DRAFT RULE approved for circulation 1-14-15

4731-11-01 **Definitions.**

As used in Chapter 4731-11 of the Administrative Code:

(A) "Controlled substance" means a drug, compound, mixture, preparation, or substance included in schedule I, II, III, IV, or V pursuant to the provisions of Chapter 3719. of the Revised Code.

(B) "Controlled substance stimulant" means any drug, compound, mixture, preparation, or substance which is classified as a stimulant in controlled substance schedule II, III, or IV listed in section 3719.41 of the Revised Code, or which is classified as a stimulant in controlled substances schedule II, III, or IV pursuant to section 3719.43 or 3719.44 of the Revised Code.

(C) "Utilize a controlled substance or controlled substance stimulant" means to prescribe, administer, dispense, supply, sell or give a controlled substance or controlled substance stimulant.

(D) "Recognized contraindication" means any contraindication to the use of a drug which is listed in the United States food and drug administration (hereinafter, "F.D.A.") approved labeling for the drug, or which the board determines to be accepted as a contraindication.

(E) "The board" means the state medical board of Ohio.

(F) "BMI" means body mass index, calculated as a person's weight in kilograms divided by height in meters squared.

(G) "Physician" means an individual holding a certificate under Chapter 4731. of the Revised Code to practice medicine and surgery, osteopathic medicine and surgery, or podiatric medicine and surgery and practicing within his or her scope of practice as defined by section 4731.51 of the Revised Code.

(H) "Board certified addictionologist or addiction psychiatrist" means a medical doctor or doctor of osteopathic medicine and surgery who holds one of the following certifications:

(1) Subspecialty board certification in addiction psychiatry from the American board of psychiatry and neurology;

(2) Board certification in addiction medicine from the American board of addiction medicine;

(3) Certification from the American society of addiction medicine; or

(4) Board certification with additional qualification in addiction medicine from the American osteopathic association.

(I) "Office based opioid treatment", or "OBOT", means treatment of opioid addiction utilizing a schedule III, IV or V controlled substance narcotic.

(J) ~~"Opioid treatment program", or "OTP", sometimes referred to as a "methadone clinic", means a program licensed by the state to administer or dispense schedule II controlled substance narcotics in the maintenance or detoxification treatment of opioid addiction.~~

"SHORT TERM ANOREXIANT" MEANS A SCHEDULE III OR IV CONTROLLED SUBSTANCE BEARING F.D.A. APPROVED LABELING STATING THAT IT IS INDICATED FOR WEIGHT LOSS FOR "A FEW WEEKS."

(K) " MEDICAL EVALUATION" MEANS AN EVALUATION THAT IS CONDUCTED WITH THE PATIENT IN THE PHYSICAL PRESENCE OF THE PRACTITIONER, WITHOUT REGARD TO WHETHER PORTIONS OF THE EVALUATION ARE CONDUCTED BY OTHER HEALTH PROFESSIONALS.

(L) "PRESCRIPTION DRUG" MEANS A DRUG WHICH UNDER STATE OR FEDERAL LAW MAY BE ADMINISTERED OR DISPENSED ONLY BY OR UPON THE ORDER OF A LICENSED PRACTITIONER. PRESCRIPTION DRUG INCLUDES A DANGEROUS DRUG, AS THAT TERM IS DEFINED IN SECTION 4729.01 OF THE REVISED CODE.

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4731-11-09 Prescribing to persons the physician has never personally examined.

(A) A physician may prescribe, dispense, ~~or~~ otherwise provide, or cause to be provided a prescription drug that is not a controlled substance to a person on whom the physician has never previously conducted a medical evaluation, as that term is defined in rule 4731-11-01 of the Administrative Code, and who is at a location remote from the physician, when the physician complies with all of the requirements of this paragraph.

(1) A physician shall complete and document a medical evaluation and collection of relevant clinical history that conforms to minimal standards of care consistent with an evaluation that was completed in a face-to-face interaction necessary to establish diagnosis and identify underlying condition and/or contra-indications to the treatment recommended or provided;

(2) The physician shall complete an examination of the patient using appropriate diagnostic medical equipment that meets both of the following criteria:

(a) The diagnostic medical equipment is capable of transmitting in real-time the patient's physical data; and

(b) The diagnostic medical equipment is capable of transmitting in real-time images of the patient's physical condition and also has the ability to be adjusted for better image quality and definition;

(3) The physician shall document having had dialogue with the patient regarding treatment options and the risks and benefits of treatment, sufficient to permit the patient to provide informed consent to treatment;

(4) The physician shall maintain a contemporaneous medical record that is readily available to the patient and to the patient's other health care professionals;

(5) The physician shall include the electronic prescription information as part of the patient medical record; and

(6) As necessary, the physician shall follow up with the patient to assess the therapeutic outcome.

(B) A physician may prescribe, dispense, ~~or~~ otherwise provide, or cause to be provided a prescription drug, including a controlled substance, to a person on whom the physician has never conducted a medical evaluation, as that term is defined in rule 4731-11-01 of the Administrative Code, in the following situations:

(1) The person is a patient of a colleague of the physician and the drugs are provided pursuant to an on call or cross coverage arrangement between the physicians;

(2) The physician is consulting with another physician or health care provider who is authorized to practice in this state and is acting within the scope of their professional license, including having prescriptive authority, when the following requirements are met:

a) The physician shall establish that the other physician or health care provider has an ongoing professional relationship with the patient and has agreed to supervise the patient's use of the drug or drugs to be provided.

b) If the health care provider is a physician assistant, the physician has a supervision agreement with the physician assistant.

c) If the health care provider is an advanced registered practice nurse, the physician has a written standard care arrangement with the advanced registered practice nurse.

(3) The physician is a medical director or hospice physician of a hospice program licensed pursuant to Chapter 3712. of the Revised Code, and the patient to whom the drugs are prescribed, dispensed, or otherwise provided is enrolled in that hospice program.

(4) The person has been admitted as an inpatient to or is a resident of an institutional facility. For purposes of this rule, "institutional facility" has the same meaning as in rule 4729-17-01 of the Administrative Code.

This paragraph does not authorize or legitimize practices that would violate other applicable standards or legal requirements.

(C) A physician shall not advertise, offer or permit the physician's name or certificate to be used in an advertisement or offer, to provide any prescription drug in a manner that would violate any provision of this rule.

(D) Except as provided in paragraph (B) of this rule, a physician shall not prescribe, dispense, otherwise provide, or cause to be provided, any controlled substance to a person on whom the physician has never conducted a medical evaluation, as that term is defined in rule 4731-11-01 of the Administrative Code.

(E) Except as provided in paragraphs (A) and (B) of this rule, a physician shall not prescribe, dispense, otherwise provide, or cause to be provided, any prescription drug that is not a controlled substance on whom the physician has never conducted a medical evaluation, as that term is defined in rule 4731-11-01 of the Administrative Code.

(F) Nothing in this rule shall be construed to imply that one in-person medical evaluation demonstrates that a prescription has been issued for a legitimate medical purpose within the course of professional practice.

(G) A violation of any provision of this rule, as determined by the board, shall constitute any or all of the following:

(1) "Failure to maintain minimal standards applicable to the selection or administration of drugs," as that clause is used in division (B)(2) of section 4731.22 of the Revised Code;

(2) "Selling, prescribing, giving away, or administering drugs for other than legal and legitimate therapeutic purposes," as that clause is used in division (B)(3) of section 4731.22 of the Revised Code; or

(3) "A departure from, or the failure to conform to, minimal standards of care of similar practitioners under the same or similar circumstances, whether or not actual injury to a patient is established," as that clause is used in division (B)(6) of section 4731.22 of the Revised Code.

(H) For purposes of this rule, the following definitions apply:

1) Cross-coverage: An agreement between Ohio-licensed physicians under which one physician covers the established active patients of the other when that physician is not available. This type of agreement includes on-call coverage for after hours and weekends.

2) Consult: A request for an opinion and/or advice by an Ohio-licensed physician to another Ohio-licensed physician for a recommended course of action concerning a particular established active patient of the referring physician.

4731-11-11 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 to obtain an OARRS report on behalf of a physician;

(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;

(4) "Personally furnish" means the distribution of drugs by a physician to their patients for use outside the physician's practice setting; and

(5) "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 substances in schedules II, III, IV, and V.

(B) Accepted and prevailing standards of care require that when prescribing or personally furnishing a reported drug under the following circumstances:

(1) A physician shall take into account the potential for abuse of the reported drug, the possibility the reported drug may lead to dependence, the possibility the patient will obtain the reported drug for a nontherapeutic use or distribute it to other persons, and the potential existence of an illicit market for the reported drug. When considering these circumstances in the course of determining whether to prescribe or personally furnish a reported drug to a patient, a physician shall use sound clinical judgment and consider obtaining and reviewing an OARRS report, consistent with the requirements of this rule;

(2) A physician shall obtain and review an OARRS report following a course of treatment for a period of more than ninety days that includes the prescribing or personal furnishing of reported drugs that are not an opioid analgesic or benzodiazepine, and at least annually thereafter until the course of treatment utilizing these reported drugs has ended, unless the physician is excepted from having to do so under the terms of paragraph (E) of this rule; and

(3) A physician shall obtain and review an OARRS report before initially prescribing or personally furnishing to a patient a reported drug that is an opioid analgesic or benzodiazepine, unless the physician is excepted from having to do so under the terms of paragraph (E) of this rule. If the patient continues to receive opioid analgesics or benzodiazepines for more than ninety days after the initial report is requested, the physician

shall obtain and review OARRS reports for the patient at intervals not exceeding ninety days, determined according to the date the initial request was made, and until the course of treatment has ended.

(C) A physician shall obtain and review an OARRS report to help determine if it is appropriate to continue prescribing or personally furnishing reported drugs to a patient when a physician believes or has reason to believe that a patient may be abusing or diverting drugs. A physician shall use sound clinical judgment consistent with accepted and prevailing standards of care in the course of determining whether or not to prescribe or personally furnish any reported drug to the patient under these circumstances. A physician shall take the following steps if the physician then determines to provide further treatment utilizing reported drugs:

(1) Review and documentation of the reasons why the physician believes or has reason to believe that the patient may be abusing or diverting drugs;

(2) Review and documentation of the patient's progress toward treatment objectives over the course of treatment;

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

(3) Utilization of a patient treatment agreement including more frequent and periodic review 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 or personally furnishing 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

(4) Consultation with or referral to a substance abuse specialist.

(D) When a physician or their delegate requests an OARRS report to assist compliance with this rule, a physician 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 practices primarily in a county of this state that adjoins another state, the physician 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 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.

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

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

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

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