RULE IMPACT STATEMENT

NAME OF RULEMAKING AUTHORITY:
Oklahoma State Board of Pharmacy
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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 [AMENDED]
535:15-3-4. Physical requirements for pharmacies [AMENDED]
535:15-3-9. Non-resident pharmacies [AMENDED]
535:15-3-10. Inventory [AMENDED]
535:15-3-11. Prescription drugs [AMENDED]

Subchapter 5. Hospital Pharmacies
535:15-5-2. Definitions [AMENDED]
535:15-5-7.4. Pharmacy technician tasks [AMENDED]

Subchapter 10. Good Compounding Practices
535:15-10-13. Compounding veterinarian preparations [AMENDED]
535:15-10-64.1. Compounding veterinarian sterile preparations [NEW]

Subchapter 18. Customized Adherence Medication Package (CAMP) [NEW]
535:15-18-1. Purpose [NEW]
535:15-18-2. Definition [NEW]
535:15-18-3. Packaging requirements [NEW]
535:15-18-4. Labeling [NEW]

Subchapter 19. Automation Rules [NEW]
535:15-19-1. Purpose [NEW]
535:15-19-2. Definitions [NEW]
535:15-19-4. Pharmacist verification [NEW]
535:15-19-5. Policies and procedures [NEW]
535:15-19-6. Recordkeeping [NEW]
535:15-19-7. Prepacking by automation [NEW]

Purpose or gist of the proposed rule.
The revision in 535:15-3-2 (b) (3) adds “Allows an exception to one PIC per pharmacy at a time for licensed charitable pharmacies and hospital drug rooms. The revisions in 535:15-3-2 (h) – (j) add new rules regarding remodel, closing of a pharmacy, and notification of theft.

The revision in 535:15-3-4, physical requirements for pharmacies includes a new (a) (14) Any pharmacy that dispenses controlled dangerous substances shall have computer software that supports EPCS by January 1, 2019.

The revision in 535:15-3-10 requires a closing inventory of controlled dangerous drugs be done
and be sent to the Board within 10 days of the closing of the pharmacy. No prescription drugs may be
maintained in an unlicensed location.

The rule changes in 535:15-3-9 (g) and 535:15-3-11 make it possible for a pharmacist to fill up to
a ninety day supply for maintenance, non-controlled dangerous drugs if sufficient quantity has been
authorized by the prescriber on the original script, including any refills as allowed by law. Increasing
CDS or any medications that require reporting to the controlled substance database are prohibited.

The definitions in 535:15-5-2 (a) remove the definition of “Certified pharmacy technician”.

The revision in 535:15-5-7.4 (a) (10) allows hospital pharmacy technicians to prepare sterile
compounding products with the additional requirement “following documented training and
demonstrated competency as required in OAC 535:15-10-52 (d).” 535:15-5-7.4 (10) (A) and (B) are
removed and replaced with the requirements in OAC 535:15-10-52 (d).

The revision in 535:15-10-13 for compounding veterinarian preparations adds the new (e) which
allow a licensed pharmacy to compound veterinary drug products to be used by veterinarians in their
office for administration to clients for use in a single treatment episode, not to exceed 120 hours
supply. The new (f) which specifies that Veterinarians may not transfer compounded medications to
any other party, since such transfer of compounded medications to another party is a violation of
state and federal laws and rules.

The new rule in 535-15-64.1 for compounding sterile veterinarian preparations allow a licensed
pharmacy to compound veterinary sterile drug products to be used by veterinarians in their office for
administration to clients for use in a single treatment episode, not to exceed 120 hours supply while
complying with federal law, rules and FDA guidances.

The new rules in Subchapter 18 for Customized Adherence Medication Package (CAMP)
include purpose in 535:15-18-1, definitions in 535:15-18-2, packaging requirements in 535:15-18-3,
and labeling requirements in 535:15-18-4.

The new rules in Subchapter 19 for Automation include purpose in 535:15-19-1, definitions in
535:15-19-2, medication stocking in 535:15-19-3, pharmacist verification in 535:15-19-4, policies and

(b) **Who is affected and who pays?** The agency does not anticipate any costs as a result of this
change. The majority of pharmacies already have the required software in place. **And any cost
impact information received from private or public entities.** None.

(c) **Who benefits?** Registrants and the public benefit from clearer rules. 535:15-3-2 (b) (3) allowing
an exception to the only one pharmacy pharmacist manager for charitable pharmacy or hospital drug
room is to relieve staffing shortages for these part-time locations. Registrants by clear requirements in
535:15-3-4, physical requirements for pharmacies includes pharmacies dispensing controlled
dangerous substances shall have computer software that supports EPCS by January 1, 2019 as
required by DEA. Public benefits because e-prescribing software capabilities should decrease
fraudulent and forged prescriptions.

535:15-3-10 closing inventory and no prescription drugs may be maintained in an unlicensed
location are added for registrant clarity.

State law changes are reflected in 535:15-3-9 (g) and 535:15-3-11 to make clear to registrants the
refill authorization enabling 90 day supply fill.

Because of changes in the compounding rules, 535:15-5-2 (a) removes the definition of “Certified
pharmacy technician” and (a) (10) allows hospital pharmacy technicians to prepare sterile
compounding products with the additional requirement “following documented training and
demonstrated competency is removed and replaced with OAC 535:15-10-52 (d).” 535:15-5-7.4 (10)
(A) and (B) are removed and replaced with the requirements in OAC 535:15-10-52 (d).

The revision in 535:15-10-13 adds the new (e) which allow a licensed pharmacy to compound
veterinary drug products to be used by veterinarians in their office for administration to clients for use
in a single treatment episode, not to exceed 120 hours supply for veterinary patient safety. The new
(f) which specifies that Veterinarians may not transfer compounded medications to any other party, since such transfer of compounded medications to another party is a violation of state and federal laws and rules.

The new rule in 535-15-64.1 for compounding sterile veterinarian preparations allow a licensed pharmacy to compound veterinary sterile drug products to be used by veterinarians in their office for administration to clients for use in a single treatment episode for veterinary patient safety.

The new rules in Subchapter 18 for Customized Adherence Medication Package (CAMP) include purpose in 535:15-18-1, definitions in 535:15-18-2, packaging requirements in 535:15-18-3, and labeling requirements in 535:15-18-4 for patient safety. Allows registrants and the public to benefit from new technology to improve patient ability to take the right medications at the right time.


(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. No economic impact is expected by the Board.

(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. The Board does not anticipate any costs in implement and enforcing these rules.

(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. This rule change is the least costly or intrusive method and no less costly or less intrusive methods exist for achieving the purpose 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. These rule changes make the rules more clear to registrants and help protect public safety. Allows patients and registrants access to newer, safer, advancements in automation and packaging. E-prescribing will help decrease the number of fraudulent and forged prescriptions.

(j) Risk of not implementing. Patients being unable to use new safer patient packaging using
advancements in automation. No reduction in the opioid epidemic due to no reduction in fraudulent and forged prescriptions.

(k) Prepared. This rule impact statement was originally prepared on January 22, 2018, and modified January 31, 2018.