

RULE IMPACT STATEMENT**NAME OF RULEMAKING AUTHORITY:**

Oklahoma State Board of Pharmacy
4545 N. Lincoln Boulevard, Suite 112
Oklahoma City, OK 73105-3488

For Information or Questions Contact:

Mary Ann Terral
405-522-3129
mterral@pharmacy.ok.gov

INTENDED PERMANENT RULEMAKING ACTION:

TITLE 535. OKLAHOMA STATE BOARD OF PHARMACY
CHAPTER 15. PHARMACIES
SUBCHAPTER 3. PHARMACIES

535:15-3-4.1. Pharmacy licensing requirement **[AMENDED]**

535:15-3-17. Pharmacy prescription records **[AMENDED]**

SUBCHAPTER 6. HOSPITAL DRUG ROOMS

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

SUBCHAPTER 16. PHARMACY EMERGENCY MEDICATION KITS FOR USE IN A FACILITY

[NEW]

535:15-16-1. Purpose **[NEW]**

535:15-16-2. Definitions **[NEW]**

535:15-16-3. Licensing requirements

535:15-16-4. Policies and procedures for use of emergency medication kit drugs **[NEW]**

535:15-16-5. Security **[NEW]**

535:15-16-6. Drug categories allowed in emergency medication kits **[NEW]**

535:15-16-7. Violations **[NEW]**

(a) **Purpose of the proposed rule.** The revision in 535:15-3-4.1 removes the requirement that every pharmacy list “the corporate registered agent and address” on all new or renewal applications. The revision in 535:15-3-17 allows the pharmacy prescription record to be digital while keeping the other requirement of the rule the same.

The rule revision in 535:15-6-9 (C) removes “Propoxyphene / acetaminophen” from the emergency room pre-packaged medications formulary (since it is no longer produced) and changes it to “Hydrocodone / ibuprofen” combination.

The new rules in 535:15-16-1 through 535:15-16-6 set rules for pharmacy emergency medication kits for use in a facility remote site. These rules allow pharmacies to place in specifically defined facility remote sites limited emergency medication kits to allow for emergency and urgent care for patients. These rules provide purpose in 535:15-16-1, definitions in 535:15-16-2, licensing requirements in 535:15-16-3, policies and procedures in 535:15-16-4, security in 535:15-16-5, description of drug categories and limits in 535:15-16-6 and violations in 535:15-16-7.

(b) **Who is affected and who pays?** The revisions in 535:15-3-4.1 and in 535:15-3-17 will reduce compliance costs for pharmacies. The rules in 535:15-16 allow pharmacies who desire to place pharmacy emergency medication kits in facilities remote sites to provide better urgent and emergency care of patients to reduce hospital costs for facility patients. Oklahoma licensed pharmacies may choose to participate or not.

And any cost impact information received from private or public entities. None.

(c) **Who benefits?** The revisions in 535:15-3-4.1 and 535:15-3-17 will reduce the cost of compliance for pharmacies. The revisions in 535:15-16 benefit pharmacies ability to immediately address urgent and emergency medication needs for facility patients. Facility patients benefit in having their urgent and emergency medication needs addressed without having to go to the hospital.

(d) **Probable economic impact on affected classes and/or political subdivisions, including a listing of all fee changes, and whenever possible, a separate justification for each fee change.** The revisions in 535:15-3.4.1 and 535:15-3-17 will reduce compliance costs for pharmacies. The revisions in 535:15-16 benefit pharmacies ability to immediately address urgent and emergency medication needs for facility patients. Rules will improve patient outcomes with prompt urgent and emergency medications with less disruption to the patient. The fee change is described in **Chapter 1. Administrative Operations, Subchapter 11. Fees.**

(e) **Probable costs and benefits to agency(s) in implementing and enforcing the rule, the source of revenue to be used for implementation and enforcement of the rule, and any anticipated affect on state revenues, including a projected net loss or gain in such revenues if it can be projected by the agency.** No cost is anticipated for the changes in 535:15-3-4.1 and 535:15-3-17. The changes in 535:15-16 will allow the pharmacy to provide prompt urgent and emergency medication needs and should save facility and facility patient hospital costs. The rules in 535:15-16 are revenue neutral; costs will be covered.

(f) **Political subdivision costs, and/or required cooperation in implementing or enforcing.** No involvement of political subdivisions in regards to enforcement or costs is anticipated.

(g) **Adverse affect on Small Business as provided by the Small Business Regulatory Flexibility Act.**

The Oklahoma State Board of Pharmacy as a Title 59, Exempt Profession Agency, remains mindful of the affect 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 affects 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 non-regulatory methods or less intrusive methods for achieving the purpose of the rule.** These rule changes are the least costly or intrusive method and no less costly or less intrusive methods exist for achieving the purposes of these revisions.

(i) **Affect on public health, safety and environment. If rule is to reduce risks, describe risk and how the rule will reduce the risk.** The revisions in 535:15-3-4.1 and 535:15-3-17 will eliminate delays and duplicative files with no affect on public health, safety or the environment. The rules in 535:15-16 allow pharmacies to take care of facility patients urgent and emergency medication needs without them having to go to the hospital. Improves patient care and eliminates disruption by caring for their emergency medications within the facility.

(j) **Risk of not implementing.** The revisions in 535:15-3.4.1 and 535:15-3-17 will reduce compliance costs for pharmacies. Without the revisions in 535:15-16 pharmacies will not be able to provide urgent and emergency medication needs for facility patients as quickly causing poor patient

outcomes due to delayed care. Facility patients will suffer the stress and confusion of movement between facility and hospital and the higher costs of ER and hospital care.

(k) **Prepared.** This rule impact statement was originally prepared on July 14, 2011 and amended on July 15, 2011.