

ACCEPTED 11/10/21
OFFICE OF ADMINISTRATIVE RULES
OKLAHOMA SECRETARY OF STATE
DOCKET# 21-808 OAR/cert CN

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

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking

PROPOSED RULES:

- Subchapter 3. Pharmacies
 - 535:15-3-9. Non-resident pharmacies [AMENDED]
 - 535:15-3-12. Transfer of prescription refill information [AMENDED]
 - 535:15-3-13. Pharmacist’s responsibility in a pharmacy [AMENDED]
- Subchapter 10. Good Compounding Practices
 - Part 3. Good Compounding Practices for Sterile Preparations
 - 535:15-10-54. CSP microbial contamination risk levels [AMENDED]
 - 535:15-10-55. Drug compounding facilities [AMENDED]
 - 535:15-10-65. Compounding of sterile hazardous drugs [AMENDED]
- Subchapter 11. Charitable Clinic Pharmacies
 - 535:15-11-1. Charitable clinic pharmacy license [AMENDED]
- Subchapter 13. Pharmacy Supportive Personnel
 - 535:15-13-4. Pharmacy technician qualifications and training [AMENDED]
 - 535:15-13-5. Supervision of pharmacy technicians [AMENDED]
 - 535:15-13-6. Duties [AMENDED]
- Subchapter 16. Pharmacy Emergency Medication Kits for Use in a Facility
 - 535:15-16-3. Licensing requirements [AMENDED]
 - 535:15-16-4. Policies and procedures for use of emergency medication kit drugs [AMENDED]
 - 535:15-16-5. Security [AMENDED]
 - 535:15-16-6. ~~Drug categories~~ Drugs allowed in emergency medication kits [AMENDED]
- Subchapter 17. Nuclear Pharmacy
 - 535:15-17-7. Minimum equipment [AMENDED]

SUMMARY:

The revision in 535:15-3-9 (c) (1) clarify and ass (4) and (5) add pharmacist in charge requirements for non-resident pharmacies.

The revision in 535:15-3-13 (c) clarifies a pharmacist’s right not to fill a valid prescription.

The change in 535:15-10-54 (h) (3) adds daily documentation of humidity in areas where sterile products or sterile preparations are stored or compounded.

The change in 535:15-10-55 (g) (10) and (11) regarding cleaning logs, cleaning frequency and cleaning requirements are updated and clarified.

The revision in 535:15-10-65 adds new (m) and (n) regarding rules on hazardous drug spills management, policies procedures, and location of spill kits and cleanup materials.

The revision in 535:15-13-4 (a) add HiSet Examination to minimum education and clarify language regarding good moral character.

The revision in 535:15-13-6 adds a new (12) regarding pharmacy technician duties in a filling dispensing and distribution systems in a licensed retail pharmacy.

The revision in 535:15-16-3 clarify emergency medication kit licensing requirements and that the kit permit expires at the same date as the pharmacy license.

The revision in 535:15-16-4 (f), (g) and (h) update policies and procedures to deal with issues as a result of COVID19 in caring for patients in facilities and in the handling of drugs where these residents must be protected from exposure.

The revision in 535:15-16-4 and 535:15-16-5 update who may access or resupply emergency medication kits.

The revision in 535:15-16-6 changes what drugs may be maintained in an emergency medication kit based on lessons learned in dealing with COVID in facilities.

The revision in 535:15-17-7 (a) cleans up language, adding (6) and (7), removing (8), (10) and (11).

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:

The comment period will run from December 1, 2021 through January 14, 2022, at 4:00 p.m. Written comments may be sent to the offices of the Board at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212.

PUBLIC HEARING:

A public hearing will be held to provide an opportunity for persons to orally present their views on January 19, 2022, at 1:30 p.m., in our office at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212. Written notice of intent to make oral comment must be received by this office no later than January 14, 2022, at 4:00 p.m. COVID protocols; temperature check, face mask covering nose and mouth, and social distance required.

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).

COPIES OF PROPOSED RULES:

Proposed rules are available for review in our office at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212. Copies may be viewed in our offices or on our website www.pharmacy.ok.gov, or provided at a cost of 25 cents per page.

RULE IMPACT STATEMENT:

A rule impact statement will be prepared and will be available on and after December 1, 2021, at the location listed above for copies of the proposed rules. It may be viewed in our office, on our website, or copies may be obtained for 25 cents per page.

CONTACT PERSON:

Dr. Marty Hendrick, Executive Director, Oklahoma State Board of Pharmacy located at 2920 N Lincoln Boulevard Suite A, Oklahoma City, OK 73105-4212. The Board phone number is (405) 521-3815 and the FAX number is (405) 521-3758.