

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

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking

PROPOSED RULES:

Subchapter 3. Pharmacies

535:15-3-2. Pharmacy responsibilities [AMENDED]

Subchapter 4. Remote Medication Order Processing (RMOP) and RMOP Pharmacy for Hospital Pharmacies

535:15-4-2. Definitions [AMENDED]

535:15-4-5. Responsibilities and duties of RMOP pharmacies and pharmacy manager [pharmacist in charge (PIC)] [AMENDED]

Subchapter 5. Hospital Pharmacies

535:15-5-2. Definitions [AMENDED]

535:15-5-9. Hospital pharmacy physical requirements [AMENDED]

535:15-5-19. Remote medication order processing (RMOP) [AMENDED]

Subchapter 6. Hospital Drug Room

535:15-6-2. Definitions [AMENDED]

535:15-6-6. Physical requirements [AMENDED]

535:15-6-9. Emergency room pre-packaged medications formulary [AMENDED]

535:15-6-20. Remote medication order processing (RMOP) [AMENDED]

Subchapter 7. Drug supplier permits

535:15-7-2. Definitions [AMENDED]

Subchapter 10. Good Compounding Practices

Part 1. Good Compounding Practices for Non-Sterile Preparations [AMENDED]

535:15-10-1.1 Preparation of compounded drug products for over-the-counter (OTC) sale

[NEW]

SUMMARY:

The revision in 535:15-3.2 (j) implied (1) is renumbered to (1), (2) is added describing a change in the pharmacist in charge (PIC) report is required to the Board within ten days (10 days), (3) is added requiring pharmacies that are closing for lack of staffing or other reasons where the pharmacy will not be open during their normal business hours to report to the Board; and describes what must be included in this report.

In 535:15-4-2. the 'Remote medication order processing' and the 'remote medication order processing pharmacy' definitions are changed.

For both 535:15-4-5 (1) (G) and 535:15-4-5 (2) (B) the cites are corrected from 535:15-5-9 (1) (B) and (1) (C) to 535:15-5-9.1.

In 535:15-5-2. the Remote medication order processing definition in changed.

535:15-5-9. Implied (a) (6) Security adds (A) to the implied (A) and adds (B) requiring electronic alarm and video recording system to protect against theft and diversion.

Revised in 535:15-5-19 (d) the cites are corrected from 535:15-5-9 (1) (B) and (1) (C) to 535:15-5-9.1.

In 535:15-6-2. the Remote medication order processing definition in changed.

Revised in 535:15-6-2 implied (a) the word insure is corrected to ensure. In 535:15-6-2 (a) (2) (A) ', 1 through 5' is deleted. 535:15-6-2 (a) (6) Security adds (A) to the implied (A) and

adds (B) requiring electronic alarm and video recording system to protect against theft and diversion.

The revision in 535:15-6-9 (b) (9) will allow up to three types of Asthma medication per ER formulary.

The revision in 535:15-6-20 (d) the cites are corrected from 535:15-5-9 (1) (B) and (I) (C) to 535:15-5-9.1.

Revised 535:15-7-2 (c) adds "name and address of supplier" and "lot number and expiration date of drug".

New 535:15-10-1.1 are rules for pharmacist preparation of compounded drug products in the pharmacy for over-the counter (OTC) sale to implement new legislation.

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 22, 2024, at 9:00 a.m. to Marty Hendrick at 2920 N Lincoln Blvd Ste A, Oklahoma City, OK 73105-4212 or by email to pharmacy@pharmacy.ok.gov.

PUBLIC HEARING:

A public hearing will be held at 9:00 am on Wednesday, January 24, 2024, 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 9:00 am on January 22, 2024.

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 , 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 November 1, 2023. 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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