

Rule Summary and Fiscal Analysis (Part A)**State Board of Pharmacy**

Agency Name

Division

Cameron McNamee

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4729-9-29

Rule Number

NEW

TYPE of rule filing

Rule Title/Tag Line

Licensure as a Third Party Logistics Provider.**RULE SUMMARY**1. Is the rule being filed for five year review (FYR)? **No**2. Are you proposing this rule as a result of recent legislation? **No**3. Statute prescribing the procedure in accordance with the agency is required to adopt the rule: **119.03**4. Statute(s) authorizing agency to adopt the rule: **3719.28, 4729.26**5. Statute(s) the rule, as filed, amplifies or implements: **3719.03, 4729.53**

6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

The rule proposed under this statutory authority is necessary to facilitate compliance with Chapters 3719 and 4729 of the Ohio Revised Code to promote the public's safety. Without these regulations, the Board of Pharmacy would not be able to provide uniform licensure and oversight of virtual wholesalers and third party logistics providers.

7. If the rule is an AMENDMENT, then summarize the changes and the content

of the proposed rule; If the rule type is RESCISSION, NEW or NO CHANGE, then summarize the content of the rule:

Specifies requirements for licensure as a wholesale distributor of dangerous drugs for third party logistics providers.

8. If the rule incorporates a text or other material by reference and the agency claims the incorporation by reference is exempt from compliance with sections 121.71 to 121.74 of the Revised Code because the text or other material is **generally available** to persons who reasonably can be expected to be affected by the rule, provide an explanation of how the text or other material is generally available to those persons:

This rule references the Ohio Revised Code and the Ohio Administrative Code. The O.R.C. and 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.

9. If the rule incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material electronically, provide an explanation of why filing the text or other material electronically was infeasible:

Ohio Revised Code Sections 121.75 and 121.76 exempts these texts from inclusion in this filing.

10. If the rule is being **rescinded** and incorporates a text or other material by reference, and it was **infeasible** for the agency to file the text or other material, provide an explanation of why filing the text or other material was infeasible:

Not Applicable.

11. If **revising** or **refiling** this rule, identify changes made from the previously filed version of this rule; if none, please state so. If applicable, indicate each specific paragraph of the rule that has been modified:

The rule is being revised to include the CSI recommendation and memo of response. The rule was also amended to clarify, in paragraph (C), that the initial licensing requirements also apply to existing licensees that meet the definition of a third party logistics provider and that only new officers, directors and owners are required to submit to a criminal background check for existing licenses.

12. Five Year Review (FYR) Date:

(If the rule is not exempt and you answered NO to question No. 1, provide the scheduled review date. If you answered YES to No. 1, the review date for this rule is the filing date.)

NOTE: If the rule is not exempt at the time of final filing, two dates are required: the current review date plus a date not to exceed 5 years from the effective date for Amended rules or a date not to exceed 5 years from the review date for No Change rules.

FISCAL ANALYSIS

13. Estimate the total amount by which *this proposed rule* would **increase / decrease** either **revenues / expenditures** for the agency during the current biennium (in dollars): Explain the net impact of the proposed changes to the budget of your agency/department.

This will have no impact on revenues or expenditures.

\$0.00

No net impact.

14. Identify the appropriation (by line item etc.) that authorizes each expenditure necessitated by the proposed rule:

Not applicable.

15. Provide a summary of the estimated cost of compliance with the rule to all directly affected persons. When appropriate, please include the source for your information/estimated costs, e.g. industry, CFR, internal/agency:

Specifies requirements for licensure as a wholesale distributor of dangerous drugs for third party logistics providers. Requires licensure as a wholesale distributor of dangerous drugs with a third party logistics provider classification. Depending on whether the location will be shipping controlled or non-controlled drugs, the annual license cost ranges from \$750 to \$787.50. It also takes approximately one hour to complete the license application. Additionally, the rule imposes recordkeeping and background check requirements on licensees. The cost of a background check per officer of the company is: BCI&I - \$22, FBI - \$24, and some agencies may charge a processing fee (e.g. \$5-\$40). This rule also requires a recent state inspection report if the entity is not located in Ohio. If no inspection report is available or the state does not license this type of facility, the rule requires the entity obtain and maintain Verified-Accredited Wholesale Distributors (VAWD) accreditation from the National Association of Boards of Pharmacy. VAWD accreditation is \$5,500 in

the first year and \$7,500 every three years.

16. Does this rule have a fiscal effect on school districts, counties, townships, or municipal corporations? **No**

17. Does this rule deal with environmental protection or contain a component dealing with environmental protection as defined in R. C. 121.39? **No**

S.B. 2 (129th General Assembly) Questions

18. Has this rule been filed with the Common Sense Initiative Office pursuant to R.C. 121.82? **Yes**

19. Specific to this rule, answer the following:

A.) Does this rule require a license, permit, or any other prior authorization to engage in or operate a line of business? **Yes**

Requires licensure as a wholesale distributor of dangerous 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 licensure discipline for a wholesale distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, monetary penalty and/or revocation of a license.

C.) Does this rule require specific expenditures or the report of information as a condition of compliance? **Yes**

Requires reporting of any changes to the facility as well as suspicious drug orders. Requires demonstration of state licensure of accreditation upon renewal of existing licensee.