

4731-34-01

Standards and procedures to be following by physicians when prescribing a dangerous drug that may be administered by a pharmacist by injection.

(A) As used in this rule,

- (1) "Physician" means an individual authorized under Chapter 4731. of the Revised Code to practice medicine and surgery or osteopathic medicine and surgery.
- (2) "Pharmacist" means an individual licensed under chapter 4729. of the Revised Code who has met the requirements in section 4729.45 of the Revised Code and rule 4729:1-3-03 of the Administrative Code to administer drugs by injection.
- (3) "Pharmacy," except when used in a context that refers to the practice of pharmacy, means any area, room, rooms, place of business, department, or portion of any of the foregoing where the practice of pharmacy is conducted.

(B) Subject to paragraph (C) of this rule, a physician may prescribe any of the following dangerous drugs to be administered by injection by a pharmacist to a patient with whom the physician has an ongoing physician-patient relationship:

- (1) An opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form. An opioid antagonist may also be administered for the treatment of alcohol dependence in accordance with approved labeling by the United States food and drug administration.
- (2) An antipsychotic drug administered in a long-acting or extended-release form.
- (3) Hydroxyprogesterone caproate for pregnant women.
- (4) Medroxyprogesterone acetate for non-pregnant women.
- (5) Cobalamin, to include: cyanocobalamin, hydroxocobalamin or any other vitamin B12 injection approved by the United States food and drug administration.
- (6) Any other dangerous drugs authorized for pharmacist administration pursuant to section 4729.45 of the Revised Code.

(C) If a physician chooses to prescribe the dangerous drugs in paragraph (B) of this rule to be administered by injection by a pharmacist, the physician shall comply with all the following:

- (1) Maintain an ongoing physician-patient relationship with the patient to whom the drug is being prescribed.

- (2) The physician's scope of practice must include treatment of the condition for which the patient has been prescribed the drug.
 - (3) The physician's prescription must specify the pharmacy where the drug is to be administered.
 - (4) The physician may only prescribe a drug to be administered at a pharmacy where the physician has either:

 - (a) Written and established a current protocol on file at that pharmacy that meets the requirements in paragraph (E) of this rule and that is appropriate for the patient; or
 - (b) Obtained and personally reviewed a current physician-established protocol on file at that pharmacy that meets the requirements in paragraph (E) of this rule, and agrees that this protocol is appropriate for the patient.
 - (5) The physician shall inform the patient that the drug that the physician is prescribing will be administered at a pharmacy that meets the requirements in paragraph (C)(4) of this rule, and obtain patient's consent to have the drug administered at that pharmacy. The patient's consent shall be documented in the medical record. The physician may not prescribe in the manner described in this rule without the patient's consent to both the manner and location of the administration of the prescription.
 - (6) If a physician chooses to prescribe an opioid antagonist used for treatment of drug addiction and administered in a long-acting or extended-release form to be administered by injection by a pharmacist, the physician shall also comply with all other applicable rules in Chapter 4731. of the Administrative Code for prescribing this type of drug.
- (D) A physician may terminate a prescription, which may include refills, with a pharmacy under this section at any time for any of the following reasons:
- (1) The patient or pharmacy is not following the physician-established protocol with the pharmacy;
 - (2) Failure of the pharmacist that administers the injection at the pharmacy to timely notify the physician within seven days of administration of the injection;
 - (3) Failure of the pharmacist that administers the injection at the pharmacy to report an adverse event to the physician that occurred during the administration of the injection;

- (4) In the case of an opioid antagonist, test results of the patient indicate that it is not appropriate to administer the drug;
- (5) Discontinuation of the patient-physician relationship; or
- (6) Any other medically appropriate reason.
- (E) A physician-established protocol for the administration of the dangerous drugs by injection by a pharmacist must comply with the following:

 - (1) All requirements listed in section 4729.45 of the Revised Code and paragraph (F) of rule 4729:1-3-03 of the Administrative Code.
 - (2) The protocol shall be signed and dated by the physician prior to implementation and shall be readily available to the administering pharmacist.
 - (3) A physician may sign one protocol for multiple locations licensed as terminal distributors of dangerous drugs.
 - (4) The protocol must be established by a physician who has a scope of practice that includes treatment of the conditions for which drugs administered under the protocol are intended to treat.
- (F) The physician-established protocol shall be reviewed and may be renewed by the physician on a biennial basis.
- (G) A violation of this rule, as determined by the Board, shall constitute for a physician "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.

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