(b) A pharmacist reinstatement applicant shall meet the requirements in the Oklahoma Pharmacy Act, this Title, 535:10-7-4, 535:10-7-9 and this section.

(c) A pharmacist reinstatement applicant shall send a written request to the Board.

(d) Reinstatement applicants shall submit a satisfactorily completed Board approved reinstatement application together with the requirements and fees.

(e) Applicants may be required to appear before the Board for interview as described in 535:10-7-4 (d).

(f) Applicants may be required to take the Board approved law exam as described in 535:10-7-4 (c).

(g) The applicant shall meet any additional requirements that the Board feels are necessary to protect public health.

(h) Reinstatement will be required when the suspension of a non-current pharmacist's certificate ends or when the suspension is placed on probation.

(i) An applicant who had an immunization permit must submit verification of 2 hours of immunization related ACPE Accredited CE with their pharmacist reinstatement application to also reinstate their immunization permit. If not done at reinstatement, a pharmacist may add an immunization permit later by completing a new immunization application.

SUBCHAPTER 11. PHARMACIST ADMINISTRATION OF IMMUNIZATIONS

535:10-11-3. D.Ph. administered immunization, training and CE ~~administering of immunization~~ requirements

(a) A D.Ph. must have completed an approved **Accreditation Council for Pharmacy Education**(ACPE) training course and received registration for immunizations with the Board as stated in 535:10-11-4 prior to administering immunizations.

(b) The Board will maintain a register of those pharmacists who have been approved to administer immunizations.

(c) A D.Ph. with immunization registration must maintain ongoing competency through required training, including at a minimum current CPR certification and 1 hour of immunization related ACPE accredited ~~current~~ continuing education annually.

535:10-11-5. D.Ph. training requirements for administration of immunizations [REVOKED]

~~(a) The following is a list of approved pharmacist training programs for administration of immunizations:~~

- ~~(1) Programs that include training in immunizations offered by the two state colleges of pharmacy:~~
  - ~~(A) Southwestern Oklahoma State University (SWOSU) College of Pharmacy~~
  - ~~(B) University of Oklahoma (OU) College of Pharmacy~~
- ~~(2) Immunization programs approved by the Accreditation Council for Pharmacy Education (ACPE).~~
- ~~(3) Immunization programs offered by the American Pharmaceutical Association (APHA).~~
- ~~(4) Immunization programs offered by the National Community Pharmacy Association (NCPA).~~
- ~~(5) Immunization programs offered by the American Society of Health System Pharmacists (ASHP).~~

~~(b) Each D.Ph. must have successfully completed one of these training courses in immunization prior to registering with the Board or administering immunizations prescribed by an Oklahoma licensed prescribing practitioner.~~

[OAR Docket #23-432; filed 6-6-23]

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

[OAR Docket #23-433]

RULEMAKING ACTION:

PERMANENT final adoption

RULES:

Subchapter 3. Pharmacies
535:15-3-4. Physical requirements for pharmacies [AMENDED]
535:15-3-12. Transfer of prescription refill information [AMENDED]
535:15-3-16. Adequate staffing rules for pharmacists and pharmacies [AMENDED]
Subchapter 5. Hospital Pharmacies
535:15-5-9. Hospital pharmacy physical requirements [AMENDED]
535:15-5-9.1. Hospital pharmacy library requirements [NEW]
Subchapter 6. Hospital Drug Room
535:15-6-6. Physical ~~and library~~ requirements [AMENDED]
535:15-6-6.1. Hospital drug room library requirements [NEW]
535:15-6-7. Drug distribution and control [AMENDED]
Subchapter 10. Good Compounding Practices
PART 1. Good Compounding Practices for Non-Sterile Preparations [AMENDED]
535:15-10-8.2. Beyond-use dating [AMENDED]
535:15-10-13. Compounding veterinarian preparations [AMENDED]
535:15-10-15 Compounding of non-sterile radiopharmaceuticals [REVOKED]
PART 3. Good Compounding Practices for Sterile Preparations [AMENDED]
535:15-10-55. Drug compounding facilities [AMENDED]
535:15-10-64.1 Compounding veterinarian sterile preparations [AMENDED]
535:15-10-66. Compounding of sterile radiopharmaceuticals [REVOKED]
Subchapter 13. Pharmacy supportive personnel
535:15-13-4. Pharmacy technician qualifications and training [AMENDED]
535:15-13-6.1. Technician rules for administering immunizations [NEW]
535:15-13-15. Technician reinstatement requirements [NEW]
Subchapter 17. Nuclear Pharmacy
535:15-17-5. General requirements [AMENDED]
535:15-17-11. Supervision of licensed pharmacy technicians in a licensed nuclear pharmacy [NEW]

AUTHORITY:
Oklahoma State Board of Pharmacy is the regulatory authority under Title 59 O.S., Sec. 353.7, 353.11 - 353.20.1, 353.22, 353.24 - 353.26 - 354, and 367.8.
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The revision in 535:15-3-1.1, 535:15-3-9 and 535:15-3-11 are withdrawn.
Revised in 535:15-3-4. Physical requirements for pharmacies remove (3) for Balances. It renumbers (4) Library to (3), renumbers (5) - (7) to (4) - (6). It deletes (8) filing, (9) containers, and (10) Labels. Lastly it renumbers (11) EPCS to (7) and adds a new (8) security.
Documentation is simplified in 535:15-3-12 (a) (2) (B) and (a) (2) (B) (i). It also adds "non-CDS" in (i).
Revised in 535:15-3-16 Adequate staffing rules for pharmacists and pharmacies and include punctuation changes. This rule brings the old (f) into (e), renumbers (g) to (f), and adds a new (g) that restricts pharmacies from retaliating against an employee who reports suspected violations.
The revisions in 535:15-5-9. Hospital pharmacy physical requirements change insure to ensure. They change (a) (1) (A) to (a) (2) and add Sterile compounds tag line. They remove the library requirements (a) (1) (B) from this section and adds them to 535:15-5-9.1 Hospital pharmacy library requirements. The old (a) (2) - (5) are renumbered to (3) - (6).
Revisions in 535:15-6-6 Physical requirements make the same changes described in 535:15-5-9 except for Hospital drug rooms. They remove the library requirements (a) (1) (B) and (C) from this section and adds them to 535:15-6-6.1. Hospital drug room library requirements. While the old (a) (2) - (5) are renumbered to (3) - (6).
Revised 535:15-6-7 Drug distribution and control (e) adds the missing (1) and (2) back to this rule as well as correcting punctuation and grammar.
Revisions in 535:15-10-8.2. Beyond-use dating remove from (c) USP-NF and replace with Board rules and in (c) (1) removes USP-NF and listed above.
Revised in 535:15-10-13. Compounding veterinary preparations (b) the word "guidances" is changed to "guidance" to correct grammar. The old (e) is deleted and replaced with a new (e) and the old (f) is changed to conform with new FDA law and rules.
Rule 535:15-10-15 Compounding of non-sterile radiopharmaceuticals is revoked.
The changes in 535:15-10-55 Drug compounding facilities remove USP reference in (d).
The revision in 535:15-10-64.1 Compounding veterinary sterile preparation (b) the word "guidances" is changed to "guidance" to correct grammar. The old (e) is deleted and replaced with a new (e) and the old (f) is changed to conform with new FDA law and rules.
Rule 535:15-10-66. Compounding of sterile radiopharmaceuticals is revoked.
The revision in 535:15-13-4 Pharmacy technician qualifications and training (d) corrects the cite from "535.25" to the correct cite "535:25".
Rule 535:15-13-6.1 adds new technician rules for administering immunizations.
Rule 535:15-13-15 adds new technician reinstatement requirements.
The changes in 535:15-17-5 General requirements correct punctuation and grammar. The rule 535:15-17-5 (f) is revised and added are (1) and (2) under (f) to clarify the rule.
New rules in 535:15-17-11 for supervision of licensed pharmacy technicians in a licensed nuclear pharmacy are the same ratios as for hospital pharmacies. Nuclear medications are most often prepared, dispensed and repackaged so they often don't fall within the compounding rule for technician ratios. This establishes the same technician ratio for these tasks.
CONTACT PERSON:
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PURSUANT TO THE ACTIONS DESCRIBED HEREIN, THE FOLLOWING RULES ARE CONSIDERED FINALLY ADOPTED AS SET FORTH IN 75 O.S., SECTIONS 250.3(5) AND 308(E), WITH AN EFFECTIVE DATE OF SEPTEMBER 1, 2023:

SUBCHAPTER 3. PHARMACIES

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)~~ **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.

535:15-3-12. 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 (3 years or latest edition),

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

(C) Remington (6 years),

(D) A toxicology reference (3 years),
(E) Mosby's Drug Consult (2 years),
(F) Facts and Comparisons (2 years),
(G) ASHP, American Hospital Formulary Service (AHFS) Drug Information (2 years),
(H) Monthly Prescribing Reference (MPR) (2 years),
(I) Drug Information Handbook (2 years),
(J) Thomson Micromedex, USP-DI (2 years); and/or,
(K) Current computer professional pharmacy reference program, approved by the Board (not duplicating a hard copy reference) e.g., one or two of the following:
(i) Thomson Micromedex, USP-DI
(ii) Clinical Pharmacology
(iii) Facts and Comparisons
(iv) Natural Medicines Comprehensive Database
(v) Trissel's 2 Clinical Pharmaceutical Database
(vi) Unlimited internet access to internet professional pharmacy reference program, e.g., WEB MD

(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 (3 years or latest edition),

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

(C) Remington (6 years),

(D) A toxicology reference (3 years),

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

(F) Facts and Comparisons (2 years),

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

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

(I) Drug Information Handbook (2 years),

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

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

(i) Thomson Micromedex, USP-DI

(ii) Clinical Pharmacology

(iii) Facts and Comparisons

(iv) Natural Medicines Comprehensive Database

(v) Trissel's 2 Clinical Pharmaceutical Database

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

(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 [REVOKED]

~~(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 [REVOKED]

~~(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 a 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, and 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, exception revocation, a technician may make application for reinstatement. Such applications 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) [RESERVED]

(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).

[OAR Docket #23-433; filed 6-6-23]

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 20. MANUFACTURERS, REPACKAGERS, OUTSOURCING FACILITIES, WHOLESALERS, THIRD-PARTY LOGISTICS PROVIDERS, ~~AND~~ MEDICAL GAS SUPPLIERS AND DISTRIBUTORS, DURABLE MEDICAL EQUIPMENT SUPPLIERS (DME), AND COMBINED DME AND MEDICAL GAS DISTRIBUTORS (MGD)

[OAR Docket #23-434]

RULEMAKING ACTION:
PERMANENT final adoption

RULES:
Subchapter 9. Medical gas suppliers and distributors
535:20-9-3. Medical gas suppliers [AMENDED]
535:20-9-4. Medical gas distributors [AMENDED]
Subchapter 10. Durable medical equipment (DME) suppliers and combined DME and medical gas distributors (MGD) [NEW]
535:20-10-1. Purpose [NEW]
535:20-10-2. Definitions [NEW]
535:20-10-3. DME suppliers and combined DME+MGD suppliers [NEW]
535:20-10-4. Violations and penalties [NEW]
535:20-10-5. Prohibited conduct [NEW]

Mary Terral

From: Cheryl Nolin
Sent: Tuesday, August 8, 2023 9:25 AM
To: Bryan Cleveland; Nat Barrack; Sherry Killian; John W. Maile; Travis Couch; Audrey Talley; Katherine Smith; Michelle Bouziden; Joshua Smith; Eric Ashmore; Stephanie Miller; Alexandra Edwards; Luis Estrada; Marcia Johnson; Keli Cain; Shimeka Mack; Thomas Grossnicklaus; Brent Kisling; Jennifer Gambrell; Rachel Rogers; Beavers, 330 Darrell; Danette Carr; Holli Kyker; Ashley Crall; Katy Feaver; Miller, Melissa; Sandra Ellis; Ginger Dean; Mary Terral; Janie Thompson; Kami Fullingim; Kimberly Dammen; Preston Lay; Chris Turner; Tina A. Calloway; Stephanie D. Roe; Gerri Kavanaugh; Melanie Hall; Lisa Haws; Christy Caesar; Phyllis Bennett; Sara Gibson; Chrystal Krittenbrink; Rhonda Hurst; Lauren Hammonds Johnson; Alexander Watkins
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