

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:5-3-07

Rule Type: No Change

Rule Title/Tagline: Controlled substances inventory requirements.

Agency Name: State Board of Pharmacy

Division: Terminal Distributors of Dangerous Drugs

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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? 3/18/2024 and 03/18/2029
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, 3719.28
5. What statute(s) does the rule implement or amplify? 4729.54, 4729.55
6. What are the reasons for proposing the rule?

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

Section 3719.13 of the Ohio Revised Code authorizes employees of the Board of Pharmacy to inspect prescriptions, orders, records, and stocks of dangerous drugs and controlled substances.

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

Requires all category III terminal distributors complete a controlled substances inventory on an annual basis.

- 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 Ohio Revised Code. The O.R.C. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule.

- 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?**

Depending on the stock of controlled substances, the controlled substances inventory may take several hours to complete.

- 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
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

This rule requires a license to operate as a terminal distributor of dangerous drugs in the state of Ohio.

- 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 this rule may result in administrative discipline for a licensee/registrant. Discipline might include reprimand, denial of a license, suspension of a license, required course work (pharmacists/interns/technicians), monetary fine and/or revocation 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