

Rule Summary and Fiscal Analysis

Part A - General Questions

Rule Number: 4730-2-10

Rule Type: New

Rule Title/Tagline: Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).

Agency Name: State Medical Board - Physician Assistant Licensing

Division:

Address: 30 East Broad Street 3rd floor Columbus OH 43215

Contact: Sallie Debolt

Email: sallie.debolt@med.ohio.gov **Phone:** 614-644-7021

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? Yes
 - A. If so, what is the bill number, General Assembly and Sponsor? SB 110 - 131
- Senator Burke
3. What statute is this rule being promulgated under? 119.03
4. What statute(s) grant rule writing authority? 4730.07, 4730.53
5. What statute(s) does the rule implement or amplify? 4730.21, 4730.53
6. What are the reasons for proposing the rule?

Section 4730.53 of the Revised Code requires the Medical Board to adopt rules settings the standards and procedures for checking OARRS when prescribing opioid analgesics or benzodiazepines.
7. Summarize the rule's content, and if this is an amended rule, also summarize the rule's changes.

Proposed new rule 4730-2-10 sets forth the requirements to be followed by physician assistant who prescribes controlled substances regarding review of the Ohio Automated Prescription Reporting System (OARRS) and potential "red flags" that will require a new OARRS check. The language reflects statutory requirements when prescribing opioid analgesics and benzodiazepines. The rule also includes a listing of "red flags" that is more inclusive than the previous version of the rule.

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.**
The proposed rescinded rule references multiple sections of the Ohio Revised Code, as well as multiple rules in the Ohio Administrative Code, which are readily available at public libraries and via an internet search, including the Medical Board's website.
10. **If revising or re-filing the rule, please indicate the changes made in the revised or re-filed version of the rule.**

Not Applicable

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.

0.00

Not applicable.

12. **What are the estimated costs of compliance for all persons and/or organizations directly affected by the rule?**

Complying with the requirements of Rule 4730-2-10 creates an adverse impact in that Paragraph (B) sets the minimal standards of care for considering whether a controlled substance is appropriate to prescribe for a patient. The rule also sets parameters for practice by requiring a check of the prescription monitoring program when certain "red flags" are observed. Although there is no fee to register with the prescription

monitoring program, it is also often argued that being required to check the program takes the time of the prescriber.

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?** Yes

The rule reflects that a physician assistant who prescribes controlled substances must be registered with OARRS.

- 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

Failure to follow the requirements for checking the controlled substance prescription history of a patient prior to prescribing controlled substances could result in license discipline, up to and including license revocation, as well as a statutory penalty of up to \$20,000.

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

Physician assistants who intend to prescribe controlled substances are required to run, or have a delegate run, an OARRS check on the intended patient and review the results prior to prescribing the medication, as well as requirements to run an OARRS check on a patient that exhibits "red flags." The receipt and review of the check have to be documented in the patient record.