

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

Agency Name

Division

**Cameron McNamee**

Contact

**77 South High Street Room 1702 Columbus OH  
43215-6126**

Agency Mailing Address (Plus Zip)

**614-466-7322**

Phone

Fax

**cameron.mcnamee@bop.ohio.gov**

Email

**4729-37-04**

Rule Number

**AMENDMENT**

TYPE of rule filing

Rule Title/Tag Line

**Information required for submission.****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 , 4729.84**
5. Statute(s) the rule, as filed, amplifies or implements: **4729.75 , 4729.76 , 4729.77 , 4729.78 , 4729.79 , 4729.80 , 4729.81 , 4729.82 , 4729.83 , 4729.84**
6. State the reason(s) for proposing (i.e., why are you filing,) this rule:

The Board is filing this rule in order to protect and promote public safety by ensuring uniform standards regarding the reporting of drug information to the Ohio Automated Rx Reporting System (OARRS). In addition, provisions of this rule (diagnosis code reporting) support efforts to monitor and enforce the acute pain prescribing limits currently being proposed by Ohio's prescriber regulatory boards. Such limits have the potential to reduce the number opioids prescribed in Ohio by

an additional 109 million doses.

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:

Requires the reporting of diagnosis codes to OARRS by dispensing pharmacies (outpatient) and prescribers that personally furnish controlled substances. It also includes processes for when a pharmacy cannot obtain a diagnosis code or days' supply from a prescriber.

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:

Rule is being modified to update room for public hearing.

This rule is being modified to address concerns raised by the National Association of Chain Drug Stores during the rule's public hearing:

- Paragraph A(23) is being modified to change the required code for when a prescriber does not include an ICD-10 code on a prescription from the phrase "NO CODE" to "NC".
- Paragraph A(18)(b) is being added to address an issue of when the pharmacy has to dispense a different quantity than what is originally indicated on the prescription. This will allow the pharmacy to calculate a different days' supply.

12. Five Year Review (FYR) Date: **10/1/2020**

(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:

Requiring of diagnosis codes will require an investment by pharmacies to update

their systems to record this information and adopt the ASAP 4.2A Standard (all are currently utilizing the ASAP 4.2 standard) for prescription reporting. Such costs to conduct this upgrade will vary by each pharmacy's dispensing system vendor.

Additionally, the rule places a reporting burden on prescribers and wholesalers to submit the information required in the rule. It should be noted that wholesalers use an existing report from DEA to report to the Board and there are a limited number of prescribers who personally furnish controlled substances due to restrictions placed in Ohio law.

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 this rule may result in administrative licensure discipline for a terminal or wholesale 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? **Yes**

Requires reporting of data as stated in the rule.