Rule Summary and Fiscal Analysis (Part A)

State Board of Pharmacy
Agency Name

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4729:3-3-04 NEW

Rule Number | TYPE of rule filing

Rule Title/Tag Line **Certified Pharmacy Technicians.**

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? **Yes**
Bill Number: **319** General Assembly: **131** Sponsor: **Eklund**

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: **4729.94, 4729.26**

5. Statute(s) the rule, as filed, amplifies or implements: **4729.90, 4729.901, 4729.91, 4729.92, 4729.921, 4729.93, 4729.94, 4729.95, 4729.96**

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

This rule is being proposed because of the passage of SB 319 (131st GA) that requires the State of Ohio Board of Pharmacy to register pharmacy technicians.

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:

Establishes the activities certified pharmacy technicians may perform.

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 United States Pharmacopeia (U.S.P.), which is a generally accepted industry standard for compounding drugs. The U.S.P. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule. U.S.P. is also a required reference for compounding pharmacies.

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

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:

This rule references the United States Pharmacopeia (U.S.P.), which is a generally accepted industry standard for compounding drugs. The U.S.P. is generally available in libraries and on the internet to persons who reasonably can be expected to be affected by the rule. U.S.P. is also a required reference for compounding pharmacies.

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:

Rule is being revised to correct a cross reference in paragraph (B)(2)(c). All specific references to specific versions of USP were removed from the rule. Hazardous training requirements were removed (i.e. USP 800). Paragraph (B)(1) was also amended to clarify that new verbal orders by certified techs may be accepted under certain conditions.

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.

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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:

An employer that engages in non-sterile compounding will have to provide additional training for certified technicians prior to engaging in non-sterile compounding.

An employer that engages in sterile compounding will have to provide additional training for certified technicians prior to engaging in sterile compounding.

An employer that works with hazardous drugs will have to provide additional training for certified technicians prior to engaging in the handling of those drugs.

If not already developed, pharmacies will incur added costs to develop these trainings.

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 completion of compounding training before engaging in drug

compounding. Requires completion of hazardous drug handling training before

handling hazardous 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 this rule may result in administrative licensure discipline for a pharmacist, pharmacy intern, pharmacy technician (including trainee) and terminal/wholesale distributors of dangerous drugs. Discipline might include reprimand, denial of a license, suspension of a license, required course work (pharmacists/interns), 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**