



**RULE 4730-2-10: STANDARDS AND PROCEDURES FOR REVIEW OF “OHIO
AUTOMATED RX REPORTING SYSTEM” (OARRS)**

The physician assistant rules are being reviewed by the Medical Board for amendments needed for clarity and for language that is either unnecessary or that conflict with the provisions of statute enacted in Senate Bill 110 (Effective October 15, 2015).

With input from the Physician Assistant Policy Committee, the following amendments are proposed for Rule 4730-2-10: Standards and Procedures for Review of “Ohio Automated Rx Reporting System” (OARRS). The changes reflect the provisions of Section 4730.53, Ohio Revised Code, and are consistent with the provisions of Rule 4731-11-11, Ohio Administrative Code, applicable to physicians.

Paragraph (A):

- Adds definition of “delegate” (for purposes of accessing OARRS).
- Changes the definition of “reported drugs” to reflect that drugs containing tramadol are not controlled substances.

Paragraph (B): Adds standards of care.

Paragraph (C):

- Requires an OARRS check in compliance with Section 4730.53, Ohio Revised Code.
- Requires an OARRS check when “red flags” are pertinent.

Paragraph (D): Requires certain documentation and consideration of specified actions once a prescriptive decision is made.

Paragraph (E): Sets out the frequency with which OARRS must be checked.

Paragraph (F): Sets out documentation requirements for review of the OARRS report.

Paragraph (H): Lists the situations under which the physician assistant is not required to check OARRS.

Because more than fifty percent of the current rule is being amended, the current rule will be rescinded and the “amended” language adopted as a new rule.

Please submit any comments to Sallie.Debolt@med.ohio.gov by April 14, 2016.

*** DRAFT - NOT YET FILED ***

4730-2-10

Standards and procedures for review of "Ohio Automated Rx Reporting System" (OARRS).

(A) For purposes of this rule:

(1) "Delegate" means an authorized representative who is registered with the Ohio board of pharmacy to obtain an OARRS report on behalf of the physician assistant~~"OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.~~

(2) "OARRS" means the "Ohio Automated Rx Reporting System" drug database established and maintained pursuant to section 4729.75 of the Revised Code.

(3) "OARRS" report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.

~~(2) "OARRS report" means a report of information related to a specified patient generated by the drug database established and maintained pursuant to section 4729.75 of the Revised Code.~~

~~(3) "Personally furnish" means the distribution of drugs by a prescriber to the prescriber's patients for use outside the prescriber's practice setting.~~

~~(4) "Protracted basis" means a period in excess of twelve continuous weeks.~~

~~(5)~~(4) "Reported drugs" means all the drugs listed in rule 4729-37-02 of the Administrative Code that are required to be reported to the drug database established and maintained pursuant to section 4729.75 of the Revised Code, including controlled :

(a) ~~Controlled~~ substances in schedules II, III, IV, and V ~~, and~~

~~(b) All dangerous drug products containing tramadol.~~

(B) ~~If a physician assistant believes or has reason to believe that a patient may be abusing or diverting drugs, the physician assistant shall use sound clinical judgment in determining whether or not the reported drug should be prescribed to the patient under the circumstances~~Standards of care :-

(1) ~~To assist in this determination, the physician assistant shall access OARRS and document receipt and assessment of the information received if the patient exhibits the following signs of drug abuse or diversion~~The accepted and prevailing minimal standards of care require that when prescribing a reported

drug, a physician assistant shall take into account all of the following:

- (a) ~~Selling prescription drugs~~The potential for abuse of the reported drug;
 - (b) ~~Forging or altering a prescription~~The possibility that use of the reported drug may lead to dependence;
 - (c) ~~Stealing or borrowing reported drugs~~The possibility the patient will obtain the reported drug for a nontherapeutic use or distribute it to other persons;and;
 - (d) ~~Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;~~The potential existence of an illicit market for the reported drug.
 - (e) ~~Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;~~
 - (f) ~~Having been arrested, convicted or received diversion, or intervention in lieu of conviction for a drug related offense while under the physician's care;~~
 - (g) ~~Receiving reported drugs from multiple prescribers, without clinical basis;~~
~~or~~
 - (h) ~~Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs.~~
- (2) ~~Other signs of possible abuse or diversion which may necessitate accessing OARRS include, but are not limited to the following:~~ In considering whether a prescription for a reported drug is appropriate for the patient, the physician assistant shall use sound clinical judgment and obtain and review an OARRS report consistent with the provisions of this rule.
- (a) ~~A known history of chemical abuse or dependency;~~
 - (b) ~~Appearing impaired or overly sedated during an office visit or exam;~~
 - (c) ~~Requesting reported drugs by specific name, street name, color, or identifying marks;~~
 - (d) ~~Frequently requesting early refills of reported drugs;~~

- ~~(e) Frequently losing prescriptions for reported drugs;~~
- ~~(f) A history of illegal drug use;~~
- ~~(g) Sharing reported drugs with another person; or~~
- ~~(h) Recurring emergency department visits to obtain reported drugs.~~

(C) A physician assistant ~~prescribing reported drugs to treat a patient on a protracted basis shall, at a minimum, document receipt and assessment of an OARRS report in the following circumstances~~ shall obtain and review an OARRS report to help determine if it is appropriate to prescribe an opioid analgesic, benzodiazepine, or other reported drug to a patient as provided in this paragraph and paragraph (F) of this rule:

- (1) ~~Once the physician assistant has reason to believe that the treatment will be required on a protracted basis~~ A physician assistant shall obtain and review an OARRS report before prescribing an opioid analgesic or benzodiazepine to a patient, unless an exception listed in paragraph (H) of this rule is applicable; and,
- (2) ~~At least once annually, thereafter~~ A physician assistant shall obtain and review an OARRS report when a patient's course of treatment with a reported drug other than an opioid analgesic or benzodiazepine has lasted more than ninety days, unless an exception listed in paragraph (H) of this rule is applicable.
- (3) A physician assistant shall obtain and review and OARRS report when any of the following red flags pertain to the patient:
 - (a) Selling prescription drugs;
 - (b) Forging or altering a prescription;
 - (c) Stealing or borrowing reported drugs;
 - (d) Increasing the dosage of reported drugs in amounts that exceed the prescribed amount;
 - (e) Suffering an overdose, intentional or unintentional;
 - (f) Having a drug screen result that is inconsistent with the treatment plan or refusing to participate in a drug screen;
 - (g) Having been arrested, convicted, or received diversion or intervention in lieu of conviction for a drug related offense while under the care of the

physician assistant or the physician assistant's supervising physician;

(h) Receiving reported drugs from multiple prescribers, without clinical basis;

(i) Traveling with a group of other patients to the physician assistant's office where all or most of the patients request controlled substance prescriptions;

(j) Traveling an extended distance or from out of state to the physician assistant's office;

(k) Having a family member, friend, law enforcement officer, or health care professional express concern related to the patient's use of illegal or reported drugs;

(l) A known history of chemical abuse or dependency;

(m) Appearing impaired or overly sedated during an office visit or exam;

(n) Requesting reported drugs by street name, color, or identifying marks;

(o) Frequently requesting early refills of reported drugs;

(p) Frequently losing prescriptions for reported drugs;

(q) A history of illegal drug use;

(r) Sharing reported drugs with another person; or

(s) Recurring visits to non-coordinated sites of care, such as emergency departments, urgent care facilities, or walk-in clinics to obtain reported drugs.

(D) A physician assistant ~~shall document receipt and assessment of all OARRS reports in the patient record.~~ who decides to utilize an opioid analgesic, benzodiazepine, or other reported drug in any of the circumstances within paragraphs (C)(2) and (C)(3) of this rule shall take the following steps prior to issuing a prescription for the opioid analgesic, benzodiazepine, or other reported drug:

(1) ~~Initial reports requested in compliance with this rule shall cover a time period of at least one year.~~ Review and document in the patient record the reasons why the physician assistant believes or has reason to believe that the patient may be abusing or diverting drugs;

(2) ~~Subsequent reports requested in compliance with this rule shall, at a minimum, cover the period from the date of the last report to present.~~ Review and

document in the patient's record the patient's progress toward treatment objectives over the course of treatment;

(3) Review and document in the patient record the functional status of the patient, including activities for daily living, adverse effects, analgesia, and aberrant behavior over the course of treatment;

(4) Consider using a patient treatment agreement including more frequent and periodic reviews of OARRS reports and that may also include more frequent office visits, different treatment options, drug screens, use of one pharmacy, use of one provider for the prescription of reported drugs, and consequences for non-compliance with the terms of the agreement. The patient treatment agreement shall be maintained as part of the patient record; and

(5) Consider consulting with or referring the patient to a substance abuse specialist.

~~(E) In the event an OARRS report is not available prior to writing a prescription for a reported drug or personally furnishing the reported drug, the physician assistant shall document in the patient record why the OARRS report was not available.~~
Frequency for follow-up OARRS reports:

(1) For a patient whose treatment with an opioid analgesic or benzodiazepine lasts more than ninety days, a physician assistant shall obtain and review an OARRS report for the patient at least every ninety days during the course of treatment, unless an exception listed in paragraph (G) of this rule is applicable.

(2) For a patient who is treated with a reported drug other than an opioid analgesic or benzodiazepine for a period lasting more than ninety days, the physician assistant shall obtain and review an OARRS report for the patient at least annually following the initial OARRS report obtained and reviewed pursuant to paragraph (C)(2) of this rule until the course of treatment utilizing the reported drug has ended, unless an exception in paragraph (H) of this rule is applicable.

~~(F) Paragraph (C) of this rule does not apply to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code.~~
When a physician assistant or their delegate requests an OARRS report in compliance with this rule, a physician assistant shall document receipt and review of the OARRS report in the patient record, as follows:

(1) Initial reports requested shall cover at least the twelve months immediately preceding the date of the request;

(2) Subsequent reports requested shall, at a minimum, cover the period from the

date of the last report to present:

(3) If the physician assistant practices primarily in a county of this state that adjoins another state, the physician assistant or their delegate shall also request a report of any information available in the drug database that pertains to prescriptions issued or drugs furnished to the patient in the state adjoining that county; and

(4) If an OARRS report regarding the patient is not available, the physician assistant shall document in the patient's record the reason that the report is not available and any efforts made in follow-up to obtain the requested information.

(G) Review of the physician assistant's compliance with this rule shall be included as an activity in the quality assurance plan required by division (F) of section 4730.21 of the Revised Code and rule 4730-1-05 of the Administrative Code.

(H) A physician assistant shall not be required to review and assess an OARRS report when prescribing an opioid analgesic, benzodiazepine, or other reported drug under the following circumstances, unless a physician assistant believes or has reason to believe that a patient may be abusing or diverting reported drugs:

(1) The reported drug is prescribed to a hospice patient in a hospice care program as those terms are defined in section 3712.01 of the Revised Code, or any other patient diagnosed as terminally ill;

(2) The reported drug is prescribed for administration in a hospital, nursing home, or residential care facility;

(3) The reported drug is prescribed in an amount indicated for a period not to exceed seven days;

(4) The reported drug is prescribed for the treatment of cancer or another condition associated with cancer; or

(5) The reported drug is prescribed to treat acute pain resulting from a surgical or other invasive procedure or delivery.