager, wholesale or retail drug distribution, or distribution of controlled substances;

(B) Any felony convictions of the applicant under federal, state, or local laws;

(C) The applicant's past experience in the handling, manufacture, packaging or distribution of drugs, including controlled substances;

(D) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug or device handling, manufacturing, packing, or distribution;

(E) Suspension, sanction, or revocation by federal, state, or local government of any license currently or previously held by the applicant for the handling, manufacture, packaging, or distribution of any drugs, including controlled substances; or by any of its owners for violation of state or federal laws regarding drugs or devices;

(F) Compliance with licensing requirements under previously granted licenses, if any;

(G) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section; and,

(H) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(3) The Board shall have the right to deny a license to an applicant if it determines that the granting of such a license would not be consistent with the public health and safety.

(e) **Personnel.** Personnel employed by medical gas distributors shall have sufficient education, training, and/or experience to perform assigned functions and comply with federal, state and local licensing requirements.

(f) **Minimum requirements.** Medical gas distributors must meet minimum requirements for storage and handling, and for the establishment and maintenance of distribution records for medical gases.

(1) The following shall describe the minimum requirements for the storage and handling of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas distributors and their officers, agents, representatives, and employees.

(A) All medical gas distributors of drugs shall conform to U. S. Food and Drug Administration (FDA) requirements for medical gas prescription drugs.

(B) All medical gas distributors shall conform to the Oklahoma Pharmacy Act and the rules of this Title.

(C) Each facility at which drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:

- (i) Be licensed by the Board;
- (ii) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- (iii) Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- (iv) Have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
- (v) Be maintained in a clean and orderly condition; and,
- (vi) Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2) Medical gases housed by a medical gas distributor shall conform to the Compressed Medical Gases Guidelines published by the Department of Health and Human Services, Food and Drug Administration.

(g) **Prescription requirements.** Medical gas distributors shall distribute only to an entity licensed to receive medical gas or upon a practitioner's drug order. A pharmacy, dentist, or licensed practitioner's practice license verifies their authority to receive Rx Only medical gases.

(1) An original or copy of a prescription drug order must be kept at the licensed location distributing the medical gas.

(2) A prescription drug order is only valid for one (1) year. Prescription drug orders shall be maintained for five years and be readily retrievable and available at inspection.

(3) Distributors that sell to licensed medical gas suppliers must keep an updated copy of each supplier's license on file.

(h) **Minimum requirements for storage, handling and records for medical gas Rx Only drugs.** The following shall describe the minimum requirements for the storage and handing of medical gas prescription drugs, and for the establishment and maintenance of drug records by medical gas distributors and their officers, agents, representatives, and employees.

(1) **Security.** Each facility used for medical gases shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well-controlled.

(B) The outside perimeter of the premises shall be well-lighted.

(C) Entry into areas where drugs are held shall be limited to authorized personnel.

(D) All medical gas distributors shall establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(E) All medical gas distributors shall establish and maintain a suspicious order monitoring program for controlled substances and dangerous drugs with a high likelihood of abuse:

(i) The medical gas distributor must not ship the customer's order if

the order is confirmed as suspicious;

(ii) Each medical gas distributor shall notify the Board, within ten (10) days, if an order is confirmed as suspicious; and,

(iii) Medical gas distributors shall establish guidelines and procedures for identifying dangerous drugs with a high likelihood of abuse and suspicious orders.

(2) **Storage.** All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with the requirements in the current edition of an official compendium, such as the United States Pharmacopeia/National Formulary (USP/NF).

(A) If no storage requirements are established for a drug, the drug may be held at “controlled” room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(B) Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of drugs, if required.

(C) The recordkeeping requirement in this Chapter for medical gas distributors shall be followed for all stored drugs.

(3) **Examination of materials.** Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated drugs or chemicals that are unfit. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(A) Each outgoing shipment shall be carefully inspected for identity of the drug products and to ensure that there is no delivery of drugs that have been damaged in storage or held under improper conditions.

(B) The recordkeeping requirement in this Chapter shall be followed for all incoming and outgoing drugs.

(4) **Returned, damaged, and outdated drugs.** Drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other drugs until they are destroyed.

(A) If the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, then the drug shall be destroyed, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, quality, strength, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the medical gas distributors shall consider, among other things:

(i) The conditions under which the drug has been held, stored or shipped before or during its return; and,

(ii) The condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(B) The recordkeeping requirements for medical gas distributors in this Chapter shall be followed for all outdated, damaged, deteriorated, misbranded or adulterated drugs.

(5) **Recordkeeping.** Medical gas distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of drugs.

(A) Inventories and records shall be made available for inspection and photocopying by authorized federal, state, or local law enforcement agency officials for a period of two (2) years following disposition of the drugs.

(B) Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(C) Each medical gas distributor should maintain an ongoing list of persons with whom they do business.

(6) **Written policies and procedures.** Medical gas distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories.

(A) Medical gas distributors shall include in their written policies and procedures the following:

(i) A procedure to be followed for handling recalls and withdrawals of drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to any:

(I) Action initiated at the request of the Food and Drug Administration (FDA) or other federal, state, or local law enforcement or other government agency, including the Board of Pharmacy;

(II) Voluntary action by the medical gas distributor to remove defective or potentially defective drugs from the market; or

(III) Action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(B) A procedure to ensure that medical gas distributors prepare for, protect against, and handle a crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state or national emergency.

(C) A procedure to ensure that any outdated drugs shall be segregated from other drugs and destroyed.

(i) This procedure shall provide for written documentation of the disposition of outdated drugs.

(ii) This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(7) **Responsible persons.** Medical gas distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of drug

distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

**(8) Compliance with federal, state and local laws.** Medical gas distributors shall operate in compliance with applicable federal, state, and local laws and regulations.

(A) Medical gas distributors shall permit the Board of Pharmacy and authorized federal, state, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operating procedures and to confiscate records, to the extent authorized by law and rule.

(B) Medical gas distributors that deal in controlled substances shall register with the appropriate state controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable state, local and DEA regulation.

**(9) Salvaging and reprocessing.** Medical gas distributors shall be subject to the provisions of any applicable federal, state or local laws or regulations that relate to drug product salvaging or reprocessing including U.S. 21 CFR Parts 207, 210 and 211.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 18 Ok Reg 2749, eff 7-1-01; Amended at 21 Ok Reg 2458, eff 7-1-04; Amended at 26 Ok Reg 2296, eff 7-1-09; Amended at 27 Ok Reg 2261, eff 7-11-10]

#### **535:20-9-5. Violations and penalties**

(a) Penalties for violations of this Subchapter and of federal, state and local laws and regulations are listed in Title 59, Oklahoma Statutes, Section 353, et seq.

(b) Rules of conduct, violations of the rules of conduct and other requirements of medical gas suppliers and medical gas distributors and all applicants can be found in this Title and in 535:25 as defined in Title 59, O.S., Section 353.1.

[Source: Added at 10 Ok Reg 3175, eff 6-25-93; Amended at 11 Ok Reg 3441, eff 6-27-94; Amended at 18 Ok Reg 2749, eff 7-1-01]

#### **535:20-9-6. Prohibited conduct**

(a) The following shall be considered prohibited conduct and be a violation of these rules:

(1) Engaging in medical gas distributing of drugs

(A) with intent to defraud or deceive, failing to maintain or provide a complete and accurate record, when required;

(B) destroying, altering, concealing, or failing to maintain complete and accurate records for any drug packaging, when required;

(C) knowingly purchasing or receiving drugs from a person, not authorized to distribute drugs, or,

(D) selling, bartering, brokering, or transferring drugs to a person not authorized to purchase drugs, under the jurisdiction in which the person receives the drug(s).

(2) Forging, counterfeiting, or falsely creating any label for a drug(s) or who falsely represents any factual matter contained in any label of a drug(s).

(3) Altering, mutilating, destroying, obliterating, or removing the whole or any part of the labeling of a drug or the commission of any other act with respect to a drug; that results in the drug being misbranded.

- (4) supplying, packaging, purchasing, selling, delivering or bringing into the state contraband drug(s), or any one who illegally possesses any amount of contraband drug(s); or,
- (b) Any violation of the rules of registrant conduct in 535:25-9 is prohibited conduct.  
 [Source: Added at 26 Ok Reg 2296, eff 7-1-09]

## CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

Subchapter	Section
1. General Requirements .....	535:25-1-1
3. Applicants, Registrants, and Applications .....	535:25-3-1
5. General Requirements or Procedures .....	535:25-5-1
7. Rules of Registrant Conduct .....	535:25-7-1
9. Violations of the Rules of Registrant Conduct .....	535:25-9-1

[Authority: Title 59 O.S., Section 353.7, 353.18, 353.20, and 365]  
 [Source: Codified 12-31-91; Amended at 17 Ok Reg 2636, eff 7-01-00]

### SUBCHAPTER 1. GENERAL REQUIREMENTS

Section
535:25-1-1. Purpose
535:25-1-1.1. Definitions
535:25-1-2. Multiple licenses /permits [Amended and renumbered to 535:25-3-5]
535:25-1-3. Inspector's warning notice [Amended and renumbered to 535:25-5-1]
535:25-1-4. Procedure to return a restricted license to good standing [Amended and renumbered to 535:25-5-2]

[Authority: Title 59 O.S., Section 353.7, 353.18, 353.20, and 365]  
 [Source: Codified 12-31-91; Amended at 17 Ok Reg 2636, eff 7-01-00]

#### **535:25-1-1. Purpose**

- (a) The rules of this Chapter regulate the sale of drugs, medicines, chemicals and poisons and prevent illegal diversion of dangerous drugs.
- (b) The rules of this Chapter further describe requirements and exclusions referring to various registrants.
- (c) The rules of this Chapter describe an inspector's notice to registrants to correct deficiencies and give notice of compliance.
- (d) The rules of this Chapter describe the method which registrants must use to formally lift the suspension and/or probation from their license, permit, and/or certificate.
- (e) The rules of this Chapter describe minimum qualifications and requirements for all applicants and registrants.
- (f) The rules of this Chapter describe registrant conduct and violations of registrant conduct.

[Source: Amended at 9 Ok Reg 2147, eff 6-11-92; Amended at 17 Ok Reg 2636, eff 7-1-00]

### **535:25-1-1.1. Definitions**

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

“**Applicant**” means a “person” as defined in Title 59, O.S., Section 353.1 who is making application for any registration, certificate, license or permit or renewal of the same.

“**License**” means any license, permit, registration or certificate.

“**Registrant**” means any holder of registration, certificate, license or permit that is regulated by the Board.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 18 Ok Reg 2749, eff 7-1-01]

## **SUBCHAPTER 3. APPLICANTS, REGISTRANTS, AND APPLICATIONS**

Section

535:25-3-1. [Reserved]

535:25-3-2. [Reserved]

535:25-3-3. Qualifications and requirements for registrant applicants

535:25-3-4. Requirements for applicants or registrants who have had action against any license, permit or certificate

535:25-3-5. Multiple licenses /permits

535:25-3-6. Individual address change

535:25-3-7. Change requirements and notification

[Authority: Title 59 O.S., Section 353.7, 353.18, 353.20, and 365]

[Source: Added at 17 Ok Reg 2636, eff 7-01-00; Amended at 18 Ok Reg 2757, eff 7-01-01]

### **535:25-3-3. Qualifications and requirements for registrant applicants**

(a) The Board shall consider at least the following factors in reviewing the qualifications of registrants or applicants for licensure e.g.:

(1) Any charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under any federal, state, or local laws relating to drug samples, drug distribution, or distribution of controlled substances;

(2) Any felony charges, convictions, receipt of deferred sentence or deferred prosecution, or pleading of no contest of the applicant or registrant under federal, state, or local laws;

(3) The applicant's or registrant's past experience with prescription drugs, including controlled substances;

(4) The furnishing by the applicant or registrant of fictitious, false, misleading, or fraudulent material in any application (original, new or renewal) or failing to provide information relevant to this application;

(5) The suspension or revocation by federal, state, or local government of any license currently or previously held by the applicant or registrant;

(6) Compliance with licensing requirements under previously granted licenses, if any;

(7) Compliance with requirements to maintain and/or make available to the State Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this section;

(8) Abuse of alcohol or habit-forming drugs, or use of illegal CDS drugs or positive drug screen for such illegal substance or its' metabolite;

(9) Practicing as a registrant without reasonable skill and safety by reason of use and/or abuse of drugs, narcotics, chemicals or any other type of material, or as a result of any mental or physical condition; and,

(10) Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The applicant shall be forthright and open in the provision of information to the Board in the application process. No license, permit or certificate shall be awarded to an applicant who does not provide the Board with complete open and honest responses to all requests for information.

(c) The applicant shall be candid in regards to providing information related to any academic misconduct, malpractice, legal, or disciplinary action.

(d) The applicant shall fully and completely disclose ownership of any pharmacy, wholesaler, manufacturer packager, medical gas supplier or medical gas distributor or any other person licensed under Title 59 O.S. Section 353.18.

(e) The Board shall have the right to deny a license to an applicant or registrant if it determines that the granting of such a license would not be consistent with the public health and safety.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 18 Ok Reg 2757, eff 7-1-01; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 21 Ok Reg 2460, eff 7-1-04; Amended at 24 Ok Reg 2265, eff 7-1-07; Amended at 27 Ok Reg 2269, eff 7-11-10]

**535:25-3-4. Requirements for applicants or registrants who have had action against any license, permit or certificate**

(a) If the Board approves an applicant or registrant who has had a previous registration, license, permit, or certificate which was revoked or subject to Board action at cancellation, the applicant shall be subject to the following terms:

(1) A minimum of two years probation.

(2) Any specific requirements placed on the applicant by the Board based on the previous action and applicant's or registrant's current status.

(3) Any violations by the applicant or registrant shall subject the applicant or registrant to cumulative action based on previous violation on the previous license and the current violation.

(4) Failure of the applicant or registrant to meet any terms or requirements of the Board shall subject the applicant to Board action based on current failure and previous Board action against previous License

(b) The Board shall have the right to order any additional terms or conditions that it determines are required to protect the public health and safety.

[Source: Added at 17 Ok Reg 2635, eff 7-1-00; Amended at 26 Ok Reg 2310, eff 7-1-09]

### **535:25-3-5. Multiple licenses /permits**

(a) **Pharmacy and Manufacturer, Packager, or Wholesaler.** There shall be no multiple licensing that would include a pharmacy and manufacturer, packager or wholesaler in the same location.

(b) **Pharmacy/Pharmacy.** No more than one pharmacy license will be allowed in one location.

(c) **Wholesaler/Wholesaler.** More than one wholesale license will not be allowed in one location.

(d) **Wholesaler/Packager.** The licensing of a wholesaler and a packager in the same location will be allowed.

(e) **Pharmacy/Drug Supplier.** The licensing of a pharmacy and drug supplier in the same location will be allowed.

(f) **Pharmacy/Parenteral.** The licensing of a pharmacy and a parenteral pharmacy permit in the same location will be allowed.

(g) **Intern/Technician.** Applicants may not hold an intern license and a technician permit at the same time.

(h) **Pharmacist/Technician.** Applicants may not hold a pharmacist license and a technician permit at the same time. A pharmacist who has had Board action taken against his pharmacist license for whatever reason and no longer holds a current pharmacist license is not eligible for a technician permit.

[Source: Amended and renumbered from 535:25-1-2 at 17 Ok Reg 2636, eff 7-1-00; Amended at 19 Ok Reg 1798, eff 7-1-02]

### **535:25-3-6. Individual address change**

Every individual applicant and/or registrant (e.g.: pharmacist, intern, technician, etc.) shall notify the Board in writing within 10 days of an address change.

[Source: Added at 18 Ok Reg 2757, eff 7-1-01]

### **535:25-3-7. Change requirements and notification**

(a) Change of name, ownership, and/or location shall require a new license on all business permits, certificates or licenses (e.g. pharmacy, wholesaler, packager, manufacturer, medical gas supplier and distributor, training areas, parenteral, drug supplier, etc.)

(1) A change of ownership occurs when:

(A) the original owner(s) transfers 20% or more of the ownership of the entity owning the license, permit or certificate to another owner;

(B) a change of 20% or more of the ownership of the entity owning the license, permit or certificate occurs (for example, when the corporation owning the license, permit or certificate sells 20% or more of the stock); or

(C) a change of ownership form occurs (for example, from a sole proprietor ownership to a partnership, limited liability company or corporation).

(2) Any ownership change not reported as a change of ownership because it involves a transfer of less than 20% of the ownership of the entity owning the license, permit or certificate must be reported at the next renewal of the entity license, permit or certificate.

(3) 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.)

(b) Changes of ownership and/or location will require a special inspection and special inspection fee.

(c) Every applicant for change or renewal of license, permit or certificate shall meet the requirements in 535:25 at a minimum.

(d) Changes in any information required for licensure must be reported to the Board within ten (10) days (e.g. for businesses the manager, contact person, phone, etc. and/or for individuals name, address, etc.)

[Source: Added at 18 Ok Reg 2757, eff 7-1-01; Amended at 19 Ok Reg 1798, eff 7-1-02; Amended at 24 Ok Reg 2265, eff 7-1-07]

## **SUBCHAPTER 5. GENERAL REQUIREMENTS OR PROCEDURES**

### Section

535:25-5-1. Inspector's warning notice

535:25-5-2. Procedure to return a restricted license to good standing

535:25-5-3. Drug screening

535:25-5-4. Board order(s) due date

[Authority: Title 59 O.S., Section 353.7, 353.18, 353.20, and 365]

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at Ok 18 Reg 2757, eff 7-1-01]

### **535:25-5-1. Inspector's warning notice**

(a) **Purpose.** An inspector's warning notice protects public health by allowing registrants to expeditiously correct violations of laws and rules, and report these corrections to the Board in writing.

(b) **Recipient.** A warning notice may be issued to any registrant found to be violating the rules of this Title, Oklahoma Statutes, Title 59, Section 353 et seq., and/or any federal, state and local laws and rules.

(c) **Issuance.** An inspector may issue a warning notice at the time a violation is found.

(d) **Filing.** The warning notice shall become an integral part of a file.

(e) **Failure to respond.** A recipient's failure to satisfactorily respond within ten days to a warning notice may be referred by the Director to the Board for review or complaint and hearing.

(f) **Board review of two warning notices.** Any registrant receiving two or more warning notices within a twelve-month period may be referred to the Board for review, or complaint and hearing.

[Source: Added at 17 Ok Reg 2635, eff 7-1-00; Amended at 19 Ok Reg 1799, eff 7-1-02]

### **535:25-5-2. Procedure to return a restricted license to good standing**

(a) Upon the expiration date of a restriction, the registrant must request in writing that the Board return the license to good standing.

(b) The registrant may be requested to appear before the Board prior to any action being taken on the request.

[Source: Added at 17 Ok Reg 2635, eff 7-1-00]

### **535:25-5-3. Drug Screening**

(a) Any registrant who is suspended and/or placed on probation may be required to submit to random drug screening.

(b) Random drug screening required by the Board will be done at the registrant's expense.

[Source: Added at 17 Ok Reg 2635, eff 7-1-00]

### **535:25-5-4. Board order(s) due date**

Any fine(s) ordered or agreed to in a Final Order, Agreed Order, or any other Order of the Board is due and payable upon receipt of such Order by the registrant; unless otherwise stated in the Order.

[Source: Added at 18 Ok Reg 2757, eff 7-1-01]

### **535:25-5-5. Prescription drug (Rx only) purchases and record requirements**

(a) All registrants shall keep adequate records to assure prescription drugs are legally received and/or distributed or dispensed, as appropriate. Such records shall include, but not be limited to, all prescription drug purchase (e.g. invoices, etc.) and inventory records and shall be maintained and be readily retrievable for a period of at least 2 years.

(b) Prescription drug purchases may only be made from entities licensed to sell prescription drugs. A registrant shall exercise professional judgment regarding the purchase of prescription drugs in order to assure a safe, sanitary and legal prescription drug supply is maintained.

[Source: Added at 24 Ok Reg 2265, eff 7-1-07]

## **SUBCHAPTER 7. RULES OF REGISTRANT CONDUCT**

### Section

535:25-7-1. Scope and purpose

535:25-7-2. Definitions

535:25-7-3. Compliance with laws

535:25-7-4. Confidentiality

535:25-7-5. Practice of medicine

535:25-7-6. Governing body

[Authority: Title 59 O.S., Section 353.7, 353.18, 353.20, and 365]

[Source: Added at 17 Ok Reg 2636, eff 7-01-00]

### **535:25-7-1. Scope and purpose**

The rules of this subchapter provide standards of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

### **535:25-7-2. Definitions**

The definitions of this subchapter shall be the same as those set out in 535:25-1-1.1.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

### **535:25-7-3. Registrant Conduct**

(a) Registrants will at all times conduct business in conformity with all federal, state and municipal laws.

(b) Registrants shall conduct themselves at all times in a manner that will entitle

them to the respect and confidence of the community in which they practice.

(c) Registrants shall not abuse alcohol or drugs, nor shall they use an illegal CDS substance, nor test positive for such substance or its' metabolite.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 21 Ok Reg 2460, eff 7-1-04]

#### **535:25-7-4. Confidentiality**

A registrant will hold the health and safety of their patrons as their first consideration and will not divulge the nature of the patrons' problems or ailments or any confidence entrusted to them in their licensed capacity except in response to legal requirements or in the best interest of the patron.

[Source: Added at 17 Ok Reg 2635, eff 7-01-00]

#### **535:25-7-5. Practice of medicine**

Registrants will refrain from any attempt at diagnosis or treatment that is the legally constituted right or obligation of any practitioner of the healing arts.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

#### **535:25-7-6. Governing body**

(a) A registrant will recognize the State Board of Pharmacy as the governing body in the State of Oklahoma and report to them any violation of pharmacy laws or regulations that may come to their attention.

(b) A registrant who fails to report such violations will be subject to Board action against their license, permit or certificate.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 20 Ok Reg 2488, eff 7-1-03]

### **SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT**

#### Section

535:25-9-1. Scope and purpose

535:25-9-2. Violating confidentiality

535:25-9-3. Violating laws or rules

535:25-9-4. False report or record, billing incorrectly, fraudulent billings or reports

535:25-9-5. Conducting business without reasonable skill and safety

535:25-9-6. Discrimination

535:25-9-7. Theft

535:25-9-8. Failure to maintain effective controls

535:25-9-9. Misfilling

[Authority: Title 59 O.S., Section 353.7, 353.18, 353.20, and 365]

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

#### **535:25-9-1. Scope and purpose**

The rules of this subchapter describe some violations of the rules of registrant conduct. Violations of professional conduct include, but are not limited to, those violations described in this subchapter.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

#### **535:25-9-2. Violating confidentiality**

A registrant shall not violate patron confidentiality. This does not prevent pharmacies from providing drug therapy information to physicians for their patients, nor does it prevent the provision of information as required by law.

[Source: Added at 17 Ok Reg 2635, eff 7-01-00]

### **535:25-9-3. Violating laws or rules**

A registrant shall not violate directly, (or indirectly, through actions of another), assist or abet in the violation of, or conspire to violate, any provision of the Oklahoma Pharmacy Act, Title 59, 353 et seq., the Prescription Drug Marketing Act (21 U.S.C., Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C., Sec. 13 et seq.), or federal, state and local laws and rules.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 21 Ok Reg 2460, eff 7-1-04]

### **535:25-9-4. False report or record, billing incorrectly, fraudulent billing or reports**

The following are violations of registrant conduct:

- (1) A report or record which a registrant knows to be false, intentionally or negligently failing to file a report or record required by federal, state or local laws or rules, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the registrant is required to make or file in his capacity as a registrant;
- (2) Billing or charging for quantities greater than delivered, or for a brand when a generic is dispensed.
- (3) Fraudulent billing or reports to a third party payer of prescription drugs.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

### **535:25-9-5. Conducting business without reasonable skill and safety**

Conducting business in a registrant's capacity without reasonable skill and safety by reason of illness, use and/or abuse of drugs, narcotics, chemicals, or any other type of material, or as a result of any mental or physical condition is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

### **535:25-9-6. Discrimination**

Discriminating in any manner between patients or groups of patients for reasons of a particular disease, religion, race, creed, color, sex, age or national origin is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00]

### **535:25-9-7. Theft**

Theft while working as a registrant is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 25 Ok Reg 1984, eff 7-1-08]

### **535:25-9-8. Failure to maintain effective controls**

- (a) Failure to establish and maintain effective controls to prevent prescription errors is a violation of registrant conduct.
- (b) Failure to establish and maintain effective controls against the diversion of prescription drugs and/or controlled dangerous drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules is a violation of registrant conduct.
- (c) The sale of dangerous drugs to a person or entity not eligible to receive such drugs is a violation of registrant conduct.

(d) The purchase of dangerous drugs from a person or entity not eligible to possess such drugs is a violation of registrant conduct.

(e) Failing to establish and maintain suspicious order monitoring records in a suspicious order monitoring program; and failure to notify the Board of confirmed suspicious orders.

(f) It is a violation to ship orders that are confirmed as suspicious.

[Source: Added at 17 Ok Reg 2636, eff 7-1-00; Amended at 26 Ok Reg 2310, eff 7-1-09; Amended at 27 Ok Reg 2269, eff 7-11-10]

### **535:25-9-9. Misfilling**

Misfilling of a prescription or drug order which departs from the standards of care ordinarily exercised by a registrant with proof of actual injury not having to be established is a violation of registrant conduct.

[Source: Added at 17 Ok Reg 2636 eff 7-1-00]

# Appendix A

## OBN Rules

\*UNOFFICIAL\*

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

[Selected portions of Chapters 20, 25, 30, 40, 45 and 55 are included for use by Oklahoma licensed pharmacies and facilities]

and

### **OBN Effect of HIPAA on State Law**

and

### **Acceptable ID for PSE and CDS purchases**

For a complete copy of the unofficial Title 475 rules or interpretation of these rules, contact the Oklahoma Bureau of Narcotics  
(405) 521-2885 - [www.ok.gov/obnndd](http://www.ok.gov/obnndd)

\*Official copies of the rules in Title 475 may be obtained from the Oklahoma Secretary of State Code office.

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

## **Chapter 20 - Security Requirements**

### **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**

Physical security controls for nonpractitioners and storage areas shall comply with Title 21 Code of Federal Regulations §1301.72

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

Physical security controls for nonpractitioners and manufacturing areas shall be in compliance with Title 21 Code of Federal Regulations §1301.73.

**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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or with the Drug Enforcement Administration to determine that the person is registered to possess the controlled 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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control 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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control 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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

(1) Each such person may distribute such samples of controlled dangerous substances only after simultaneously preparing a specific written list of the items to be distributed on forms purchased (at cost of printing) from the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

(2) Forms provided by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control shall be prepared in triplicate, listing the controlled dangerous substances to be distributed, shall be signed by the company representative distributing the samples, shall denote the registration number assigned to the company representative in the C.O.D. blank of the form, signed by the practitioner receiving the samples, and shall denote the practitioner's registration number issued by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control.

(3) From the completed forms, the original shall be forwarded to the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control on the first (1st) and fifteenth (15th) of each month. One (1) copy of the completed form will be left with the practitioner and shall be retained by the practitioner as a permanent record for a period of two (2) years. The remaining copy of the completed form shall be retained by the company representative and become a part of the company's permanent records.

(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 which 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) to guard against storage or in-transit losses and comply with all current Federal regulations. 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 of 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 of 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 such person on a case-by-case basis.

(h) The registrant shall immediately notify OBN and seek authorization to employ any individual that has been convicted or is serving a deferred or probationary sentence related to any controlled dangerous substance as defined by the Uniform Controlled Dangerous Substances Act in this state, any other state, or the United States.

#### **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 safety 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.

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

(a) All registrants shall 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 notify the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control or 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.

## **Chapter 25 - Records and Reports of Registrants**

### **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.

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

(a) Each registrant shall maintain the 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 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 item, 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 items 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, and notations of date, amount and type of controlled dangerous substance for each occasion the patient receives a controlled dangerous substance. 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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control of the name, address and registration number of the establishment maintaining such records.

#### **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 and be available for at least two (2) years from the date of such inventory or record, 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, 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.

#### **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.

#### **475:25-1-7. Biennial inventory date**

Every two (2) years following the date on which the initial inventory is taken by a registrant pursuant to 475:25-1-6, 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.

**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**

Inventories of manufacturers of controlled dangerous substances shall conform to Title 21 Code of Federal Regulations, §1304.15.

**475:25-1-10. Inventories of distributors**

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, §1304.16.

**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.

**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).

**475:25-1-14. Records for manufacturers**

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 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 and the Federal Drug Enforcement Administration registration number of the person to whom distributed, and the quantity of the substance in finished form distributed or disposed.

**475:25-1-17. Records of scientific analyst**

(a) Each person registered or otherwise authorized to conduct scientific analysis 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 of controlled dangerous substances used in chemical analysis or other laboratory work are not required.
  - (c) Records relating to known or suspected controlled dangerous substances received as evidentiary material for analysis are not required under (a) of this Section.
  - (d) Each person registered as a scientific analyst conducting scientific analysis of anonymous 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 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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control 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.
  - (e) Quantitative analysis may be conducted of anonymous samples. However, to prevent the possibility of illegal drug traffickers utilizing these laboratories as quality control, only qualitative results may be given to the donor. Analysis should be sufficient to determine if the strength is so great that use would be harmful to the user. In these cases, the submitter can only be told what the drug was and that use would be dangerous.
    - (1) Security of standards and samples 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 anonymous sample shall be disposed of in accordance with 475:35-1-4.
    - (3) All controlled dangerous substances distributed to 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.

#### **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.

#### **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.

### **Chapter 30 - Labeling Requirements**

#### **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.

#### **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. 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.

#### **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 written prescription in the same manner as 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, 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. Electronic prescriptions for schedule III, IV, or V drugs containing an electronic or computer-generated signature shall be treated as a call-in prescription as described in 475:30-1-10.

(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, exempted from registration or registered in fee-exempt status with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, shall include on all prescriptions issued by him/her the hospital or institutional Federal Drug Enforcement Administration 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 Federal Drug Enforcement Administration 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 written prescription for any controlled dangerous substance the name, address and Federal Drug Enforcement Administration 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 written by the prescribing practitioner.

(A) A pharmacist may add to the prescription the patient's address or age, the prescribing practitioner's federal DEA 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 written prescription for a controlled dangerous substance in Schedule II becomes invalid thirty (30) days after the date of issuance, with day one (1) of the thirty (30) day period being the first day after date of issuance.

(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 Drug Enforcement Administration 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 and IV, 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.

(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 CDS is dispensed.

(g) The pharmacist still bears the responsibility for ensuring that prescriptions for controlled 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.

#### **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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control and the State of Oklahoma Drug Treatment Rehabilitation Authority. It will be reviewed by the State of Oklahoma Drug Treatment Rehabilitation Authority and the Mental Health Department for scientific merit and qualifications and by the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control for controlled dangerous substances 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 written prescription signed by the prescribing registered individual practitioner, except as provided in (d) of this Section.

(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 written 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 written 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 the 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 insure 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 written 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

written 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 written prescription; failure of the pharmacy to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing registered individual practitioner.

**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 in a written or emergency oral prescription. A notation of the quantity supplied on the face of the written prescription (or written record of the emergency oral prescription) is required. The remaining portion of the prescription may be filled within seventy-two (72) hours of the first partial filling if the initial partial filling occurred within thirty (30) days of the issuance of the prescription. If the remaining portion is not or cannot be filled within the 72-hour period, the pharmacy shall so notify the prescribing registered individual practitioner. No further quantity may be supplied beyond the seventy-two (72) hours without the issuance of a new prescription.

(b) A prescription for a Schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient. The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient". A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" shall be deemed to have been filled in violation of the Uniform Controlled Dangerous Substances Act. 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 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.

**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 written prescription signed by a registered or otherwise authorized individual practitioner or 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. 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 written prescription signed by the "Limited Institutional Practitioner's" supervising chief medical practitioner, or 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.

**475:30-1-11. Refilling of prescriptions**

(a) 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 entered on the back of the prescription, which indicates 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 CDS voids any existing refills or other prescriptions for the same drug.

(b) 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 and

21 CFR §1306.22.

**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 after six (6) months after the date on which the prescription was issued.

**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.

**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) The pharmacy requires every purchaser of controlled dangerous substances under this Chapter not known to him/her to furnish suitable identification (including proof of age where appropriate).

(7) 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).

(8) 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".

#### **475:30-1-15. Identification requirement**

Pharmacists are required to obtain positive 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.

### **Chapter 35 - Transfer and Disposal of Controlled Dangerous Drugs**

#### **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.

**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 Registration. Any controlled dangerous substances in his/her possession may be disposed of in accordance with Title 21 Code of Federal Regulations, § 1307.21.

(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 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 Oklahoma State Bureau of Narcotics and Dangerous Drugs Control, 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. 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 not be necessary to file a copy of the inventory with the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control unless requested by the Director. Transfers of any substances listed in Schedule I or II requires 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, 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.

#### **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 obtain appropriate forms from the Oklahoma State Bureau of Investigation Laboratory in Oklahoma City, Oklahoma. The drugs must be inventoried and submitted pursuant to Title 63 Okl.St. Ann. §2-315. Registrants may alternatively request the Regional Director of the Drug Enforcement Administration in the region in which the person is located for authority and instructions to dispose of such substances pursuant to Title 21 Code of Federal Regulations, §1307.21.

#### **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.

### **Chapter 40 - Enforcement and Administrative Inspections**

#### **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 and other records required to be kept pursuant to the Uniform Controlled Dangerous Substances Act, this Title, and the Code of Federal Regulations governing controlled dangerous substances; order form records required to be kept pursuant to Title 63

Okl.St. Ann. § 2-308; prescriptions and distribution records required to be kept pursuant to Title 63 Okl.St. Ann. § 2-307; 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).

#### **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.

### **Chapter 45 - Oklahoma Control Reporting Requirements**

#### **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, or IV.

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

Every pharmacy or dispensing practitioner filling any schedule II, III, or IV 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 identification number;
- (3) National Drug Code number of the substance dispensed,
- (4) Date of the dispensation;
- (5) Quantity of the substance dispensed;
- (6) Prescriber's U.S. Drug Enforcement Agency registration number; and,
- (7) Dispenser's registration number and location.

#### **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 or by computer diskette, magnetic tape, or other electronic medium.

#### **475:45-1-4. Waiver of UCF submissions**

(a) The Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (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, or IV Controlled Dangerous Substance to submit prescription data on Universal Claim Forms if the dispenser has an appropriate hardship.

(b) A formal request for this waiver must be made in writing to the Director of the Oklahoma State Bureau of Narcotics and Dangerous Drugs Control (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 annually to determine whether or not the hardship will be extended.

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

The information required by this section must be reported to the central repository within thirty (30) days of the time that the controlled dangerous substance was dispensed.

#### **475:45-1-6. Failure to report**

Failure to accurately report the required 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 Two Thousand Dollars (\$2000) per violation.

### **Chapter 55 - Pseudoephedrine Control**

#### **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.

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

(a) All products that are either: (1) soft gelatin liquid-filled capsules; or, (2) liquid preparations, are exempt from Schedule V. Conversely, all solid dosage forms of medications, including powders, that contain any quantity of pseudoephedrine are classified as Schedule V controlled dangerous substances and are subject to the rules of this section.

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

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

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

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

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

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

#### **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 nine (9) gram limit for a thirty (30) day period. The pharmacist or other authorized person must utilize the real-time electronic pseudoephedrine tracking system established and maintained by the Oklahoma Bureau of Narcotics and Dangerous Drugs Control. 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;

- (2) Pseudoephedrine products regulated by Oklahoma law will only be sold to customers who present a valid form of identification, which shall be a valid state driver's license or valid state identification card;
- (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 (either the driver's license number or the state issued 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 current street address;
  - (J) Customer's current city, state, and zip code;
- (4) If the electronic log is unavailable (time-out of twenty seconds or more) because of a failure on the Oklahoma Bureau of Narcotics and Dangerous Drugs Control network, the pharmacist or other authorized person may continue with the transactions until the system is available; if the electronic log is unavailable because of a failure attributable to systems other than the Oklahoma Bureau of Narcotics and Dangerous Drugs Control, all transactions must be recorded manually and entered into the electronic logbook by the registrant as soon as is practicable after the problem is resolved.

#### **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.

**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.

**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.

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

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

**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.

**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.

## **The Effect of HIPAA on State Law**

Oklahoma State Law authorizes the Oklahoma State Bureau of Narcotics (OBN) to perform administrative inspections of pharmacies and other registrants without a subpoena. This authority to make public health investigations is derived from Title 63. Public Health and Safety. HIPAA does not prevent OBN from performing this duty, nor does it require a subpoena for this information. The following section of HIPAA, in pertinent part, makes this clear:

**§ 164.512 Uses and disclosures for which an authorization or opportunity to agree or object is not required.**

A covered entity may use or disclose protected health information without the written authorization of the individual, as described in § 164.508, or the opportunity for the individual to agree or object as described in § 164.510, in the situations covered by this section, subject to the applicable requirements of this section. When the covered entity is required by this section to inform the individual of, or when the individual may agree to, a use or disclosure permitted by this section, the covered entity's information and the individual's agreement may be given orally.

**(a) Standard: uses and disclosures required by law.**

(1) A covered entity may use or disclose protected health information to the extent that such use or disclosure is required by law and the use or disclosure complies with and is limited to the relevant requirements of such law.

(2) A covered entity must meet the requirements described in paragraph (c), (e), or (f) of this section for uses or disclosures required by law.

**(b) Standard: uses and disclosures for public health activities.**

(1) **Permitted disclosures.** A covered entity may disclose protected health information for the public health activities and purposes described in this paragraph to:

(i) A public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; or, at the direction of a public health authority, to an official of a foreign government agency that is acting in collaboration with a public health authority;

This section does not require a subpoena. In fact, requiring a subpoena would invalidate the authority and duty of OBN to make administrative inspections which never required a subpoena.

It is a privilege to have an OBN narcotic registration. This privilege may be revoked for failing to provide records required to be kept by the Rules of OBN and Title 63. It is also a crime to interfere with an investigation of an OBN Agent. If you have any questions or concerns, please e-mail Travis White, Assistant General Counsel, at [twhite@obn.state.ok.us](mailto:twhite@obn.state.ok.us)

## **Acceptable ID for PSE and CDS purchases**

[O.S. Title 63 § 2-309B (7) and (9)]

7. "Recipient's identification number" and "recipient's agent's identification number" means the unique number contained on a valid passport, military identification card, driver license, or identification card issued to a recipient pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state<sup>9</sup> if the recipient is not a resident of the State of Oklahoma, or, if the recipient is less than eighteen (18) years old and has no such identification, the unique number contained on a valid passport, military identification card, driver license, or identification card issued to the recipient's parent or guardian pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the parent or guardian is not a resident of the State of Oklahoma, or, if the controlled dangerous substance is obtained for an animal, the unique number contained on the animal owner's valid driver license or identification card issued pursuant to Section 6-105 of Title 47 of the Oklahoma Statutes or similar statute of another state if the owner is not a resident of the State of Oklahoma. Nonresident drug outlets registered pursuant to the Oklahoma Pharmacy Act and resident drug outlets defined in Section 353.1 of Title 59 of the Oklahoma Statutes are exempt from the picture identification requirement if the nonresident and resident drug outlets have obtained the identification of the patient through the prescription benefit plan of the patient;

9. "State" means any state, territory, or possession of the United States, the District of Columbia, or foreign nation.

If any questions arise, contact the Oklahoma Bureau of Narcotics legal department, Susan Rogers, General Counsel or Travis White, Deputy General Counsel.

# **Appendix B**

## **Pharmacy Change / Closing**

### **PHARMACY CHANGE OF OWNERSHIP, NAME AND/OR LOCATION**

- A.** An Oklahoma State Board of Pharmacy application for pharmacy license should be completed and sent to the Board office well ahead of the effective date.
- B.** The pharmacy should notify the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD) and the Federal Drug Enforcement Agency (DEA) in writing at least fourteen (14) days in advance.
- C.** In the case of a change of ownership, dangerous drugs, controlled dangerous substances and prescription files may be transferred to the new owner. An inventory of all controlled dangerous substances (CDS) must be taken on the date of the transfer and a copy sent to the Board of Pharmacy. The pharmacy inventory copy shall serve as the final inventory of the old owner and the initial inventory of the new owner and must be maintained in the pharmacy.
- D.** No inventory is required if there is a change of location or name only with no change of ownership.

### **CLOSING A PHARMACY (*in-state*)**

- A.** Perform a final CDS inventory.
- B.** Return the following to the Board:
  - 1. Pharmacy license
  - 2. A copy of final CDS inventory
  - 3. Letter stating the date of closing and the disposition of pharmacy records and “Rx Only” drugs.
- C.** “RX Only” drugs may be sold to another licensed pharmacy, returned to the wholesaler or destroyed.
- D.** CIII-V’s must be invoiced and CII’s require DEA 222 for transfer.
- E.** “Rx Only” drugs may NOT be kept in an unlicensed location.
- F.** All outdated or unwanted CDS drugs must be destroyed in accordance with State law. The Oklahoma State Bureau of Investigation (OSBI), (405) 427-5421, provides forms and instructions for CDS drug destruction.
- G.** Prescription records may be sold or kept. However, they must be maintained and accessible for inspection for a period of five (5) years.
- H.** Return DEA license and blank 222 forms to DEA. Contact DEA for any further requirements at (405) 475-7500.
- I.** Return OBN license to OBN with a letter that the pharmacy is closing. Contact OBN for further requirements at (405) 530-3120.
- J.** Remove all signs stating “pharmacy” “drug store”, etc. unless another pharmacy will be replacing the closed pharmacy.

# Appendix C - D

## DEA FORMS 222 AND 106

### APPENDIX C

#### DEA Form 222

For information concerning DEA Form 222, see the following:

<http://www.deadiversion.usdoj.gov/faq/dea222.htm>

Questions concerning DEA Form 222 may be directed to the OKC DEA at 405-475-7500.

### APPENDIX D

#### DEA Form 106 Report Lost / Stolen CDS

1. Upon a loss or theft of controlled dangerous substances (CDS) a pharmacy must fill out a **DEA Form 106**:  
[http://www.deadiversion.usdoj.gov/21cfr\\_reports/theft/index.html](http://www.deadiversion.usdoj.gov/21cfr_reports/theft/index.html)
2. Copies of the completed DEA 106 may be sent to:  
  
**OBN, Oklahoma Bureau of Narcotics**  
440 NE 39<sup>th</sup> St  
Oklahoma City, OK 73105  
  
**OSBP, Oklahoma State Board of Pharmacy**  
4545 N. Lincoln Blvd, Ste 112  
Oklahoma City, OK 73105-3488
3. Keep a copy of the completed Form 106 in your files.
4. If a crime was committed (i.e. robbery or burglary), a police report must be filed. In the case of a loss of a controlled dangerous substance pharmacists must use their professional judgment, as it may not be necessary to file a police report.
5. Questions may be directed to DEA at 405-475-7500 or to OBN at 800-522-8031 or locally at 405-521-2885.
6. Theft or any violation of the Oklahoma Controlled Substance Act by a Pharmacist, Technician, Intern, or other registrant must be reported to the Oklahoma State Board of Pharmacy.

# Appendix E

## Oklahoma Mid-Level Practitioner Prescribing Summary

This summary dated October 2010 is subject to change. For specific information, contact the appropriate practice boards, the OK Bureau of Narcotics (OBN) and/or the Drug Enforcement Agency (DEA). **Only OK licensed mid-level practitioners may prescribe and issue valid OK scripts.**

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**PHYSICIAN ASSISTANTS (PA's)** have prescribing authority under the direction of a supervising physician. They must obtain a mid-level DEA and OBN license to prescribe controlled dangerous substances and they have a formulary with certain drug categories they may not prescribe. **The name of the PA may be placed on the prescription label.** They must prescribe within the Medical Board adopted Drug Formulary.

***C-II's are limited to orders for immediate or ongoing administration on-site pursuant to an Oklahoma supervising physician and on-site facility approved written protocol.***

***C-III thru C-V prescriptions are limited to a 30-day supply as an individual prescription. No refills are allowed on controlled substances.***

***Non-controlled drugs prescribed for the first time for a patient are limited to a 30-day supply with two (2) refills.***

***Non-controlled drugs prescribed for chronic, stable conditions are limited to a 90-day supply with three (3) refills.***

For licensure status and formulary information, contact the Medical Board at 405-962-1400 or access their website at: [www.okmedicalboard.org](http://www.okmedicalboard.org).

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The following **Advanced Practice Nurses** (APN's) may apply for authority from the Oklahoma Board of Nursing to prescribe drugs subject to supervision by a physician: **Advanced Registered Nurse Practitioners, Clinical Nurse Specialists, Certified Nurse Midwives.** Parameters of prescribing include: the prescribed drug must be within the APN's specialty area of practice, prescribing includes C-III thru C-V limited to a 30-day supply, may be combination of initial and refill but can't exceed 30 day supply. (APN must have OBNDD and DEA registrations) and prescribing is subject to an Exclusionary Formulary (a list of drugs which may not be prescribed). The Exclusionary Formulary is available at: [www.ok.gov/nursing/prac-exclusfrm.pdf](http://www.ok.gov/nursing/prac-exclusfrm.pdf). **Certified Registered Nurse Anesthetists** (CRNA's) authorized by the Oklahoma Nursing Board may select, order, obtain and administer drugs only in the perioperative and periparturient periods. CRNA's may select, order, obtain and administer drugs including C-II thru C-V (with OBNDD and DEA registrations) from an Inclusionary Formulary (list a drugs which may be prescribed.) The Inclusionary Formulary available at: [www.ok.gov/nursing/prac-crnafrm.pdf](http://www.ok.gov/nursing/prac-crnafrm.pdf). CRNA's do not write outpatient Rx's.

Verification licensure/advanced practice/prescriptive authority from the Oklahoma Nursing Board's website at: [www.ok.gov/nursing](http://www.ok.gov/nursing) or by contacting the Board at 405-962-1800.

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**OPTOMETRISTS** certified by the OK Optometry Board to prescribe may obtain a mid-level DEA and OBN license for prescribing ***C-III thru C-V limited to a 7-day supply (no refills without a follow-up examination). Drugs prescribed have to be for abnormalities of the eye.*** For licensure status and formulary information, contact the Optometry Board at 405-733-7836.

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PA's, Advanced Practice Nurses and Optometrists may receive and distribute drug samples of drugs they may prescribe. **They may NOT prescribe CDS for themselves nor for their immediate family members (see OBN rule 475:30-1-3(d)).**

Language is included in the statutes of the professions above to require their prescriptions be filled by a pharmacist for added patient protection. Pharmacists are responsible for the dosage and drug utilization review. There is a great opportunity to work with these health professionals and share your drug knowledge for the benefit of the patient.

# Appendix F

## Consanguinity / Affinity Table (Blood / Marriage)

Showing Degrees of Relationships

PERSON  
(Practitioner)

1st *	Spouse	Parents	Children
2nd *	Brothers Sisters	Grandchildren	Grandparents
3rd **	Nieces Nephews	Great Grandchildren	Aunts Uncles Great Grandparents

\* A practitioner may NOT prescribe a Controlled Dangerous Substance (CDS) for a patient related within the first or second degree, whether by blood or marriage

\*\* A practitioner MAY prescribe for the 3rd degree and below.

(see Bureau of Narcotics Rule 475:30-1-3 and the appropriate professional licensure board rules)

## Appendix G

All registrants of the Oklahoma Bureau of Narcotics and the Drug Enforcement Administration should review the waiver requirements for persons who will have access to controlled dangerous substances in their working environment. Regulations require that the registrant (pharmacy, hospital, drug room, wholesaler, manufacturer, etc.) obtain a waiver from the appropriate agency or agencies PRIOR to the employment of a person who “has been convicted of a misdemeanor or felony relating to any controlled dangerous substances.” Due diligence on the part of registrants may include a nationwide background check prior to employment to determine employment eligibility. As waiver requirements vary significantly from state to state, the eligibility of a person to work in an environment with access to controlled dangerous substances may be different. A review of the person’s background is important whether the person is a new hire, or a transfer, especially if the transfer is from another state.

### Waiver References:

- **Oklahoma Bureau of Narcotics:** OAC 475:20-1-5(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 of 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 of 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 such person on a case-by-case basis.
- **DEA:** 21 CFR 1301.76(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term “for cause” means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual’s handling of controlled substances.

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