

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:5-3-07

Rule Type: New

Rule Title/Tagline: Controlled substances inventory requirements.

Agency Name: State Board of Pharmacy

Division: Terminal Distributors of Dangerous Drugs

Address: 77 South High St. 17th floor Columbus OH 43215

Contact: Alexandra Simon

Email: Alexandra.Simon@pharmacy.ohio.gov **Phone:** 614-502-7161

I. Rule Summary

1. Is this a five year rule review? No
 - A. What is the rule's five year review date?
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?

Without these regulations, the Board would not be able to provide uniform inventory requirements of controlled substances for terminal distributors.

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

Establishes requirements that all category III terminal distributor licenses complete a controlled substances inventory.

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. 121.71 to 121.76, please explain the basis for the exemption and how an individual can find the referenced material.**

This rule references the Code of Federal Regulations. The C.F.R. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule. Ohio Revised Code Sections 121.75 and 121.76 exempts these texts from inclusion in this filing.

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

Paragraph (B): Change the requirement an inventory must be completed within one year of the previous inventory to within 13 months of the previous inventory.

11/26/2018 Paragraph (A): Added the phrase "of the Administrative Code" and changed the word licenses to licensees.

10/25/2018 Rule is being revised to specify a cross reference to the code of federal regulations.

10/15/2018 The rule was refiled to add clarification for the annual inventory. Language was added to allow for the annual inventory may be taken on any date which is within one year of the previous inventory date.

II. Fiscal Analysis

11. **As a result of this proposed rule, please estimate the increase / decrease in revenues or expenditures affecting this agency, or the state generally, in the current biennium or future years. If the proposed rule is likely to have a different fiscal effect in future years, please describe the expected difference and operation.**

This will have no impact on revenues or expenditures.

0

Not applicable.

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

Requires all category III terminal distributors complete a controlled substances inventory on an annual basis. Depending on the stock of controlled substances, this 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**

III. Common Sense Initiative (CSI) Questions

15. **Was this rule filed with the Common Sense Initiative Office? Yes**

16. **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? No**

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 licensure discipline for a location licensed as or applying to be a terminal distributor of dangerous drugs. 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? Yes**

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