

## RULE IMPACT STATEMENT

### NAME OF RULEMAKING AUTHORITY:

Oklahoma State Board of Pharmacy  
2920 N Lincoln Boulevard Ste A  
Oklahoma City, OK 73105-4212

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### INTENDED PERMANENT RULEMAKING ACTION:

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY

CHAPTER 15. PHARMACIES

Subchapter 3. Pharmacies

535:15-3-2. Pharmacy responsibilities

Subchapter 4. Remote medication order processing (RMOP) and RMOP pharmacy for hospital pharmacies

535:15-4-2. Definitions

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

Subchapter 5. Hospital pharmacies

535:15-5-2. Definitions

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

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

Subchapter 6. Hospital drug room

535:15-6-2. Definitions

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

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

535:15-6-20. Remote medication order processing

Subchapter 7. Drug supplier permits

535:15-7-2. Drug supplier requirements

Subchapter 10. Good compounding practices

PART 1. Good compounding practices for non-sterile products

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

#### a. Brief description of the purpose of the proposed rule.

The revision in 535:15-3.2 (j) implied (1) is renumbered to 535:15-3-2 (j) (1). Added 535:15-3-2 (2) describes the requirement that a change in the pharmacist in charge (PIC) report must be sent to the Board within ten days (10 days). Added is 535:15-3-2 (j) (3) which requires 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 further describes what must be included in this report.

In 535:15-4-2 the definitions are changed for 'remote medication order processing' and the 'remote medication order processing pharmacy'. Both 535:15-4-5 (1) (G) and 535:15-4-5 (2) (B) have the cites corrected from 535:15-5-9 (1) (B) and (I) (C) to 535:15-5-9.1.

In 535:15-5-2 the definition is changed for Remote medication order processing. The revision in 535:15-5-9 in implied (a) (6) Security, adds (A) and (B) which requires

an electronic alarm and video recording system to protect against theft and diversion. Revised cites in 535:15-5-19 (d) corrected from 535:15-5-9 (1) (B) and (I) (C) to 535:15-5-9.1.

Changed definitions in 535:15-6-2 for Remote medication order processing. Revised the word 'insure' in 535:15-6-2 implied (a) to 'ensure'. In 535:15-6-2 (a) (2) (A), '1 through 5' is deleted. Security in 535:15-6-2 (a) (6) adds (A) to the implied (A); and new (B) requires electronic alarm and video recording system to protect against theft and diversion. The revision in 535:15-6-9 (b) (9) now allows up to three types of Asthma medication per ER formulary. The revision in 535:15-6-20 (d) corrects cites 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.

**b. Description of the classes of persons who will most likely be affected by the proposed rule, including classes that will bear the costs of the proposed rule, and any information on costs of the proposed rule, and any information on the cost impacts received by the agency from any private or public entities,**

The public and registrants will be affected by the rule change, no costs are anticipated. The rule change increases the clarity of the rules.

**c. Description of the classes of persons who will benefit from the proposed rule,**

The public and registrants will benefit from more clear rules.

**d. Description of probable economic impact of the proposed rule on affected classes of persons or political subdivisions, including a listing of all fee changes and, whenever possible, a separate justification for each fee,**

No economic impact is expected.

**e. Probable costs and benefits to the agency and to any other agency of the implementation and enforcement of the proposed rule, the source of revenue to be used for implementation and enforcement of the proposed rule, and any anticipated effect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency,**

No economic impact is expected. Rules are clear for registrant and the public.

**f. Determination of whether implementation of the proposed rule will have an economic impact on any political subdivisions or require their cooperation in implementing or enforcing the rule. No impact is anticipated.**

**g. Determination of whether implementation of the proposed rule may have an adverse economic effect on small business as provided by the Oklahoma Small Business Regulatory Flexibility Act,**

No economic impact is expected.

The Oklahoma State Board of Pharmacy as a Title 59, Exempt Profession Agency, remains mindful of the effect of our rules on businesses. We cannot protect public health if rules make it impossible for individuals and businesses to provide pharmaceutical services.

All Board rules affect businesses. The Board involves a range of pharmacies practice sites and individuals in the rulemaking process to minimize adverse effects on all businesses, including small businesses. This makes for better rules as the affected individuals can help the agency avoid pitfalls and unintended consequences.

**h. Explanation of the measures the agency has taken to minimize compliance costs and a determination of whether there are less costly or nonregulatory methods or less intrusive methods for achieving the purpose of the proposed rule,**

These rule changes are the least costly or intrusive method; and no less costly or less intrusive methods exist for achieving the purpose of these revisions.

**i. Determination of the effect of the proposed rule on the public health, safety and environment and, if the proposed rule is designed to reduce significant risks to the public health, safety and environment, an explanation of the nature of the risk and to what extent the proposed rule will reduce the risk,**

These rule changes make the rules clear for the public and registrants. Cites are corrected. These rules provide for notice to the Board of closing during the regular business hours of a pharmacy and the reasons to assure public access to their medications. Remote medication order processing rules are updated across subchapters 4, 5, and 6, as are security requirements updated. New rules for preparation of compounded drug products for over-the-counter (OTC) sale to comply with new legislation.

**j. Determination of any detrimental effect on the public health, safety and environment if the proposed rule is not implemented, and**

Without these applicants will be confused and the rules will be unclear. Rules are also added to comply with new legislation and to require notice and security.

**k. The date the rule impact statement was prepared and if modified, the date modified.** This rule impact statement was originally prepared on October 9, 2023.