

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

Agency Name

Division

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4729-9-12

Rule Number

AMENDMENT

TYPE of rule filing

Rule Title/Tag Line

**Verification of license as a distributor of dangerous drugs or
exempt status of a prescriber.****RULE SUMMARY**1. Is the rule being filed for five year review (FYR)? **Yes**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: **3719.04, 4729.51, 4729.54, 4729.541, 4729.60**

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 the provisions in Chapters 4729 and 3719 of the Ohio Revised Code to promote the public's safety and uniformity of care throughout Ohio. Without these regulations, the Ohio State Board of Pharmacy would not be able to ensure that entities that sell dangerous drugs verify that a purchaser is properly licensed to possess those drugs.

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:

Clarifies a recent change in the ORC that requires certain prescriber businesses that were exempt from terminal distributor of dangerous drugs (TDDD) licensure to become licensed if they possess certain drugs on-site. Also, requires TDDDs to check the status of entities if they are providing compounded drugs for in-office administration pursuant to a new OAC section that went into effect on May 1, 2015.

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. 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.

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 this text 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:

Not Applicable.

12. Five Year Review (FYR) Date: **7/15/2015**

(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 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:

This will result in increased administrative costs for pharmacies to verify that a site is properly licensed to possess compounded drugs. Verification would take approximately 1 minute by querying the entity placing the order via the state's e-licensing system.

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? **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 these rules may result in administrative licensure discipline for a wholesale distributor of dangerous drugs or terminal distributor of dangerous drugs. Discipline might include reprimand, suspension of a license, 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**