

**OKLAHOMA PHARMACY RULES**  
**(as of 07-01-07)**

**CHAPTER 15. PHARMACIES**  
**SUBCHAPTER 1. GENERAL PROVISIONS**

Section

535:15-1-1. Purpose

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(a) The rules of this Chapter regulate the sale or storage of drugs, medicines, chemicals and poisons and the dispensing of drugs and medicines in all places where drugs and medicines are compounded, dispensed or stored.

(b) The rules of this Chapter concern all places, including premises, equipment, contents and records, where drugs, medicines, chemicals or poisons are sold, stored, vended, given away, compounded, dispensed or manufactured.

(c) The rules of this Chapter further describe the Board's authority and duty to confiscate all drugs, medicines, chemicals or poisons found to be sold, stored, vended, given away, compounded, dispensed or manufactured contrary to the provisions of Title 59 O.S., Section 353 et seq.

(d) The rules of this Chapter prescribe minimum standards with respect to floor space and other physical characteristics of pharmacies, including retail pharmacies with drug supplier and parenteral permits, and Hospital pharmacies, which are necessary to the maintenance of professional surroundings and to the protection of the safety and welfare of the public, and which are required to receive new or renewal licenses or to close a pharmacy.

**SUBCHAPTER 3. PHARMACIES**

Section

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**535:15-3-1.1. Definitions**

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

**“Automated dispensing systems”** means a mechanical system controlled by a computer that perform operations or activities, relative to the storage, packaging, compounding, labeling, dispensing, administration, or distribution of medications, and which collects, controls, and maintains all transaction information.

**“Controlled dangerous substance”** or **“CDS”** or **“Scheduled drug”** or **“Sch”** means a drug, substance or immediate precursor in Schedules I through V of the Oklahoma Uniform Controlled Dangerous Substance Act, Title 63, Section 2-101 et seq.

**“Pharmacist in charge”** or **“(PIC)”** means a pharmacist manager. This is the pharmacist manager required for pharmacy licensure in Title 59 O.S. Section 353.18 (A)(2).

**535:15-3-2. Pharmacy responsibilities**

(a) **Pharmacy staffing responsibility.** Each pharmacy shall employ an adequate number of pharmacists to perform the practice of pharmacy as defined by the Oklahoma Pharmacy Act with reasonable safety.

(b) **Pharmacy manager.** Each pharmacy, in order to obtain and maintain a pharmacy license, must have a registered pharmacist as the pharmacy manager.

(1) A pharmacy manager (i.e. pharmacist in charge) is designated by his signature on the original pharmacy application or by the appropriate notification to the Board as required in 535:15-3-10(a), and is responsible for all aspects of the operation related to the practice of pharmacy. These responsibilities include, but are not limited to the:

(A) supervision of all employees as they relate to the practice of pharmacy;

- (B) establishment of policies and procedures for safekeeping of pharmaceuticals that satisfy Board requirements, including security provisions when the pharmacy is closed;
- (C) proper record keeping system for the purchase, sale, delivery, possession, storage, and safekeeping of drugs;
- (D) proper display of all licenses;
- (E) annual controlled drug inventory; and,
- (F) maintenance of prescription files;

(2) No pharmacist may serve as a pharmacy manager in more than one pharmacy at a time.

(3) A pharmacy manager shall work sufficient hours in the pharmacy to exercise control and meet the responsibilities of the pharmacy manager.

**(c) Pharmacy manager's and pharmacy's responsibilities.** The following describe responsibilities of the pharmacy and pharmacy manager.

(1) Where the actual identity of the filler of a prescription is not determinable, the manager of the pharmacy and the pharmacy where the prescription was filled will be the subject of any charges filed by the Board of Pharmacy.

(2) The pharmacy and the pharmacy manager are responsible to establish and maintain effective controls against prescription errors or misfills.

(3) The pharmacy and/or pharmacy manager shall notify the Board immediately of the separation of employment of any pharmacist, pharmacy intern, or pharmacy technician for any suspected or confirmed drug or pharmacy related violation. If the pharmacy manager (PIC) is terminated for such reason, the owner or other person in charge of the pharmacy shall notify the Board.

**(d) Responsibility for automated pharmacy systems.** This subsection describes the responsibilities of the pharmacy and the pharmacy manager for automated pharmacy systems.

(1) Prior written notice must be provided to the Board of the installation or removal of automated pharmacy systems. Such notice must include, but is not limited to the:

- (A) name and address of the pharmacy,
- (B) name of pharmacy manager,
- (C) name of the manufacturer & model of system.

(2) The system being implemented should conform to Board automated pharmacy system guidelines.

(3) The pharmacy shall monitor the automated pharmacy system with a quality assurance program.

**(e) Responsibilities for personnel identification.** The pharmacy manager and the pharmacy are responsible to assure that the public be able to distinguish pharmacy technicians, auxiliary support personnel, and/or interns from any pharmacist in the pharmacy.

(1) All pharmacy technicians, auxiliary support personnel, and/or interns must wear a designation tag and be distinctly identifiable from a practicing pharmacist.

(2) Designation tags must be clear, readable and lettered with "Rx Tech", "Tech", "Clerk", or "Intern".

(3) All pharmacy interns, technicians or clerks must identify themselves as such on any phone calls initiated or received while performing pharmacy functions.

### **535:15-3-3. Requirements for pharmacies employing assistant pharmacists**

All regularly licensed pharmacies employing registered assistant pharmacists must have a fully registered pharmacist actively engaged in the operation of said pharmacy for a period of not less than twenty-eight (28) hours per week.

### **535:15-3-4. Physical requirements for pharmacies**

The following are physical requirements for pharmacies:

(1) **Size.** The prescription department shall occupy no less than 125 square feet.

(2) **Sanitary facilities.** There shall be installed the proper sanitary facilities which shall include a sink with hot and cold running water separate from the restroom facilities.

(3) **Balances.** There shall be one set of prescription balances with capacity from 1/10 grain to at least one (1) ounce. If the pharmacy proves to the Board that the practice of pharmacy at this particular site does not require weighing of drugs and/or ingredients, an exception may be made by the Board to the balances requirement.

(4) **Graduates.** There shall be graduates scaled in both metric and apothecary measure sufficient in size and number to assure proper operation of the prescription department.

(5) **Spatulas.** There shall be spatulas of sufficient size and number to assure its proper operation.

(6) **Mortars and pestles.** There shall be mortars and pestles of sufficient size and number to assure its proper operation.

(7) **Sterilization.** There shall be installed sufficient equipment with which to perform all necessary sterilization procedure or heat processes common to the ordinary prescription department.

(8) **Library.** There shall be the necessary library which has been prescribed and standardized by the Board of Pharmacy in Section 535:15-3-6.

(9) **Refrigeration.** There shall be sufficient refrigeration facilities to store all necessary biologicals, injectables, suppositories and other products requiring refrigeration. This refrigerator shall be entirely separate from the storage of any food products in open packages.

(10) **Exempt narcotic book.** There shall be a book suitable for the registration of all sales of exempt narcotics.

(11) **Poison Book.** There shall be a book suitable for the registration of all sales of poisons in accordance with applicable laws.

(12) **Filing.** There shall be a system of filing for all prescriptions which shall be kept for a period of not less than five (5) years.

(13) **Containers.** There shall be sufficient stock of containers suitable for the dispensing of all prescriptions both for internal and external usage.

(14) **Labels.** There shall be sufficient stock of labels both for the dispensing of prescriptions and the sale of medicines and chemicals. Label requirements described in Title 59 O.S. Section 353.13A(C)

#### **535:15-3-4.1. Pharmacy licensing requirement**

(a) Every pharmacy conducting interstate and/or intrastate transactions in Oklahoma must be licensed as required under Title 59, O.S., Section 353.18(A).

(b) Every pharmacy shall list the corporate registered agent and address as required on their new and/or renewal application.

(c) Every applicant for pharmacy license issued under Title 59 O.S. Section 353.18 shall fully and completely disclose ownership as required by the Board on their new and/or renewal application.

#### **535:15-3-4-2. Minimum required information for licensure**

(a) Minimum required information for licensure shall be that information required by Title 59 O.S. Section 353.18(A) and the rules in 535:25-3.

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

(c) Changes of location, name, or ownership shall require a new license.

(d) Each location and/or pharmacy shall require a license.

#### **535:15-3-5. Lock out pharmacy or prescription department**

(a) **“Lock out Pharmacy or Prescription Department”** means a prescription department that is to be operated for a period less than the regular business hours of the entire store.

The following shall apply to lock out pharmacies or prescription departments:

(1) **Separate area.** The prescription room shall be separated from other departments of the store by a floor to ceiling partition which shall be a secure partition, secured by lock from other departments of the store.

(2) **Space.** No prescription department shall occupy less than 125 square feet of space, all of which must be contiguous and on the same floor level.

(3) **Responsibility.** The prescription department or pharmacy will be under the direction and in the charge of a registered pharmacist or assistant pharmacist at all times the department is open for business.

(4) **Minimum hours.** The hours of said department shall be a minimum of forty (40) hours per week five (5) days per week, excluding holidays.

(5) **Posting of hours.** The business hours of the prescription department shall be plainly posted on all entrances to such department and no unregistered personnel will have access to this department either before or after these hours.

(6) **Equipment.** The equipment of such pharmacy departments shall be the same as specified in the regular application for pharmacy license contained in 535:15-3-4.

#### **535:15-3-6. Required library reference books or computer sources**

A pharmacy library shall contain the following current reference books or computer sources:

(1) **Oklahoma law books.** The latest copy of Oklahoma State Laws and Rules Pertaining to the Practice of Pharmacy and a recent copy of Oklahoma State Bureau of Narcotics & Dangerous Drugs Control Rules.

(2) **Library menu.** A recent copy of any two of the following:

(A) USP/NF (3 years or latest edition);

(B) Merck Manual (3 years or latest edition);

(C) Remington (6 years);

(D) A toxicology reference (3 years);

(E) Mosby's Drug Consult (2 years);

(F) Facts and Comparisons (2 years);

(G) ASHP, American Hospital Formulary Service (AHFS) Drug Information (2 years);

(H) Monthly Prescribing Reference (MPR) (2 years);

(I) Drug Information Handbook (2 years);

(J) Thomson Micromedex, USP-DI (2 years); and/or,

(K) Current computer professional pharmacy reference program, approved by the Board (not duplicating a hard copy reference) e.g. one or two of the following:

(i) Thomson Micromedex, USP-DI

(ii) Clinical Pharmacology

(iii) Facts and Comparisons

(iv) Natural Medicines Comprehensive Database

(v) Trissel's 2 Clinical Pharmaceutical Database

- (vi) Unlimited internet access to internet professional pharmacy reference program, e.g. WEB MD

**535:15-3-7. Condemnation authority for open packages of drugs taken in thefts/burglaries**

The Board of Pharmacy or their authorized representatives shall be the authority to condemn any packages of drugs taken in a criminal action and that these drugs be destroyed and not returned to the owner as these drugs would be unfit for human consumption.

**535:15-3-8. Closing a drug store; violation notice**

In the event it becomes necessary for the Board to close a drug store for a direct violation of the Oklahoma State Pharmacy law the following notice shall be placed on the front door where it will be plainly visible to the public. This sign should not be less than 10" by 12". This sign should have letters not less than one-half inch in height.

"This drug store closed by order of the Oklahoma State Board of Pharmacy for (violation stated) . . . . ., which is a direct violation of . . . . . (pharmacy law section) . . . . ."

**535:15-3-9. Non-resident pharmacies**

(a) **Definitions.** "Non-resident pharmacy" means a pharmacy, not located in Oklahoma, that transacts or does business in Oklahoma by soliciting, receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

- (b) **Licensing requirements.** A non-resident pharmacy shall:
- (1) make application and receive an annual non-resident pharmacy license at a fee set by the Board;
  - (2) maintain in good standing a pharmacy license in its resident state; and,
  - (3) comply with the Oklahoma Secretary of State requirements for conducting business in this state.

(c) **Laws and regulations.** Oklahoma pharmacy laws and regulations shall apply to the practice of pharmacy for the Oklahoma portion of the non-resident pharmacy's practice or operation.

- (1) The pharmacist manager (pharmacist in charge (PIC)) and all other pharmacists performing pharmacist-only functions in Oklahoma licensed non-resident pharmacies must be currently licensed in the state in which they are practicing.
- (2) The pharmacist manager (PIC) and/or pharmacy owner(s), or partners, or corporate officer(s) shall be responsible for compliance with Oklahoma laws and regulations pertaining to the provisions of

receiving, dispensing, and/or delivering prescription medications and devices to Oklahoma residents.

(3) The requirement of 535:15-3-9 (c) and (e) shall apply only to the extent that such requirements are consistent with the laws and rules of the pharmacy's resident state.

(d) **Inspections.** Non-resident pharmacies are subject to inspection as follows:

- (1) Oklahoma pharmacy inspectors may conduct on-site periodic routine inspections during reasonable business hours; or
- (2) The Oklahoma Board may request copies of the resident state Board of Pharmacy's periodic routine inspection reports.

(e) **Records.** Prescription records documenting prescriptions delivered and distributed to Oklahoma residents shall be identifiable, readily retrievable and available for Board review.

- (1) Records must be maintained for not less than five years.
- (2) Patient records shall comply with 535:15-3-14.
- (3) Schedule II prescription records should be sent to the Oklahoma Schedule Two Abuse Reduction (OSTAR) program as set out in Title 63 of the Oklahoma Statutes.

(f) **Counseling services.** Non-resident pharmacies shall provide an accessible toll-free telephone counseling service with a licensed pharmacist for patient drug inquiries during regular working hours. The counseling provided shall comply with the pharmaceutical care requirements listed in OAC 535:10-9.

(g) **Prescription integrity.** A pharmacy shall not increase the quantity of a prescription without the authorization of the prescriber.

**535:15-3-10. Inventory**

(a) **Change of ownership or pharmacy manager inventory.** When changing the owner or pharmacy manager, a controlled drug inventory must be taken and sent to the Board within ten (10) days. (It is recommended that both the out-going and in-coming managers sign the inventory). The inventory must indicate the new manager's name and registration number. The inventory should indicate the former manager's name, registration number and current employment, if known.

(b) **Inventory at renewal.** An inventory of all controlled dangerous substances (CDS) must be taken between May 1 and July 1 of each year. A copy of this inventory will be included with the pharmacy renewal application.

**535:15-3-11. Prescription drugs**

(a) **Authorization; Original and refill prescriptions.** No prescription for a "dangerous drug" (as defined in Title 59, O.S., Section 353.1) shall be filled or refilled without the authorization of a practitioner licensed by law to prescribe within the scope of his practice.

(b) **Refill time limit; Non-CDS prescriptions.** Prescriptions may only be refilled as authorized by the prescriber. There shall be a maximum of one year from date of original prescription that the prescription may be refilled. At that time a new prescription shall be required.

(c) **Drug expiration dating.** All outdated prescription drugs shall be removed from the active inventory area upon expiration and cannot be used to fill prescriptions. The removal from the pharmacy of these expired drugs must occur within six months either by destruction or by being returned to the supplier.

### **535:15-3-12. Transfer of prescription refill information**

For the purpose of refill dispensing, the transfer of original prescription drug order information is permissible between pharmacies, subject to the following requirements:

(1) the transfer of original prescription drug order information for dangerous drugs is permissible between pharmacies:

(A) for up to the number of originally authorized refills remaining on Rx Only drugs that are not controlled; or

(B) on a **one-time** basis only, the transfer of original prescription and refill information for a controlled dangerous substance (**CDS**) listed in Schedules III, IV or V for the purpose of refill dispensing. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(2) the transfer must be communicated orally directly between two licensed pharmacists and/or licensed interns;

(3) both the original and the transferred prescription drug order must be maintained for a period of five years from the date of last refill;

(4) the pharmacist transferring the prescription drug order information shall:

(A) write the word "void" on the face of the invalidated prescription drug order; and

(B) record on the reverse of the invalidated prescription drug order the following information:

(i) the name and address of the pharmacy to which such prescription drug order is transferred;

(ii) the last name and registration number of the pharmacist receiving the prescription drug order information;

(iii) the last name and registration number of the pharmacist transferring the prescription drug order information;

(iv) the date of the transfer; and

(v) as required in federal DEA rules, pharmacies must exchange and document the sending and receiving pharmacy DEA number on a controlled dangerous substance prescription transfer.

(5) the pharmacist receiving the transferred prescription drug order information shall:

(A) write the word "transfer" on the face of the transferred prescription drug order, see 535:15-3-12 (8); and

(B) record on the transferred prescription drug order the following information:

(i) the date of the original prescription (refills are allowed only as prescribed for a one-year maximum from original prescription date on non-scheduled, as stated in 535:15-3-11 (b) et seq. and up to five refills for no more than six months on Schedule III-V, as stated in 475:30-1-11 (a));

(ii) the original prescription number and the number of refills authorized on the original prescription drug order;

(iii) the number of valid refills remaining and the date of last refill;

(iv) the name and address of the pharmacy from which such prescription information is transferred;

(v) the last name and registration number of the pharmacist transferring the prescription drug order information; and,

(vi) as required in federal DEA rules, pharmacies must exchange and document the sending and receiving pharmacy DEA number on a controlled dangerous substance prescription transfer.

(6) pharmacies with computer systems shall invalidate the prescription drug order in their system for purposes of filling or refilling, but shall maintain the information for refill history purposes;

(7) if the computer system has the capacity to store all of the information required in (4) and (5) of this paragraph, the pharmacist is not required to record this information on the original or transferred prescription drug order.

(8) the computer system used by the pharmacy receiving the transfer must be able to show that a CDS or scheduled prescription is a transferred prescription. (This is to prevent the possible second transfer of a Scheduled prescription in violation of federal law and 535:15-3-12 (1).)

#### **535:15-3-12.1. Electronic transfer of prescription refill information**

(a) Two or more pharmacies that have established and use a common electronic file to maintain required prescription information may transfer the

refill information electronically as described in Subsection (b), except as restricted in 535:15-3-12(1).

(b) Electronic transfer of prescription refill information shall be completed by a licensed pharmacist as follows:

- (1) Prior to the transfer or dispensing the pharmacist accessing the file of the original pharmacy shall review the profile of the patient.
- (2) There shall be the ability in the electronic transfer file system for the pharmacist to void the original prescription and identify the pharmacy and pharmacist taking the prescription refill information.
- (3) The original pharmacy shall be notified electronically of the transfer.
- (4) The rules in 535:15-3-12 (1), (3) and (5)(B),(i),(ii), (iii) apply to electronic transfers.

### **535:15-3-13. Pharmacist's responsibility in a pharmacy**

(a) **Access to drugs.** Only a pharmacist shall be responsible for control and distribution of all drugs.

- (1) Only the pharmacist shall be permitted to unlock the pharmacy area or any additional storage areas for dangerous drugs, except in extreme emergency.
- (2) An extreme emergency shall be in case of fire, water leak, electrical failure, public disaster or other catastrophe whereby the public is better served by overlooking the safety/security restrictions on drugs.
- (3) Prescription medications shall not be left outside the prescription area when the pharmacist is not in attendance.

(b) **Professional judgement.** A pharmacist is required to exercise sound professional judgement with respect to the legitimacy of a prescription. The law does not require a pharmacist to dispense a prescription if the pharmacist doubts its origin or if he believes that the prescription may not have been issued for a legitimate medical purpose.

(c) **Legitimate purpose.** The pharmacy or pharmacist shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner acting in the usual course of the practitioner's professional practice.

(d) **Valid patient practitioner relationship.** The pharmacy or pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the prescription was issued solely on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation without a valid preexisting patient-practitioner relationship.

(e) **Valid prescription drugs.** Only those prescription drugs legal to sell in the United States shall be dispensed. (e.g. FDA approved prescription

drugs, or legally compounded prescription drugs, or drugs in a drug-testing protocol, or other legal prescription drugs.)

### **535:15-3-14. Patient records**

(a) A patient record system shall be maintained by all pharmacies for patients for whom prescription drug orders are dispensed.

(b) The patient records system shall provide for the immediate retrieval of the following information:

- (1) full name of the patient for whom the drug is intended;
- (2) address and telephone number of the patient;
- (3) patient's age or date of birth;
- (4) a list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record during the previous six months showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and
- (5) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(c) The pharmacist shall be responsible to assure that a reasonable effort is made to obtain and record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs or devices currently being used by the patient which may relate to prospective drug review.

(d) A patient record shall be maintained for a period of not less than two years. This record may be a hard copy or a computerized form.

(e) This information shall be deemed privileged and released only to the patient or, to persons designated by the patient; to those practitioners and other pharmacists where, in the pharmacist's professional judgment, such release is necessary to protect the patient's health and well being; and to such other persons or governmental agencies authorized by law to receive such confidential information. Rules regarding a pharmacist's confidentiality responsibility can be found in 535:10-3-1.1.(6) and 535:10-3-1.2.(14).

### **535:15-3-15.1. Transmission of prescription orders other than verbal**

(a) All transmitted prescription drug orders, other than verbal, shall be transmitted:

- (1) to a pharmacy of the patient's choice with no intervening person or persons altering the prescription order or breaching patient confidentiality;
- (2) by an authorized practitioner; or his designated agent when
  - (A) designated agents are allowed by the practitioner's practice act, and

(B) if transmitting designated agent's identity is included in the order.

(b) Transmitted prescription drug orders shall include the transmitter's phone number for verbal confirmation, the time and date of transmission and the identity of the pharmacy intended to receive the transmission;

(c) The pharmacist shall exercise professional judgment regarding the accuracy, validity and authenticity of a prescription drug order transmitted consistent with federal, state and local laws and rules.

(d) All equipment for receipt of prescription drug orders shall be maintained so as to ensure against unauthorized access.

(e) Prescriptions may be transferred if all requirements of federal, state and local laws and rules are met.

(f) No agreement between a prescribing practitioner and a pharmacy or device and medical equipment holder shall require that prescription orders be transmitted from the prescribing practitioner to only that pharmacy or device or medical equipment permit holder.

#### **535:15-3-16. Adequate staffing rules for pharmacists and pharmacies**

(a) Adequate staffing to safely fill prescriptions is the responsibility of the pharmacy, the pharmacy manager, and the pharmacist. If conditions exist that could cause prescriptions to be filled in an unsafe manner they shall take action to correct the problem.

(b) In order to ensure adequate staffing levels there shall be a staffing report form available in each pharmacy. A copy of this form, when executed, will be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection.

(1) Such form shall include, but not be limited to the following:

- (A) Date and time the inadequate staffing occurred;
- (B) Number of prescriptions filled during this time frame;
- (C) Summary of events; and
- (D) Any comments or suggestions.

(2) Such forms are not to be sent to the Board.

(c) A pharmacist shall complete the staffing report form when:

(1) A pharmacist is concerned regarding staffing:

- (A) inadequate number of support persons (cashiers, technicians, auxiliary supportive personnel, etc.); or,
- (B) excessive workload;

(2) Filling out the form may enable management to make a better decision concerning staffing.

(d) If the pharmacy manager feels the situation warrants earlier Board review the pharmacy manager should inform the Board.

(e) Each pharmacy shall review completed adequate staffing forms and address any issues described as well as documenting any corrective action taken or justification for inaction to assure continual self-improvement. If

issue is not staffing related, describe what measures are being taken to address the issue.

(f) Each pharmacy shall retain completed adequate staffing forms until reviewed and released by the Board. Such forms requiring further review may be held by the Board and may become part of an investigation file.

(g) A registrant including pharmacy, a pharmacy manager, or a pharmacist shall not be subject to discipline by the employing pharmacy for completing a staffing report form in good faith.

#### **535:15-3-17. Pharmacy prescription records**

The original prescription shall be maintained and readily retrievable for five years.

#### **535:15-3-18. Pharmacy prescription drug purchase records**

(a) All prescription purchases (e.g. invoices, etc.) and inventory records shall be maintained and be readily retrievable for a period of at least 2 years.

(b) A pharmacist and/or pharmacy shall exercise careful professional judgment regarding where they purchase the pharmacy's drugs to assure a safe and sanitary drug supply is maintained. Prescription drug purchases may only be made from entities licensed to sell such drugs.

#### **535:15-3-19. Three prescription files**

Three prescriptions files will be kept as follows:

- (1) Dangerous Drugs file,
- (2) Controlled Dangerous Substances (CDS) - Schedule II's file, and
- (3) Controlled Dangerous Substances (CDS) - Schedule III's, IV's, V's file.

#### **535:15-3-21. Prescription fill, refill and partial fill records and reports**

(a) **Dangerous drugs.**

- (1) Refills may be entered on the back of each original prescription.
- (2) Refills may be kept by using an automated data processing system to maintain the refill information.

(b) **Controlled dangerous Substances (CDS) - Schedule II.** No refills are allowed on Schedule II CDS.

(c) **Controlled dangerous Substances (CDS) - Schedule III, IV and V Hard copy method.** The refills are entered on the back of the original (hard copy) prescription according to Oklahoma Bureau of Narcotics and Dangerous Drugs' rules in OAC 475:30-1-11 et seq.

(d) **CDS automated data processing method.** A pharmacy may elect to use an automated data processing system to maintain the prescription files including the original information the refill information. **Caution:** The pharmacy must maintain complete and retrievable prescription records for five years whether you use logbooks, nightly reports, or a manual system. If

the pharmacy elects the automated system certain compliance reports will be required.

(1) **Nightly reports.** Nightly reports will be required for Schedule II's and for Schedule III, IV and V's. These reports will include but are not limited to:

(A) Schedule II reports will include the information in ASAP/NABP Committee on Standardization's Computerized Compliance Reports (e.g run date, run by, Rx #, drug name, dose form, quantity, date written, date dispensed; pharmacist, patient and prescriber names, DEA number, and patient and prescriber addresses.)

(B) Schedule III, IV and V's reports will include the same information as in (A) above, except patient and prescriber address are not required. These reports may be mixed or be Schedule III, IV or V specific.

(C) These nightly reports shall be verified, signed and dated by the pharmacist as required. (See CFR 1306.22 (b) (3), et seq.)

(D) These reports must be kept for five years.

(2) **Logbook or file alternate procedure.** In lieu of the nightly reports procedure for Schedule II, III, IV & V's provided in 535:15-3-21, the pharmacy may choose to use the following method:

(A) The pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such refill dispensing shall sign a statement (in the manner described in CFR 1306.22 (b)) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by them and is correct as shown.

(B) Such a book or file must be maintained at the pharmacy employing such a system for a period of five years after the date of dispensing the appropriately authorized refill.

(3) **Refill reports.** Any pharmacy using an automated data processing system to track refills shall be able to print such reports as required in CFR 1306.22 (b) et seq.

(4) **Audit reports.** If an automated data processing system is used to maintain refill information, the ability to print upon request the following Controlled Dangerous Substance (CDS) audit reports is required. The following required audit reports must include the information in ASAP/NABP Committee on Standardization's Computerized Compliance Reports:

- (A) CDS Audit Report by Drug
- (B) CDS Audit Report by Prescriber
- (C) CDS Audit Report by Pharmacist
- (D) Patient Profile Report

## CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS SUBCHAPTER 3. APPLICANTS, REGISTRANTS, AND APPLICATIONS

### 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.)

(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.)