

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:5-8-03

Rule Type: New

Rule Title/Tagline: Compliance.

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? 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
5. What statute(s) does the rule implement or amplify? 4729.551, 4729.54, 4729.55
6. What are the reasons for proposing the rule?

Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for nonresident terminal distributors of dangerous drugs.

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

Specifies the Ohio requirements that must be followed by a nonresident terminal distributor of dangerous drugs selling drugs into the state, including inspection

procedures. Generally prohibits the sale of controlled substances by non-resident, non-pharmacy licensees.

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. 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.**

Rule revised to add cross reference to remote processing rules in paragraph (F)(9).

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?**

There may be additional administrative costs associated with this rule, including compliance with Ohio regulations for compounding dangerous drugs and dispensing controlled substance medications. This depends on the state in which the non-resident TDDD is located.

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

A non-pharmacy, non-resident terminal distributor needs approval by the Board's executive director to sell controlled substances into the state.

- 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 submission of information upon request as a condition of compliance.

- 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? Yes

Compliance with this rule may result in administrative costs to ensure the nonresident terminal distributor is complying with the requirements of the rule.

IV. Regulatory Restrictions (This section only applies to agencies indicated in R.C. 121.95 (A))

18. Are you adding a new or removing an existing regulatory restriction as defined in R.C. 121.95? No

A. How many new regulatory restrictions do you propose adding?

Not Applicable

B. How many existing regulatory restrictions do you propose removing?

Not Applicable