

This supplement to the 2016 OKLAHOMA PHARMACY LAW BOOK contains revised rules effective September 11, 2017.

Pharmacy Board Officers and Members

Kyle Whitehead, D.Ph., President Enid
Mark St. Cyr, D.Ph., Vice-President Jones
Greg Adams, D.Ph., Member Clinton
Jim Spoon, D.Ph., Member Sand Springs
Justin Wilson, D.Ph., Member Norman
Stephen Dudley, Public Member Edmond

It is the sincere desire of the members of the Oklahoma State Board of Pharmacy together with the Executive Director and employees to perform a uniform service to the citizens of this state.

All correspondence should be addressed to:

Chelsea O. Church, Pharm.D., D.Ph., Executive Director
Oklahoma State Board of Pharmacy
2920 N. Lincoln Boulevard, Suite A
Oklahoma City, OK 73105

Phone: (405) 521-3815

Fax: (405) 521-3758

E-mail: pharmacy@pharmacy.ok.gov

Website: www.pharmacy.ok.gov

CHAPTER 1. ADMINISTRATIVE OPERATIONS

SUBCHAPTER 7. INDIVIDUAL PROCEEDINGS

535:1-7-3. Hearings

(a) **Notice time; continuances.** The time set for a hearing, specified in the notice, shall not be less than ten (10) days after the date of the notice. Written motions for any continuances or extensions of time shall state the time desired and the reasons for the request, and shall be filed with the Board at least five (5) business days before the hearing, and may be denied by the Director if not filed at least (five) 5 business days before the hearing. The Director is authorized to rule on said motions. If the motion is denied; the party may renew the request for continuance at the hearing.

(b) **Imminent Danger Suspension.** If the Director finds that there is imminent danger to the public health or safety, he may immediately suspend any registration simultaneously with the scheduling of a Board hearing.

(1) **Method.** The registrant shall be notified of such suspension through an imminent danger letter signed by the Director.

(2) **Notice.** Notice shall be given in the manner described in 535:1-7-2.

(c) **Order of procedure.** Hearings shall be conducted in an orderly manner by the President of the Board, or his designee. The order of procedure and rules of evidence shall be those specified by the Oklahoma Administrative Procedures Act.

(d) **Admissibility.** The President of the Board, or his designee, shall rule upon the admissibility of evidence and objections thereto, and shall rule upon other motions or objections arising in the course of the hearing.

CHAPTER 15. PHARMACIES

SUBCHAPTER 3. PHARMACIES

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) **PIC.** Each pharmacy, in order to obtain and maintain a pharmacy license, must have a licensed pharmacist as the PIC.

(1) A PIC 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) Failure of the pharmacy to have a PIC who fulfills these responsibilities is a violation of this code by both the pharmacy and PIC.

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

(4) The PIC shall be present and practicing at the pharmacy for which he holds the PIC position no less than 20 hours per week during the pharmacy's ordinary course of business. In the event the pharmacy's normal hours of business are less than 40 hours per week the PIC shall be present and practicing at least 50 percent of the normal business hours.

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

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

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

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

(3) The pharmacy and/or PIC shall notify the Board immediately by certified mail 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 PIC is terminated for such reason, the owner or other person in charge of the pharmacy shall notify the Board by certified mail.

(4) The pharmacy, pharmacist, and/or PIC shall establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.

(5) The pharmacy, pharmacist and PIC are responsible for supervision of all employees as they relate to the practice of pharmacy.

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

(4) The pharmacy, pharmacist, and/or PIC shall establish and maintain effective controls against the diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels as provided by federal, state or local laws or rules.

(5) The pharmacy, pharmacist and PIC are responsible for supervision of all employees as they relate to the practice of pharmacy regarding automation.

(e) **Responsibilities for personnel identification.** The PIC and the pharmacy are responsible to assure that the public is 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.

(f) **Written drug diversion detection and prevention.** The pharmacy, pharmacist, and/or PIC shall implement and follow a written drug diversion detection policy. The policy shall be available for Board review.

(g) **Inspections.** Pharmacies are subject to inspection. The Board and/or its authorized representatives may conduct on-site periodic routine inspections and investigations during reasonable business hours.

535:15-3-17. Pharmacy prescription records

(a) The original prescription [as defined in 353.1] shall be maintained and readily retrievable for five years.

(b) Faxed prescriptions received in electronic format (which have not been printed) or electronically transmitted prescriptions may be electronically stored and maintained in a readily retrievable format for five years.

(c) Prescriptions for controlled dangerous substances (CDS) must additionally meet the requirements of the federal Drug Enforcement Administration (DEA) and the Oklahoma Bureau of Narcotics and Dangerous Drugs (OBNDD).

CHAPTER 15. PHARMACIES

SUBCHAPTER 5. HOSPITAL PHARMACIES

535:15-5-2. 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.

"Auxiliary supportive personnel" or **"auxiliary supportive person"** means all persons, other than pharmacists, interns and techs, who are regularly paid employees of the hospital pharmacy and who work or perform tasks in the hospital pharmacy that do not require a permit or license (e.g. clerk, typist, delivery, or data entry person, etc.).

"Certified medication order" means a filled prescription that has been reviewed and certified by a pharmacist.

"Certified pharmacy technician" means a pharmacy technician who has a current Board approved pharmacy technician certification in addition to a current Oklahoma pharmacy technician permit.

"Director of Pharmacy" means a pharmacist licensed to engage in the practice of pharmacy in Oklahoma who is thoroughly familiar with the specialized functions of a hospital pharmacy and directs the activities of a hospital pharmacy.

"Drug room" means a secured room where drug inventories are maintained for use in a facility licensed and regulated by the Oklahoma Health Department, and which may be inspected by the Board.

"Hospital employee" means any individual employed by a hospital whose compensation for services or labor actually performed for a hospital is reflected on the payroll records of a hospital.

"Hospital" or "Hospital facility" or means hospital as defined in 59 O.S. Section 353 et seq.

"Hospital pharmacy" means the place or places in which drugs, chemicals, medicines, prescriptions, or poisons are stored, controlled and prepared for distribution and administration for the use and/or benefit of patients in a hospital facility. Hospital pharmacy shall also mean the place or places in which drugs, chemicals, medicines, prescriptions or poisons are compounded and prepared for dispensing to the members of the medical staff, hospital employees, and the members of their immediate families, patients being discharged, and for other persons in emergency situations.

"Medical staff" means a prescriber who has privileges to practice in the hospital facility.

"Medication order" means a prescription as defined in Title 59 O.S. Section 353.1.

"Pharmacist" means any person licensed to practice pharmacy by the Oklahoma Board.

"Pharmacy technician", "Tech", "Technician" or "RxTech" means a person who has been issued a permit by the Board to assist the pharmacist and performs nonjudgmental, technical, manipulative, nondiscretionary functions in the prescription department under the pharmacist's immediate supervision.

"Remote medication order processing" or "RMOP" means the processing of a medication order for a hospital facility by a pharmacist located in a remote medication order processing pharmacy site. Remote medication order processing does not include the dispensing of a drug, but may include receiving, interpreting, evaluating, clarifying and approval of medication orders. Additionally, remote medication order processing may include order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, performing therapeutic interventions, and providing drug information services, and authorizing release of the medication for administration.

"Remote site" means a site located within the continental United States (US) or District of Columbia (DC) that is electronically linked to the hospital via a computer and/or other electronic communications system as defined in the operations, policies and procedures manual of a hospital pharmacy for the purposes

of remote medication order processing (RMOP) of a remote medication order processing pharmacy.

"Supportive personnel" means supportive personnel as defined in 59 O.S Section 353.1 et seq.

CHAPTER 15. PHARMACIES

SUBCHAPTER 6. HOSPITAL DRUG ROOM

535:15-6-8. Emergency dispensing and pre-packaged medications

(a) **Emergency dispensing.** A pharmacist or licensed practitioner on duty may label and dispense an appropriate supply of a medication from the hospital drug room when ordered by a prescriber for a patient of the hospital to take with them when dismissed. An appropriate supply would include only sufficient doses required from the time of dismissal until resumption of normal business hours of local pharmacies.

(b) **Pre-packaged medications.** A pharmacist may pre-package medications in sufficient amounts to meet the immediate needs of patients of the hospital. The pre-dispensed medications must be labeled and packaged properly as required under sub-section 535:15-6-7 (c) Labeling, excepting items B, C, D, and E, and adding the medication expiration date and lot number. Such pre-packaged medications shall be securely stored, and an accurate accounting of their use shall be kept.

(1) When such medications are ordered by prescriber, to be used after dismissal from the hospital, the prescriber [with dispensing privileges] shall complete the medication label with the appropriate information including the patient's name, the prescriber's name, appropriate directions for use, the date the medication is distributed to the patient, and an identifying number.

(2) The prescriber who orders the medication shall be responsible for appropriate patient counseling and drug information dissemination.

CHAPTER 15. PHARMACIES

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PRODUCTS

535:15-10-11. Pharmacy generated preparations requirements

- (a) A Pharmacy Generated Preparations (PGP) if prepared from RX Only drugs, may not exceed recommended OTC strengths and doses.
- (b) PGP will be labeled properly and will be sold with the public's health and welfare in mind.
- (c) Compounded PGP's are to be sold directly to the consumer after professional interaction or consultation with the health care provider and the consumer.
- (d) A PGP cannot be bulk compounded to sell to a second entity for resale. This would require a manufacturer's license.
- (e) Compounded PGPs must be labeled in compliance with FDA OTC labeling regulations.

535:15-10-12. Compounding for a prescriber's office use [REVOKED]

535:15-10-13. Compounding veterinarian preparations

- (a) Prescriptions for animals may be compounded based on an order or prescription from a licensed prescriber.
- (b) Compounded preparations must comply with federal statutes, rules and FDA guidances.
- (c) Caution should be taken ~~as~~ to not violate federal patent laws by duplicating an available product in inordinate quantities.
- (d) Compounding with bulk chemicals for food-producing animals is not permitted.

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SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL

535:15-13-6. Duties

(a) The following tasks may be performed by auxiliary supportive personnel:

- (1) retrieval tasks such as retrieving prescriptions or files as necessary;
- (2) clerical tasks such as data entry, typing labels and maintaining patient profiles;
- (3) secretarial tasks such as telephoning, filing, and typing;
- (4) accounting tasks such as record keeping, maintaining accounts receivables, third party billing and posting;
- (5) inventory control tasks including monitoring, pricing, dating, invoicing, stocking pharmacy, and preparation of purchase orders; and
- (6) help maintain a clean and orderly pharmacy.

(b) The following tasks may be performed by pharmacy technicians:

- (1) count and/or pour medications;
- (2) prepackage (e.g. unit dose) and properly label medications;
- (3) affix the prescription label to the proper container;
- (4) affix auxiliary labels to the container as directed by the pharmacist;
- (5) reconstitution of medications (i.e. liquid antibiotics);
- (6) bulk compounding, including such items as non-sterile topical compounds, sterile bulk solutions for small volume injectables, sterile irrigation solutions and products prepared in relatively large volume for internal or external use. Documentation of a system of in-process and final checks and controls must be developed or approved by the certifying pharmacist and carefully and systematically enforced;
- (7) functions involving reconstitution of single dose units of sterile compounded preparations that are to be administered to a given patient as a unit, and functions involving the addition of one manufacturer's prepared unit (whole or in part) to another manufacturer's prepared unit if the unit is to be administered as one dose to a patient. The pharmacist must establish the procedures for compounding sterile preparations and certify the ingredients, label and finished preparation;
- (8) any duties auxiliary personnel are allowed to perform;
- (9) assist the pharmacist in the annual CDS inventory. The pharmacist remains responsible for completeness and accuracy; and,
- (10) take verbal authorizations from licensed prescriber or licensed prescriber's authorized agent (when allowed) for refill of non-controlled prescriptions with no changes to strength or directions.

CHAPTER 15. PHARMACIES

SUBCHAPTER 15. HOME CARE AGENCY PHARMACY AGREEMENTS

535:15-15-1. Definitions

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

"Administer Drugs" means the direct application of a drug as defined in Title 59, O.S., Section 353.1.

"Authorized Employee" means any employee of a Home Care Agency who in the course of their duties, is licensed by their appropriate Board to administer legend or dangerous drugs.

"Home Care Agency" or **"HCA"** means an entity required to license under the 1992 Home Care Act with the Oklahoma State Department of Health.

"Pharmacy manager" or **"PIC"** means the PIC as described in 535:15-3-2.

CHAPTER 15. PHARMACIES

SUBCHAPTER 17. NUCLEAR PHARMACY

535:15-17-5. General requirements

(a) A permit to operate a nuclear pharmacy shall only be issued to a person who is, or who employs a qualified nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals and ancillary drugs shall be under the direct supervision of a qualified nuclear pharmacist, who shall be in personal attendance when the pharmacy is open for business. The nuclear pharmacist-in-charge shall be responsible for all operations of the pharmacy.

(b) The permit to operate a nuclear pharmacy is effective only so long as the pharmacy also holds a current Radioactive Material License issued by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency. Copies of inspection reports from Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission, or appropriate agreement state nuclear regulatory agency shall be available for Board inspection.

(c) Nuclear pharmacies shall have adequate space and equipment, commensurate with the scope of services required and provided, meeting minimal space requirements established for all pharmacies in the state. All pharmacies handling radiopharmaceuticals shall include, but not be limited to, the following areas: radiopharmaceutical preparation/dispensing area; radioactive material shipping / receiving area; radioactive material storage area; and radioactive waste decay area.

(d) The nuclear pharmacy professional service area shall be secured from unauthorized personnel and must be totally enclosed and lockable.

(e) Nuclear pharmacies shall maintain records of acquisition, inventory and disposition of all radioactive drugs and other radioactive materials in accordance with Board and Nuclear Regulatory Commission statutes and regulations.

(f) Nuclear pharmacies shall compound and dispense radiopharmaceuticals in accordance with accepted standards of radiopharmaceutical quality assurance, including compounded sterile products. The Board recognizes that the preparation of radiopharmaceuticals involves the compounding skills of the nuclear pharmacist to assure that the final drug product meets accepted professional standards.

(g) A radiopharmaceutical shall be dispensed only to a licensed prescriber authorized by the Oklahoma Department of Environmental Quality Control, or if in another state the Nuclear Regulatory Commission or appropriate agreement state nuclear regulatory agency to possess, use and administer such drug. A radiopharmaceutical shall be dispensed only upon receipt of a prescription or medication order from such licensed prescriber. Otherwise, a radiopharmaceutical may be transferred to a person who is authorized to possess and use such drug for non-clinical applications as described in 535:15-17-5 subsection (k) below. Separate records will be kept for these transfers and sales, see drug supplier permit rules in 535:15-7.

(h) A nuclear pharmacy, upon receiving an oral prescription order for a radiopharmaceutical, shall immediately have the prescription order reduced to writing, or recorded in a data processing system.

(1) This writing or record shall contain at least the following:

(A) the name of the institution and prescriber, or prescribers' agent;

(B) the date of dispensing (or calibration) and the calibration time of the radiopharmaceutical;

(C) the name of the procedure;

(D) the name of the radiopharmaceutical;

(E) the dose or quantity of the radiopharmaceutical;

(F) the serial number assigned to the order for the radiopharmaceutical;

(G) any specific instructions; and

(H) the initials of the pharmacist who dispensed the order.

(2) Whenever an order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing.

(i)

(1) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

- (A) the name and address of the pharmacy;
- (B) the name of the prescriber;
- (C) the date of dispensing (or calibration);
- (D) the serial number assigned to the order for the radiopharmaceutical;
- (E) the standard radiation symbol;
- (F) the words "Caution Radioactive Material";
- (G) the name of the procedure;
- (H) the radionuclide and chemical form;
- (I) the amount of radioactivity and the calibration date and time;
- (J) if a liquid, the volume;
- (K) if a solid, the number of items or weight;
- (L) if a gas, the number of ampules or vials;
- (M) the BUD and time; and,
- (N) the name of the patient or the words e.g. "Per Physician's Orders" in the absence of a patient name.

(2) When the prescription is for a therapeutic or blood-product radiopharmaceutical, the patient name shall appear on the label. The requirements of this sub-section shall be met when the name of the patient is readily retrievable from the physician upon demand.

(j) The inner container label of a radiopharmaceutical to be dispensed shall be labeled with, but not limited to:

- (1) the standard radiation symbol;
- (2) the identity of the radionuclide;
- (3) the amount of radioactivity and the calibration date and time;
- (4) the name of the procedure; and
- (5) serial number of the radiopharmaceutical.

(k) When a radiopharmaceutical is dispensed under the authority of an Investigational New Drug Application (IND), the nuclear pharmacy records shall include an investigator's protocol for the preparation of the radiopharmaceutical, a copy of the institutional radiation safety committee or equivalent radioactive use oversight committee approval, a copy of the Institutional Review Board approval form (or letter), and a letter from the manufacturer (sponsor) indicating that the physician requesting the radiopharmaceutical is a qualified investigator.

(l) Each nuclear pharmacy shall have an adequate library and a current copy of state and federal regulations governing the safe storage, handling, use, dispensing, transport and disposal of radiopharmaceuticals.

CHAPTER 20. MANUFACTURERS, REPACKAGERS, OUTSOURCING FACILITIES, WHOLESALERS, THIRD-PARTY LOGISTICS PROVIDERS, AND MEDICAL GAS SUPPLIERS AND DISTRIBUTORS

SUBCHAPTER 6. OUTSOURCING FACILITIES

535:20-6-6. Personnel

(a) Outsourcing facilities shall establish and maintain for Board inspection a list of each partner, limited liability company member or corporate officer and corporate director, as well as designated representatives and facility managers, including a description of their duties and a summary of their qualifications.

(b) Each outsourcing facility shall designate, in writing on a Board-approved form, a person to serve as the designated facility manager of the outsourcing facility for each location licensed.

(c) Each outsourcing facility shall designate, in writing on a Board-approved form, a person to serve as the PIC who is a pharmacist licensed by the Board. No pharmacist may serve as the PIC for more than one outsourcing facility and/or pharmacy at a time unless they are located at the same physical address and are dually licensed with the Board.

(d) No outsourcing facility shall have as an owner, designated representative, facility manager, or pharmacist-in-charge anyone convicted of any felony for conduct relating to compounding prescription drugs, any felony for violation of 21 U.S.C. § 331(i) or (k) or any felony for violation of 18 U.S.C. § 1365 relating to product tampering. No outsourcing facility shall have as an owner, designated representative, facility manager or pharmacist-in-charge anyone who has violated federal or state requirements for licensure that presents a threat of serious adverse health consequences or death to humans.

CHAPTER 25. RULES AFFECTING VARIOUS REGISTRANTS

SUBCHAPTER 9. VIOLATIONS OF THE RULES OF REGISTRANT CONDUCT

535:25-9-9. Misfill or incorrect fill of a prescription or drug order

The incorrect fill or misfill 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.