

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

**RULEMAKING ACTION:**

Notice of proposed PERMANENT rulemaking

**PROPOSED RULES:**

Subchapter 3. Pharmacies

535:15-3-1.1. Definitions [AMENDED]

535:15-3-4. Physical requirements for pharmacies [AMENDED]

535:15-3-9. Non-resident pharmacies [AMENDED]

535:15-3-11. Prescription drugs [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 preparation [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]

**SUMMARY:**

The revision in 535:15-3-1.1 Definitions adds a definition for "Qualified Packaging System".

Revised in 535:15-3-4. Physical requirements for pharmacies removes (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.

The revisions in 535:15-3-9. Non-resident pharmacies correct grammar and punctuation, they update (j) Prescription shipping and add (k) Prescription delivery for changes in how patient's receive their prescription medications to assure safe transport and delivery.

Rule 535:15-3-11 Prescription drugs corrects grammar and punctuation. In 535:15-3-11 (f) Prescription shipping and (k) Prescription delivery similar changes as those made for non-resident pharmacies are made for in-state pharmacies to assure safe transport and delivery.

The revision simplifies documentation 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 are 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) guidances are corrected to guidance for 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) guidances are corrected to guidance for 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.

#### **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.

#### **COMMENT PERIOD:**

Persons may submit written comments through January 23, 2023, at 3:30 p.m. to Marty Hendrick at 2920 N LINCOLN BLVD STE A, OKLAHOMA CITY OK 73105-4212 or by email to [pharmacy@pharmacy.ok.gov](mailto:pharmacy@pharmacy.ok.gov).

**PUBLIC HEARING:**

A public hearing will be held at 1:30 pm on Wednesday, February 1, 2023, at 2920 N LINCOLN BLVD STE A, Board room, OKLAHOMA CITY OK 73105-4212. Anyone who wishes to speak must sign in at the door by 1:35 p.m.

**REQUEST FOR COMMENTS FROM BUSINESS ENTITIES:**

Business entities affected by these proposed rules are requested to provide the Board, within the comment period, in dollar amounts if possible, the increase in the level of direct costs such as fees and indirect costs such as record keeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred due to compliance with the proposed rule(s). Business entities may submit this information in writing to Marty Hendrick at the above addresses, before the close of the comment period at 3:30 pm on January 23, 2023.

**COPIES OF PROPOSED RULES:**

Proposed rules are available for review at 2920 N LINCOLN BLVD STE A, OKLAHOMA CITY OK 73105-4212. Copies may be viewed in our offices or on website [www.pharmacy.ok.gov](http://www.pharmacy.ok.gov), or provided at a cost of 25 cents per page.

**RULE IMPACT STATEMENT:**

Pursuant to 75 O.S., Section 303 (D), a rule impact statement will be prepared and may be obtained from OSBP at the above address beginning December 15, 2022. It may be viewed in our office, on our website, or copies may be obtained for 25 cents per page.

**CONTACT PERSON:**

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