TITLE 535: OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 15. PHARMACIES

SUBCHAPTER 3. PHARMACIES

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, O.S. Section 2-101 et seq.

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

"**Qualified Packaging System**" means a container, along with auxiliary materials, that have been tested to ensure the final system can maintain a specific temperature range for the duration of the shipping process.

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 and shall be in a commercial location and not in a personal dwelling or residence.

(2) **Sanitary facilities.** There shall be installed the proper sanitary facilities which shall include a sink with hot (minimum 104 degrees F) 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 Executive Director of the Board to the balances requirement.~~

~~(4)~~ (3) **Library.** There shall be the necessary library which has been prescribed and standardized by the Board in Section 535:15-3-6.

~~(5)~~ (4) **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.

~~(6)~~ (5) **Exempt narcotic book.** There shall be a book suitable for the registration of all sales of exempt narcotics if such are sold or dispensed.

~~(7)~~ (6)**Poison Book.** There shall be a book suitable for the registration of all sales of poisons in accordance with applicable laws if such are sold or dispensed.

~~(8) **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.~~

~~(9) **Containers.** There shall be sufficient stock of containers suitable for the dispensing of all prescriptions both for internal and external usage.~~
~~(10) **Labels.** There shall be sufficient stock of labels both for the dispensing of prescriptions and the sale of medicines and chemicals. Label requirements are described in the Act.~~
~~(11)~~ (7) **E-Prescribing of Controlled Substances (EPCS).** Any pharmacy that dispenses controlled dangerous substances shall have computer software that supports EPCS by January 1, 2019.
(8) **Security.** There shall be an electronic alarm and video recording system in place to provide protection against theft and diversion.

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

(a) **Definitions.** "Non-resident pharmacy" means a pharmacy, not located in Oklahoma, which 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~~;~~ .

(3) Comply with the Oklahoma Secretary of State requirements for conducting business in this state~~;~~ .

(4) Submit on initial licensure and on renewals a written report of an inspection conducted within the previous twenty-four (24) months by the non-resident's state or by any organization approved by the Board~~;~~ .

(5) Be in a commercial location and not a personal dwelling or residence~~;~~ .

(6) Submit on initial licensure the name and license number of an Oklahoma licensed pharmacist in charge (PIC) who is responsible for the non-resident's pharmacy compliance with Oklahoma laws. The name of the Oklahoma licensed PIC shall be reported to the Board, in writing, with each renewal and/or within 10 days of any change of such PIC~~;~~ .

(7) The pharmacy registrant may request, in writing, that the Board allow additional time for a new pharmacist-in-charge to get Oklahoma licensed in emergency or urgent situations. If the Board determines circumstances warrant, they may grant up to a ~~90-day~~ 90-day extension.

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

(1) The pharmacist manager (also called 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 the non-resident pharmacy is located. The PIC must also be licensed by the Oklahoma Board.

(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 of prescriptions or prescription medications and devices to Oklahoma residents.

(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.

(d) **Inspections.** Non-resident pharmacies are subject to inspection and investigation. The Board may conduct on-site periodic routine inspections and investigations during reasonable business hours.

(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, III, IV, and V prescription records. These records shall be sent to the Oklahoma Prescription Drug Monitoring program as set out in Title 63 of the Oklahoma Statutes.

(f) **Counseling services.** Non-resident pharmacies shall provide accessible toll-free telephone counseling by 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 or registrant shall not increase the quantity of a prescription without the authorization of the prescriber. Unless specified otherwise by the prescriber, a pharmacist may exercise his professional judgement to dispense up to a ninety (90) day supply for maintenance non-controlled dangerous drugs, if sufficient quantity has been authorized by the prescriber on the original prescription, including any refills. Increasing controlled dangerous drugs or any medications that require reporting to the controlled substance database are prohibited. See 59 OS 353.20.2

(h) **Written drug diversion detection and prevention.** The pharmacy and the pharmacy manager shall implement and follow a written drug diversion detection and prevention policy and procedure. This policy and procedure shall be available for Board review.

(i) **Pharmacy refrigerator and freezer temperature logs.**

(1) All refrigerators and freezers used to store medications shall have a sensor or thermometer capable of reading internal temperatures.

(2) The internal temperatures maintained in the refrigerators and freezers shall be appropriate for the products stored.

(3) Temperatures in refrigerators and freezers shall be logged twice daily (AM and PM) on days the pharmacy is open for business or shall have continuous temperature monitoring.

(A) Pharmacy name, date, time, temperature and staff person taking reading shall be logged at a minimum for paper logs.

(B) Temperature logs shall be maintained on paper or electronically for two years and be available for inspection.

(4) If there is a temperature reading that falls outside of appropriate ranges, a notation must be made on the temperature log detailing the corrective measures which were taken.

(5) It is the PIC's responsibility to review the temperature readings to ensure compliance with appropriate storage temperatures.

(j) **Prescription shipping.** The pharmacy shall maintain and use qualified packaging systems and/or devices ~~adequate storage or shipment containers and use shipping processes~~ to ensure drug stability and potency. Such shipping processes shall include the use of qualified packaging systems ~~appropriate packaging material~~ and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the ~~delivery~~ shipping process.

(1) Any pharmacy which ships medications to residents of Oklahoma must provide evidence to OSBP upon request that the shipping system meets the definition of a Qualified Packaging System for each category (frozen, refrigerated, room temperature) of medications shipped.

(2) No prescription shipped to a citizen of Oklahoma should have a temperature excursion that exceeds the temperature storage conditions outlined in the package insert or by the manufacturer of the drug product.

~~(3) A mail order or non-resident pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy.~~

(3) ~~(2)~~ A pharmacy or pharmacist shall refuse to deliver by mail or common carrier a prescription drug which, in the professional opinion of the pharmacy or pharmacist, may be therapeutically compromised by delivery by mail or common carrier.

(4) Appropriate Temperature. For shipping prescriptions in/into Oklahoma, pharmacies shall ensure products are shipped according to the manufacturer's labeled storage requirements. USP definitions for controlled cold and control room temperature outlines temperature allowances during shipping and how to address temperature excursion, See USP <659>, <1079>, and <1079.2>.

(5) Patients must be notified of shipments and the notification method of shipping shall be by verbal, written, electronic, or other technological means. If verbal, then the pharmacy must document the notification and maintain such documentation.

(6) A pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy with every prescription shipment for the purpose of the patient being able to file a complaint if necessary. Information to be included is the name of the pharmacy and the Oklahoma State Board of Pharmacy phone number, physical address, and website address.

(k) **Prescription Delivery.** Prescription drug delivery/same day delivery (24hrs) containers will be secured in the passenger or cargo portion of the delivery vehicle.

1. Delivery vehicles with the cargo portion having the same environmental moderation (i.e., heating and air conditioning) as the driver will ensure that pharmaceuticals in transit are kept within the temperature requirements recommended by the manufacturer or the United States Pharmacopeia (USP).

2. When weather extremes are anticipated, temperature moderating devices can be used in the delivery case (i.e., ice blocks, warm water containers).

3. For delivery vehicles with a segregated cargo portion and no environmental moderation (i.e., heating and air conditioning), the guidelines for "Qualified Packaging System" and "appropriate temperature" should be followed.

535:15-3-11. Prescription drugs

(a) **Authorization**; Original and refill prescriptions. No prescription for a "dangerous drug" (as defined in 59 O.S., Section 353.1) shall be filled or refilled without the authorization of a prescriber 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. After 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 of expiration either by shipping to a reverse distributor for 80 destruction or by being returned to the supplier.

(d) **Prescription integrity**. A pharmacy or registrant shall not increase the quantity of a prescription without the authorization of the prescriber. Unless specified otherwise by the prescriber, a pharmacist may exercise his professional judgement to dispense up to a ninety (90) day supply for a maintenance non-controlled dangerous drug, if sufficient quantity has been authorized by the prescriber on the original prescription, including any refills. Increasing controlled dangerous drugs or any medications that require reporting to the controlled substance database are prohibited.

(e) **Refills for patient safety**. The following prescription medications and devices are included in an inclusionary formulary of potentially life-saving prescription and devices authorized under 59 OS 353.20.2 (C) (4) which may be refilled by a pharmacist without an authorization in accordance with the requirements in 59 OS Section 353.20.2(C):

(1) Insulin and any devices or supplies necessary for the administration of insulin; .

(2) Glucometers and any devices or supplies necessary for the operation of the glucometer; .

(3) Rescue inhalers and any devices utilized that are necessary for the administration of a rescue inhaler; .

(4) Inhalers for chronic asthma and chronic obstructive pulmonary disease (COPD) and any devices or supplies necessary for administration; .

(5) Medication for nebulizers that treat acute and chronic pulmonary conditions and any devices necessary for administration; . ~~or~~

(6) Ophthalmic products for topical treatment of chronic condition.

(7) No CDS medications can be dispensed pursuant to 353.20.2 (C) (4).

(8) A form will be posted on the Board website for the Pharmacist to complete to document attempts to obtain refill authorization from the prescriber by the patient and by the pharmacist. This completed form shall be maintained in the pharmacy and be available for inspection.

(f) **Prescription shipping.** The pharmacy shall maintain and use adequate storage or shipping containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of qualified packaging systems ~~appropriate packaging material~~ and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the shipping ~~delivery~~ process.

(1) Any pharmacy which ships medications to residents of Oklahoma must provide evidence to OSBP upon request that the shipping system meets the definition of a Qualified Packaging System for each category (frozen, refrigerated, room temperature) of medications shipped.

(2) No prescription shipped to a pharmacy, patient, or any other recipient ~~citizen of Oklahoma~~ should have a temperature excursion that exceeds the temperature storage conditions outlined within the package insert or by the manufacturer of the drug product.

~~(2)~~ (3) A pharmacy or pharmacist shall refuse to deliver by mail or common carrier a prescription drug which, in the professional opinion of the pharmacy or pharmacist may be therapeutically compromised by delivery by mail or common carrier.

~~(3) A mail order or non-resident pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy~~.

(4) Appropriate Temperature. For shipping prescriptions in/into Oklahoma, pharmacies shall ensure products are shipped according to the manufacturer's labeled storage requirements. USP definitions for controlled cold and control room temperature outlines temperature allowances during shipping and how to address temperature excursion, See USP <659>, <1079>, and <1079.2>.

(5) Patients must be notified of shipments and the notification method of shipping shall be by verbal, written, electronic, or other technological means. If verbal, then the pharmacy must document the notification and maintain such documentation.

(6) A pharmacy shall make available to the patient or patient's caregiver the contact information for the Oklahoma State Board of Pharmacy with every prescription shipment for the purpose of the patient being able to file a complaint, if necessary. Information to be included is the name of the pharmacy and the Oklahoma State Board of Pharmacy phone number, physical address, and website address.

(g) **Prescription delivery.** Prescription drug delivery/same day delivery (24hrs) containers will be secured in the passenger or cargo portion of the delivery vehicle.

1. Delivery vehicles with the cargo portion having the same environmental moderation (i.e., heating and air conditioning) as the driver will ensure that pharmaceuticals in transit are kept within the temperature requirements recommended by the manufacturer or the United States Pharmacopeia (USP).

2. When weather extremes are anticipated, temperature moderating devices can be used in the delivery case (i.e., ice blocks, warm water containers).

3. For delivery vehicles with a segregated cargo portion and no environmental moderation (i.e., heating and air conditioning), the guidelines for "Qualified Packaging System" and "appropriate temperature" should be followed.

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, for original prescriptions and refills 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.

(C) CDS prescription transfers must be communicated directly between two licensed pharmacists and cannot be done by an intern.
(D) Non controlled prescription transfers must be communicated directly between two licensed pharmacists and /or licensed interns.

(2) The transfer as allowed in 535:15-3-12 (1) (C) and (D) above must be:
(A) Communicated orally directly between two licensed pharmacists and / or licensed interns~~;~~ . or,
(B) The prescription transfer information may ~~shall~~ be faxed from one pharmacy to another. ~~Upon receipt of the faxed information, a licensed pharmacist or licensed intern at the receiving pharmacy shall communicate receipt of the prescription transfer information orally directly with a licensed pharmacist or licensed intern at the originating pharmacy; and shall document the communication.~~ The original prescription transfer faxed information shall be printed and stored for~~;~~ .
(i) A non-controlled drug substance (non-CDS) prescription in the same manner as a non-controlled drug substance prescription or shall be electronically stored~~;~~ .
(ii) A controlled drug substance prescription in the same manner as a controlled drug substance prescription~~;~~ .

(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
(C) As required in federal DEA rules, 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

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

(6) Transferring 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).)

535:15-3-16. 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, each shall take action to correct the problem.

(b) In order to ensure adequate staffing levels a staffing form shall be 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 due to:
(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 that the situation warrants earlier Board review, the pharmacy manager shall inform the Board.

(e) Each pharmacy shall review completed staffing reports and address any issues listed as well as document any corrective action taken or justification for inaction to assure continual self-improvement. If the issue is not staffing related, measures taken to address the issue should be

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

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

(g) An employing pharmacy shall not retaliate against or discipline an employee for filing a complaint with the Board of Pharmacy or other licensing body or reporting a suspected violation of state or federal statute or any ordinance or regulation of a political subdivision. As used in this paragraph, retaliation or discipline of an employee includes, but is not limited to the following:

(1) Removing or suspending the employee from employment.

(2) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled.

(3) Transferring or reassigning the employee.

(4) Denying the employee, a promotion that otherwise would have been received, or

(5) Reducing the employee in pay or position.

SUBCHAPTER 5. HOSPITAL PHARMACIES

535:15-5-9. Hospital pharmacy physical requirements

A hospital pharmacy shall have sufficient facilities to ensure ~~insure~~ that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this Chapter. The following are in addition to the equipment ~~and library~~ requirements listed in 535:15-3-4 ~~and 535:15-3-6~~.

(1) **Equipment and materials.** Each hospital pharmacy shall have sufficient equipment and physical facilities for proper compounding, dispensing and storage of drugs.

~~(A)~~ (2) **Sterile compounds.** For sterile compounded preparations, a hospital must comply with 535:15-10 Part 3.

~~(B) A library shall be maintained which includes four of the following current references (not more than 2 years old or most recent). Current electronic sources may be substituted for hard copy information sources:~~

~~(i) Drug interactions;~~

~~(ii) Drug compatibility;~~

~~(iii) Poison and antidote information;~~

~~(iv) Toxicology;~~

~~(v) Pharmacology;~~

~~(vi) Bacteriology;~~

~~(vii) Patient counseling;~~

~~(viii) Rational therapy;~~

~~(ix) Dispensing information; and,~~

~~(x) Applicable USP standards.~~

~~(C) The library shall include 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)~~ (3) **Storage.** All pharmaceuticals bearing a federal legend such as "RX Only" and medications administered in the hospital shall be stored in designated areas within the hospital which are sufficient to insure proper sanitation, temperature, light, ventilation,

moisture control, segregation and security. The storage shall be as directed by the Director of Pharmacy and shall remain under the direct supervision of a pharmacist.
~~(3)~~ (4) **Alcohol and flammables.** Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or regulations as may apply.
~~(4)~~ (5) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked and inspected on a regular schedule of at least monthly as directed by the Director of Pharmacy.
~~(5)~~ (6) **Security.** All areas occupied by a hospital pharmacy shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

535:15-5-9.1. Hospital pharmacy library requirements

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

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

(A) USP/NF (within 3 years or latest edition),
(B) Merck Manual (within 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

(2) The required two reference sources must contain professional reference information on four of the following topics listed below:

(A) Drug interactions,
(B) Drug compatibility,
(C) Poison and antidote information,
(D) Toxicology,
(E) Pharmacology,
(F) Bacteriology,
(G) Patient counseling,
(H) Rational therapy,
(I) Dispensing information; and,

(J) Applicable USP standards.

(3) The library shall include 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.

SUBCHAPTER 6. HOSPITAL DRUG ROOM

535:15-6-6. Physical ~~and library~~ requirements

A hospital drug room shall have sufficient facilities to ~~insure~~ ensure that drugs are prepared in sanitary, well-lighted and enclosed places, and which meet the other requirements of this Chapter.

(1) **Equipment and materials.** Each hospital drug room shall have sufficient equipment and physical facilities for proper compounding, dispensing and storage of drugs.

~~(A)~~ (2) **Sterile Compounds.** For compounded sterile preparations:

~~(i)~~ (A) If a laminar hood is used, a hospital drug room shall comply with 535:15-9-6 and 535:15-9-10, 1 through 5.

~~(ii)~~ (B) If a laminar hood is not used, a closed system for parenteral admixtures should be utilized. If sterile compounding must be done, an area must be designated for that activity. This area must be at least a counter used for only this purpose and be away from patient care areas. Acceptable aseptic techniques shall be used.

~~(B) A library shall be maintained which includes four of the following current references (not more than 2 years old or most recent). Current electronic sources may be substituted for two hard copy information sources:~~

~~(i) Drug interactions;~~
~~(ii) Drug compatibility;~~
~~(iii) Poison and antidote information;~~
~~(iv) Toxicology;~~
~~(v) Pharmacology;~~
~~(vi) Microbiology;~~
~~(vii) Patient counseling;~~
~~(viii) Rational therapy;~~
~~(ix) Dispensing information; and,~~
~~(x) Applicable USP standards~~

~~(C) The library shall include 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)~~ (3) **Storage.** All drugs bearing a federal legend such as "RX Only" and medications administered in the hospital shall be stored in designated areas within the hospital which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation and security. The storage shall be as directed by the PIC and shall remain under the supervision of such pharmacist.

~~(3)~~ (4) **Alcohol and flammables.** Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatiles and such other laws, ordinances or regulations as may apply.

~~(4)~~ (5) **Unattended areas.** In the absence of authorized personnel in a hospital medication area, such area shall be locked.

~~(5)~~ (6) **Security.** All areas occupied by a hospital drug room shall be capable of being locked by key or combination to prevent access by unauthorized personnel.

535:15-6-6.1. Hospital Drug Room Library requirements

A hospital drug room library shall contain the following current reference books or computer sources:

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

(A) USP/NF (within 3 years or latest edition),
(B) Merck Manual (within 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

(2) The required two reference sources must contain professional reference information on four of the following topics listed below:

(A) Drug interactions,
(B) Drug compatibility,
(C) Poison and antidote information,
(D) Toxicology,
(E) Pharmacology,
(F) Bacteriology,
(G) Patient counseling,
(H) Rational therapy,
(I) Dispensing information; and,
(J) Applicable USP standards.

(3) The library shall include 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.

535:15-6-7. Drug distribution and control

(a) **General.** The PIC shall establish written procedures for the safe and efficient distribution of medicine products. A copy of such procedures shall be on hand for inspection by the Board.

(b) **Responsibility.** The PIC shall be responsible for the safe and efficient distribution, control, and accountability of drugs, see 535:15-6-5 (b).

(c) **Labeling.** Hospital drug room labeling requirements shall be as follows:

(1) **Labeling for use inside the hospital facility.** All drugs outside of the drug room intended for use within the facility shall be adequately labeled by the pharmacist or in their original container.

(2) **Labeling for use outside the hospital facility.** All drugs labeled by the pharmacist or licensed practitioner for after-hours dispensing to discharge or emergency room patients shall be labeled with the following:

(A) Name and address of the hospital facility,

(B) Date and identifying number,

(C) Name of the patient,

(D) Directions for use to the patient,

(E) Name of the prescriber,

(F) Initials of the dispenser,

(G) Required precautionary information regarding controlled substances,

(H) Such other accessory or cautionary information as may be required or desirable for proper use and safety to the patient, and~~,~~

(I) the name of the drug, its strength, and the number of units dispensed.

(3) **Sterile compounded admixtures.** When any drugs are added to sterile solutions or suspensions, such admixtures shall be labeled whether within or outside the direct personal supervision of a pharmacist. This label shall indicate the name and amount of the drug added, date and time of such addition, expiration date and time of admixture, and the initials of the persons (preparer and the verifier) responsible for the admixture.

(d) **Discontinued and outdated drugs.** The PIC shall develop and implement policies and procedures to insure that discontinued and outdated drugs, and containers with worn, illegible or missing labels are returned to the drug room for proper disposition.

(e) **Prescriber's orders.** Hospital drug room requirement regarding prescriber's orders shall be as follows:

(1) Drugs may be dispensed to specific patients only upon the written or verbal order of an authorized prescriber. A pharmacist or other authorized individual in a patient care area of the hospital facility must commit verbal prescriber's orders to writing.

(A) **Authorization.** The appropriate hospital committee shall designate those prescriber's authorized to issue and accept orders for hospital patients.

(B) **Requirements.** Orders for drugs for use by inpatients of the facility shall, at a minimum, contain the ~~patient~~ patient's name and room number, drug name, strength, directions for use, any relevant stop date or time, order date and time, and prescriber's signature. A copy of the order is to be provided to the drug room from which the order is to be processed.

(2) Orders for drugs for outpatients shall be considered prescriptions and must fulfill all of the requirements of a prescription identified within the Pharmacy Practice Act, ~~,~~ and state and federal law and rules.

(f) **Controlled drug accountability.** The hospital facility shall establish effective written procedures and maintain adequate records as required by law and rule regarding the use and accountability of controlled substances and such other drugs as the hospital may designate.

(g) **Drug recall procedures.** The PIC shall develop and implement a written recall procedure that can be readily activated which assures that drugs involved, inside or outside the facility, are returned to the hospital drug room for proper disposition. All actions taken in this area are to be properly documented.
(h) **Records and reports.** The PIC shall develop a mechanism for maintaining and submitting as appropriate, such records and reports as are required to insure patient health, safety, and welfare. These should include the following:

(1) Adverse drug reaction reports,
(2) Floor stock inventories of night cabinets and emergency boxes,
(3) Drug list or formulary of the hospital drug room as required by state health department rules,
(4) Controlled substance inventory,
(5) Ethyl alcohol inventory,
(6) Pharmacy and therapeutics committee minutes; and
(7) Reports and records as may be required by law, and the rules of this chapter.

SUBCHAPTER 10. GOOD COMPOUNDING PRACTICES

PART 1. GOOD COMPOUNDING PRACTICES FOR NON-STERILE PREPARATIONS

535:15-10-8.2. Beyond-use dating

(a) Pharmacies engaging in compounding shall assign every compounded preparation an appropriate beyond-use date (BUD).
(b) BUD may be assigned based on criteria different from those applied to assigning expiration dates to manufactured drug products.
(c) BUD are to be assigned conservatively~~,~~ and should be based on the following State Board of Pharmacy regulations ~~USP-NF~~ standards in (d) through (f) below.

(1) ~~The USP-NF~~ These standards ~~listed above~~ may be exceeded when there is supporting scientific stability information that is directly applicable to the specific preparation (e.g., the same drug concentration range, pH, excipients, vehicle, water content, etc.)
(2) Information to be considered when assigning a BUD includes chemical, physical and microbiological stability; nature of the drug, its chemical degradation mechanism, the container in which it is packaged, expected storage conditions, and the intended duration of therapy.

(d) Non-aqueous Formulations. The BUD for non-aqueous formulations is not later than the time remaining until the earliest expiration date of any ingredient utilized or 6 months, whichever is earlier.
(e) Water-Containing Oral Formulations. The BUD for water-containing oral formulations is not later than 14 days when stored at controlled cold temperatures.
(f) Water-Containing Topical / Dermal and Mucosal Liquid and Semisolid formulations. The BUD for water-containing topical / Dermal and Mucosal Liquid and semisolid formulations is not later than 30 days.

(g) If water is not added to a topical compounded preparation itself then the compound could be considered anhydrous with a BUD of 6 months or the earliest expiration of products used, whichever is less.

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 guidance ~~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.

~~(e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.~~

(e) It is acceptable for any licensed pharmacy to compound animal drugs from bulk substances for office use without patient-specific prescriptions for nonfood-producing animals if:

(1) The drug is compounded by or under the direct supervision of a pharmacist in a state-licensed pharmacy or a federal facility,

(2) The drug is intended for use in a nonfood-producing species and is compounded from a bulk drug substance listed on FDA's "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals",

(3) The drug is compounded in full compliance with state laws and regulations governing drugs, pharmacy, and veterinary medicine. All bulk drug substances, inactive ingredients, and finished drug products used in compounding meet the standards set in any applicable USP-NF monograph and comply with other FD&C Act requirements for drug components,

(4) Upon becoming aware of any adverse event or product defect associated with an animal drug compounded from a bulk drug substance, the pharmacist that compounded the drug reports the event on Form FDA 1932a within 15 business days, and

(5) The labeling of the compounded drug includes all the following:

(A) Name of drug,

(B) Strength of drug,

(C) Species of the patient(s) and indication(s) for which the drug will be used,

(D) Name, address, and contact information for the compounding pharmacy,

(E) BUD,

(F) The statement, "Report suspected adverse reactions to the [pharmacist who compounded the drug] and to the FDA using online Form 1932a",

(G) The statement, "This is a compounded drug. Not an FDA approved or indexed drug.",

(H) The statement, "Not for use in food-producing animals", and

(I) The statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(f) Veterinarians may dispense or ~~not~~ transfer compounded medications to: ~~any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.~~

(1) the owner or caretaker of animal patient, or
(2) a veterinarian within the same practice.

~~**535:15-10-15. Compounding of non-sterile radiopharmaceuticals**~~
~~(a) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. Facility design and variation in certain chapter standards may be required and shall be 129 documented with supporting evidence upon request.~~
~~(b) Radiopharmaceuticals prepared for oral administration shall be designated as, and conform to, the standards for non-sterile preparations. Any variation in certain chapter standards may be required to meet radiation safety concerns to operators and shall be documented with supporting evidence upon request.~~

PART 3. GOOD COMPOUNDING PRACTICES FOR STERILE PREPARATIONS

535:15-10-55. Drug compounding facilities
(a) Pharmacies engaging in compounding shall have a specifically designated and adequate space for the orderly compounding of prescriptions, including the placement and storage of equipment and materials.
(b) The aseptic processing for sterile preparations shall be in an area separate and distinct from the area used for the compounding of non-sterile drug preparations. A primary engineering control (PEC), (laminar airflow workbench (LAFW), biological safety cabinet (BSC), compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI)) will be used to prepare all sterile preparations, except those compounded for Immediate Use.
(c) The area(s) used for the compounding of drugs shall be maintained in a good state of repair. These area(s) shall also be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided and sewage, trash and other refuse in the compounding area is to be disposed of in a safe, sanitary, and timely manner.
(d) Bulk drugs and other chemicals or materials used in the compounding of drugs must be stored as directed by the manufacturer, ~~or according to USP monograph requirements~~, in a clean, dry area under appropriate temperature conditions (controlled room temperature, refrigerator, or freezer in adequately labeled containers.) Bulk drugs shall also be stored such that they are protected from contamination.
(e) Adequate lighting and ventilation shall be provided in all compounding areas.
(f) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug preparation.
(g) Work area and equipment. Any pharmacy dispensing compounded sterile preparations shall meet or exceed the following requirements:

(1) A transition area from the general pharmacy (also called ante area or ante room) shall have a certified and inspected ISO Class 8 or better area which may contain a sink. All personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed in the ante area. Drugs and other materials, taken into the transition area shall be removed from corrugated cardboard and other particle-generating materials before being taken into the area.

(2) A separate controlled limited access area (also called a buffer area or buffer room) shall have a certified and inspected ISO Class 7 or better environment for compounding sterile solutions. The buffer room shall be of adequate space. Cleanliness of the area is of critical importance.
(3) A separate controlled limited access area (also called a buffer area or buffer room) for compounding sterile solutions, which shall be of adequate space for compounding, labeling, dispensing, and sterile preparation of the medication. This area shall have controlled temperature. Cleanliness of the area is of critical importance. Drugs and other materials, taken into the limited access area, shall be removed from cardboard and other particle generating materials before being taken into the area.
(4) The controlled limited access area shall have a certified and inspected ISO Class 5 environment. Such an environment exists inside a certified laminar airflow hood (clean room, biological safety cabinet or other barrier isolator meeting ISO Class 5 requirements) used for the preparation of all compounded sterile products. The ISO Class 5 environment device or area is to be inspected and certified semiannually. Barrier isolator workstations are closed systems and are not as sensitive to their external environment as laminar airflow equipment. It is recommended to place them in a limited access area with cleaning and sanitizing in the surrounding area on a routine basis.
(5) A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the clean room and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low and medium risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.
(6) Hazardous drugs shall be prepared within a certified Class II, Type A (exhaust may be discharged to the outdoors) or Class II, Type B (exhaust may be discharged to the outdoors) laminar flow biological safety cabinet. Hazardous drug compounding shall have negative pressure to adjacent positive pressure ISO Class 7 or better ante-areas, thus providing inward airflow to contain any airborne drug. All vented cabinets shall be vented through HEPA filtration, preferably to outside air or through use of suitable technology or equipment. Ventilation exhaust shall be placed as not to reenter the facility at any point.
(7) The area shall be designed to avoid excessive traffic and airflow disturbances.
(8) The area shall be ventilated in a manner not interfering with laminar flow hood conditions.
(9) PECs should be left on continuously. If a PEC has been turned off, allow the blowers to run continuously for at least 30 minutes before using.
(10) Daily procedures must be established for cleaning the compounding area. The pharmacy must keep cleaning logs consistent with the minimum cleaning frequency. Logs shall be kept for 2 years.
(11) Minimum frequency of cleaning and disinfecting compounding areas are listed below:

(A) ISO Class 5 [Primary Engineering Control (e.g., LAFW, BSC, CAI, CACI)] shall be cleaned and disinfected at the beginning of each shift, before each batch,

not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities occur, after spills, and when surface contamination is known or suspected.
(B) Counters and easily cleanable work surfaces shall be cleaned and disinfected daily.
(C) Floors shall be cleaned and disinfected daily.
(D) Walls shall be cleaned and disinfected monthly.
(E) Ceilings shall be cleaned and disinfected monthly.
(F) Storage shelving shall be cleaned and disinfected monthly.

535:15-10-64.1. Compounding veterinarian sterile 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 guidance. ~~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 .
~~(e) It is acceptable for any licensed pharmacy to compound veterinary drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode, not to exceed 120 hours supply.~~
(e) It is acceptable for any licensed pharmacy to compound animal drugs from bulk substances for office use without patient-specific prescriptions for nonfood-producing animals if:
(1) The drug is compounded by or under the direct supervision of a pharmacist in a state-licensed pharmacy or a federal facility,
(2) The drug is intended for use in a nonfood-producing species and is compounded from a bulk drug substance listed on FDA's "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals",
(3) The drug is compounded in full compliance with state laws and regulations governing drugs, pharmacy, and veterinary medicine. All bulk drug substances, inactive ingredients, and finished drug products used in compounding meet the standards set in any applicable USP-NF monograph and comply with other FD&C Act requirements for drug components,
(4) Upon becoming aware of any adverse event or product defect associated with an animal drug compounded from a bulk drug substance, the pharmacist that compounded the drug reports the event on Form FDA 1932a within 15 business days, and
(5) The labeling of the compounded drug includes all the following:
(A) Name of drug,
(B) Strength of drug,
(C) Species of the patient(s) and indication(s) for which the drug will be used,
(D) Name, address, and contact information for the compounding pharmacy,
(E) BUD,
(F) The statement, "Report suspected adverse reactions to the [pharmacist who compounded the drug] and to the FDA using online Form 1932a",
(G) The statement, "This is a compounded drug. Not an FDA approved or indexed drug.",

(H) The statement, "Not for use in food-producing animals", and
(I) The statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

(f) Veterinarians may ~~not~~ transfer compounded medications to~~: any other party. The transfer of compounded medications to another party is a violation of state and federal laws and rules.~~
(1) the owner or caretaker of animal patient, or
(2) a veterinarian within the same practice.

~~535:15-10-66. Compounding of sterile radiopharmaceuticals~~

~~(a) In the case of production of radiopharmaceuticals for positron emission tomography (PET), the USP general test chapter Radiopharmaceuticals for Positron Emission Tomography – Compounding supersedes this part 3 of Subchapter 10 or applicable federal manufacturing regulations. Upon release of a PET radiopharmaceutical as a finished drug product from a production facility, the further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.~~

~~(b) For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as, and conform to, the standards for 'Low-Risk Level CSPs'~~

~~(c) The unique circumstances and requirements for radiopharmaceutical preparations necessitate specific stipulations that must not only satisfy pharmaceutical drug quality, but also consider crucial radiation safety concerns to operators. An integrated approach which addresses both aseptic and radiation safety techniques is necessary. Facility design and variation in certain chapter standards may be required and shall be documented with supporting evidence upon request.~~

~~(d) These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to permit compliance with applicable state and federal regulations.~~

~~(e) Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.~~

~~(f) Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 or cleaner air environment.~~

~~(g) Direct visual inspection of radiopharmaceutical CSPs shall be conducted in accordance with ALARA.~~

~~(h) The handling of radiopharmaceuticals is controlled through the licensing of 'Authorized Users' by the Oklahoma Department of Environmental Quality. As such, limited numbers of distribution channels exist to obtain radiopharmaceuticals. It is recognized that there is a special population that is outside the daily distribution range of a commercial nuclear pharmacy and that radiopharmaceuticals are not reasonably available. For these facilities, if the PEC is a CAI, CACI, a LAFW or a BSC that cannot be located within an ISO Class 8 or better buffer area, then only low-risk CSPs pursuant to a physician's order may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. These Low-risk level radiopharmaceutical CSPs with a 12-hour or less BUD shall be prepared in PECs (LAFWs, BSCs, CAIs, CACIs), which shall be certified and maintain ISO Class 5 and shall be in a segregated compounding area restricted to~~

~~sterile compounding 148 activities that minimize the risk of CSP contamination. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment areas must be cleaned before being brought into controlled compounding area. Other requirements as dictated by Low-Risk Radiopharmaceuticals shall be followed as described in this chapter.~~
~~(i) Preparation of radiopharmaceuticals for Immediate-Use category is reserved for radiopharmaceuticals needed for emergency or immediate patient care. Radiopharmaceuticals under this exemption shall apply only to diagnostic radiopharmaceuticals and administration must begin no later than one hour following the start of preparing the CSP. Certain preparations may necessitate more than two punctures into the same septum, i.e. Technetium 99mTc-Red Blood Cell labeling.~~
~~(j) Preparation of radio-labeled leukocytes or blood products requires the procedure be performed in an ISO Class 5 PEC that is located in an ISO Class 8 or cleaner air environment. Blood manipulations shall be clearly separated from routine procedures and have specific standard operating procedures to avoid cross-contamination.~~
~~(k) Labeling requirements for this chapter do not supersede the labeling requirements of 535:15-17-5.~~

SUBCHAPTER 13. PHARMACY SUPPORTIVE PERSONNEL

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.
(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 ~~535.25~~ and 535:15.

535:15-13-6.1. Technician rules for administering immunizations

(a) In order to obtain and maintain eligibility to administer immunizations, an applicant must be permitted as a pharmacy technician in Oklahoma and have successfully completed an Accreditation Council for Pharmacy Education (ACPE) accredited immunization training program for pharmacy technicians.
(b) A pharmacy technician with immunization registration must complete a minimum of 1 hour of immunization related ACPE accredited, or Board approved Continuing Education (CE) annually.
(c) A pharmacy technician must maintain current Cardiopulmonary Resuscitation (CPR) certification.
(d) The pharmacist in charge and pharmacy technician are responsible for maintaining training and education documentation.
(e) A pharmacy technician with proper training may administer vaccines delegated by the pharmacist on duty if:

(1) The vaccine is authorized, approved, or licensed by the Food and Drug Administration (FDA).
(2) The vaccine is ordered and administered according to Centers for Disease Control (CDC)/Advisory Committee on Immunization Practices (ACIP) recommendations.
(3) The delegating pharmacist is readily and immediately available to the immunizing pharmacy technician.
(4) The delegating pharmacist is registered with the Board as an immunizing pharmacist and is current on all other requirements of the Board.

(f) Prior to administering immunizations, each pharmacy technician shall obtain an immunization permit from the Board.

(1) Such pharmacy technician shall apply for and obtain an immunization permit by completing an application form furnished by the Board and paying the $25 fee.
(2) The immunization permit must be displayed in the pharmacy where the pharmacy technician is performing immunizations.
(3) The Board will maintain a registry of pharmacy technicians that have been approved to administer immunizations.
(4) Duplicate immunization permits can be requested from the Board for a fee.

(g) A pharmacy technician seeking reinstatement of a technician permit must complete and submit 2 hours of immunization related ACPE accredited CE to also reinstate a previously issued immunization permit.

535:15-13-15. Technician reinstatement requirements

(a) A technician reinstatement applicant shall be an individual who possesses a technician permit that was cancelled at request or cancelled for failure to renew.
(b) A technician whose permit was revoked is not eligible for reinstatement without appearing before the Board and receiving Board permission to apply.
(c) A technician desiring reinstatement must complete a technician reinstatement application.
(d) A technician reinstatement applicant shall meet the requirements in the Oklahoma Pharmacy Act, this Title, 535:10-13-4 regarding minimum requirements.
(e) A technician reinstatement applicant shall complete the required Phase I and II training again as described in 535:10-13-13 if their technician permit has been lapsed for longer than one year.
(f) Reinstatement applicants shall submit a satisfactorily completed Board approved reinstatement application together with the required documents and fees.
(g) Applicants may be required to appear before the Board to request approval of their application.
(h) Applicants shall complete the Pharmacy technician exam. Applicants may be required to take a Board approved law exam.
(i) The applicant shall meet any additional requirements which the Board may feel necessary to protect public health.
(j) After meeting the requirements of Board discipline, excepting revocation, a technician may make application for reinstatement. Such application may go before the Board for approval.
(k) An applicant who had an immunization permit must complete and submit verification of 2 hours of immunization related ACPE accredited CE to also reinstate their immunization permit. If not done at reinstatement, a technician may add an immunization permit later by completing a new immunization application.

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~~ Radiopharmaceutical preparation, compounding, dispensing and repackaging shall be done in accordance with accepted standards of practice as defined in <USP 825>. ~~.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.

(1) Immediate use. A preparation (including preparations with minor deviations) and/or dispensing of a sterile radiopharmaceutical that is limited for a single patient. Only sterile conventionally manufactured drug products (e.g., NDA, ANDA) or drugs produced under an approved IND or RDRC protocol may be used. Administration must begin within 4 hours of the first container puncture or exposure of any critical site involved (e.g., syringe tip, needle hub, or needle) to ambient air, whichever is first. Beyond use date may be 4 hours.

(2) Facility design and controls must be in place to minimize the flow of lower-quality air into the more controlled areas. Air supplied to the classified areas should be introduced through HEPA filters that are located in the ceiling. Returns should be low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate.

(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 for ~~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's ~~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.

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 pharmacy technicians to one supervising pharmacist. Such technicians shall be supervised as described in 535:15-13-5 (a) (b) (e) and (f).