Rule Summary and Fiscal Analysis Part A - General Questions

Rule Number: 4729:3-3-04

Rule Type: Amendment

Rule Title/Tagline: Certified pharmacy technicians.

Agency Name: State Board of Pharmacy

Division: Pharmacy Technicians

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I. Rule Summary

- 1. Is this a five year rule review? Yes
 - A. What is the rule's five year review date? 11/27/2019
- 2. Is this rule the result of recent legislation? No
- 3. What statute is this rule being promulgated under? 119.03
- 4. What statute(s) grant rule writing authority? 4729.26, 4729.10, 4729.94
- 5. What statute(s) does the rule implement or amplify? 4729.90, 4729.901, 4729.91, 4729.92, 4729.921, 4729.93, 4729.94, 4729.95, 4729.96
- 6. What are the reasons for proposing the rule?

This rule is being proposed to amend pharmacy technician standards. Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for pharmacy technicians.

7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

The rule is amended to remove the requirement of documented positive identification by the sending certified pharmacist technicians and the pharmacist on duty when

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authorizing the transfer of the prescription copy. The rule has also been amended to update terminology regarding automated drugs storage systems.

- 8. Does the rule incorporate material by reference? Yes
- 9. If the rule incorporates material by reference and the agency claims the material is exempt pursuant to R.C. 121.75 please explain the basis for the exemption and how an individual can find the referenced material.

This rule references the United States Pharmacopeia (U.S.P.) and the Ohio Administrative Code (O.A.C.). The U.S.P. is a generally accepted industry standard for compounding drugs. The U.S.P. and the O.A.C. are generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule. U.S.P. is also a required reference for compounding pharmacies.

10. If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.

Not Applicable

II. Fiscal Analysis

11. Please estimate the increase / decrease in the agency's revenues or expenditures in the current biennium due to this rule.

This will have no impact on revenues or expenditures.

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Not applicable.

12. What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?

The rule is amended to remove the requirement of documented positive identification by the sending certified pharmacist technicians and the pharmacist on duty when authorizing the transfer of the prescription copy. This change will reduce administrative costs of compliance associated with the rule.

- 13. Does the rule increase local government costs? (If yes, you must complete an RSFA Part B). No
- 14. Does the rule regulate environmental protection? (If yes, you must complete an RSFA Part C). No

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15. If the rule imposes a regulation fee, explain how the fee directly relates to your agency's cost in regulating the individual or business.

Not Applicable.

III. Common Sense Initiative (CSI) Questions

- 16. Was this rule filed with the Common Sense Initiative Office? Yes
- 17. Does this rule have an adverse impact on business? Yes
 - A. Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? Yes

Requires completion of compounding training before engaging in drug compounding. Requires completion of hazardous drug handling training before handling hazardous drugs.

- B. Does this rule impose a criminal penalty, a civil penalty, or another sanction, or create a cause of action, for failure to comply with its terms? Yes
 - Violation of the rule may result in administrative discipline for a licensee or registrant. Discipline might include reprimand, suspension of a license, required course work, monetary penalty and/or revocation/denial of a license.
- C. Does this rule require specific expenditures or the report of information as a condition of compliance? No
- D. Is it likely that the rule will directly reduce the revenue or increase the expenses of the lines of business of which it will apply or applies? No