

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4729:5-19-02

Rule Type: New

Rule Title/Tagline: Personally furnishing dangerous drugs.

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? 3719.28, 4729.26

5. What statute(s) does the rule implement or amplify? 4729.51, 3719.06, 3719.81

6. What are the reasons for proposing the rule?

This rule is being proposed because all sections of OAC relating to terminal distributors are being consolidated into 4729:5 of the OAC. Without this regulation, the State of Ohio Board of Pharmacy would not be able to provide uniform requirements for clinics and prescriber offices.

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

Establishes the requirements for a prescriber who personally furnishes dangerous drugs.

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 Ohio Revised Code, the Ohio Administrative Code, and Code of Federal Regulations. The O.R.C., O.A.C. and the C.F.R. are 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.

Added paragraph (F)(2).

05/07/2019 Clarifies counseling may be refused either verbally or in writing.

Removes references to propofol, gabapentin, and exempt narcotics.

Removes requirements drugs personally furnished must be sealed in a tamper evident manner.

04/29/2019 Paragraph (B): Removed the word prescriber.

Paragraph (H)(2): Added the word "substance."

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.

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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 labeling, final check requirements by a prescriber and the counseling provisions of this rule may result in an increase in the overall time necessary to personally furnish a medication to a patient.

- 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? No**