

## 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. This requirement shall not apply to charitable pharmacies, Remote Medication Order Processing (RMOP) pharmacies or hospital drug rooms.
- (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.
- (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.

(h) **Remodel.** The pharmacy and the PIC are responsible to notify the Board in writing in advance of any remodel in the pharmacy that would result in a change in square footage or additional storage areas. Such pharmacy shall be subject to inspection by the Board and shall be required to pay an inspection fee.

(i) **Closing of a Pharmacy.** The pharmacy and the PIC are responsible to notify the Board in writing within ten (10) days of closing a pharmacy. The notification shall include, but not be limited to:

- (1) Date of closing
- (2) Copy of final CDS inventory,
- (3) Disposition of pharmacy records,
- (4) Disposition of prescription drugs, and
- (5) Return of pharmacy license.

(j) **Reporting.**

(1) The pharmacy and the PIC shall report any theft or significant loss of any drugs to the Board within one day of discovery. The pharmacy and the PIC must complete and submit a DEA 106 form for any theft or significant loss of controlled substances to DEA within the required time. A copy shall be sent to the Board within fourteen (14) days of the filing of the DEA Form 106.

(2) A change in PIC must be reported to the Board in writing within ten (10) days,

(3) A pharmacy that is closing due to lack of staffing or for some other reason and will not be open during normal business hours when patients would expect the pharmacy to be open must email the following information to the Board within twenty-four (24) hours.

- (A) License number of the pharmacy.
- (B) Name of the pharmacy.
- (C) Address of the pharmacy.
- (D) Name of the pharmacist in charge (PIC).
- (E) Date(s) that the pharmacy will be closed.
- (F) Hours the pharmacy will be closed.
- (G) Detailed explanation for closing.

## SUBCHAPTER 5. HOSPITAL PHARMACIES

### 535:15-5-7.1. Pharmacy technician qualifications and training

(a) A pharmacy technician must have completed a high school education or G.E.D. equivalence, be of good moral character, be non-impaired (e.g. alcohol or drugs) and have adequate education to perform assigned duties.

(1) Pharmacy technician applicants who are seventeen (17) years of age or older and enrolled in a youth apprenticeship program for pharmacy technicians or a pharmacy technician training program through the Oklahoma Department of Career and Technology Education shall complete Phase II pharmacy technician training in a pharmacy without the requirement to be a pharmacy employee. All pharmacy technician training programs shall be approved by the Oklahoma State Board of Pharmacy initially and on an annual basis. This permit will only be used for educational purposes for those enrolled in an Oklahoma State Board of Pharmacy-approved program.

(2) The youth apprenticeship program for pharmacy technicians and pharmacy technician training programs through the Oklahoma Department of Career and Technology Education shall carry liability insurance on the students in the respective program that covers the student anywhere the student is training in a pharmacy.

(3) Any pharmacy technician enrolled in an approved training program shall be directly supervised by a pharmacist in the same manner as any other regularly paid pharmacy employee.

(b) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job training (OJT) program as described in 535:15-13-13.

(c) The Director of Pharmacy must demonstrate that the pharmacy technician has been given additional training before being allowed to prepare sterile products and that the training given is at a level consistent with the scope of pharmaceutical product being prepared.

(d) A pharmacy technician, to be eligible for a technician permit, must comply with the requirements in this Title and 535:25.

## SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL

### 535:15-13-3. Definitions

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

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

**"Certify a prescription"** means the confirmation by the supervising pharmacist of the accuracy and completeness of the acts, tasks or functions undertaken by supportive personnel to assist the pharmacist in the practice of pharmacy. This process shall be completed before the prescription is given to the patient.

**"Pharmacy technician", "Technician", or "Rx Tech"** means a person who has been issued a permit by the Board to assist the pharmacist and perform nonjudgmental, technical, manipulative, non-discretionary functions in the prescription department under the pharmacist's immediate and direct supervision.

**"Significant compounding"** means ~~compounding activity which equals at least ten percent (10%) of the prescription volume of the pharmacy.~~

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

#### **535:15-13-4. Pharmacy technician qualifications and training**

(a) A pharmacy technician must have completed a high school education, HiSet Examination, or G.E.D. equivalence, and shall be of good moral character, be non-impaired (e.g., alcohol or drugs) and have adequate education to perform assigned duties.

(1) Pharmacy technician applicants who are seventeen (17) years of age or older and enrolled in a youth apprenticeship program for pharmacy technicians or a pharmacy technician training program through the Oklahoma Department of Career and Technology Education shall complete Phase II pharmacy technician training in a pharmacy without the requirement to be a pharmacy employee. All pharmacy technician training programs shall be approved by the Oklahoma State Board of Pharmacy initially and on an annual basis. This permit will only be used for educational purposes for those enrolled in an Oklahoma State Board of Pharmacy-approved program.

(2) The youth apprenticeship program for pharmacy technicians and pharmacy technician training programs through the Oklahoma Department of Career and Technology Education shall carry liability insurance on the students in the respective program that covers the student anywhere the student is training in a pharmacy.

(3) Any pharmacy technician enrolled in an approved training program shall be directly supervised by a pharmacist in the same manner as any other regularly paid pharmacy employee.

(b) A pharmacy manager employing a currently permitted technician must document training of that technician within 10 days of hire.

(c) The pharmacy technician must, at a minimum, satisfactorily complete a pharmacy technician on-the-job training (OJT) program described in 535:15-13-13.

(d) To be eligible for a pharmacy technician permit, an applicant must maintain compliance with the requirements in this Title, 535:25 and 535:15.

#### **535:15-13-5. Supervision of pharmacy technicians**

(a) All tasks performed by pharmacy technicians must be in a licensed pharmacy located in Oklahoma and must be accomplished under the immediate and direct supervision of a pharmacist who is currently licensed by the Board.

(1) Failure by the licensed pharmacy and pharmacist manager (PIC) to provide adequate supervision; and/or failure of a pharmacist to adequately supervise a technician is a violation of these State Board of Pharmacy regulations.

(2) An intern cannot supervise a technician.

(3) Failure to adequately supervise a pharmacy technician is a violation of these State Board of Pharmacy regulations by the pharmacist, pharmacy and pharmacist manager.

(b) A pharmacy technician may perform certain non-judgmental functions of dispensing as enumerated in this Subchapter, provided that whenever the pharmacist leaves the prescription department, other than for in-pharmacy counseling of a patient, all dispensing functions listed shall cease.

(c) A ratio of no more than ~~two~~four pharmacy technicians per supervising pharmacist on duty shall be maintained.

~~(d) A licensed pharmacy that conducts significant compounding may utilize up to two pharmacy technicians specifically trained in compounding who shall, only while performing compounding duties, not be counted for the purposes of the pharmacy technician to pharmacist ratio of two pharmacy technicians to one supervising pharmacist.~~

~~(e)(d)~~ A pharmacy intern working in the pharmacy will not affect or change this ratio.

~~(f)(e)~~ The pharmacist must certify, by reviewing, the completed prescription for accuracy and completeness before the prescription is released from the prescription department. An intern cannot certify the completion of a technician filled prescription.

### **SUBCHAPTER 17. NUCLEAR PHARMACY**

#### **535:15-17-11. Supervision of licensed pharmacy technicians in a licensed nuclear pharmacy**

(a) The ratio of pharmacy technicians to supervising pharmacists shall be set by the pharmacist in charge (PIC) and shall be a ratio that would be considered safe and reasonable by the certifying pharmacist.

(b) This ratio shall not exceed ~~three~~four pharmacy technicians to one supervising pharmacist. Such technicians shall be supervised as described in 535:15-13-5 (a) (b) (e) and (f).