

4729:5-21-02**Personally furnishing dangerous drugs from an opioid treatment program.**

(A) A prescriber who personally furnishes a dangerous drug, other than a sample drug pursuant to section 3719.81 of the Revised Code, shall affix to the container a label showing:

(1) The name and address of the prescriber;

(2) The name of the patient for whom the drug is intended;

(3) Name and strength of the dangerous drug;

(4) Directions for use;

(5) Date furnished; and

(6) If a compounded drug, the statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.

(B) A prescriber who personally furnishes a dangerous drug labeled as a sample and where the directions for use are different from the directions on or in the sample container, the prescriber shall affix a label to the sample container or provide written documentation accompanying the sample that includes the following:

(1) Name of the prescriber;

(2) The name of the patient for whom the drug is intended; and

(3) Directions for use.

(C) For controlled substances, quantities personally furnished to a patient are limited to a seventy-two-hour supply and in any thirty day period quantities personally furnished to all patients shall not exceed two thousand five hundred dosage units pursuant to section 4729.291 of the Revised Code.

(D) None of the following shall be counted in determining whether the amounts specified in paragraph (C) of this rule have been exceeded:

(1) Methadone personally furnished to patients for the purpose of treating drug dependence or addiction, if the prescriber meets the conditions specified in 21 CFR 1306.07 (6/23/2005);

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program licensed under section 5119.37 of the Revised Code.

(3) Controlled substances personally furnished to research subjects by a facility conducting clinical research in studies approved by a hospital-based institutional review board or an institutional review board accredited by the association for the accreditation of human research protection programs.

(E)

(1) A prescriber may designate a licensed health care professional acting within the scope of the professional's practice and, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (F) of this rule.

(2) The personal supervision requirement listed in paragraph (E)(1) of this rule does not apply if a licensed health care professional acting within the scope of the professional's practice is preparing and packaging either of the following:

(a) Methadone for the purpose of treating drug dependence or addiction; or

(b) Buprenorphine for the purpose of treating drug dependence or addiction.

(3) A prescriber may designate an unlicensed person, under the personal supervision of a prescriber or pharmacist, to prepare and package a dangerous drug that will be personally furnished by the prescriber or a pharmacist in accordance with paragraph (F) of this rule. An unlicensed person shall not prepare and package any of the following dangerous drugs:

(a) Anesthesia;

(b) Controlled substances; or

(c) Drugs administered intravenously.

(F) Only a prescriber shall personally furnish a drug. The prescriber may delegate the act of personally furnishing to a licensed pharmacist. The act of personally furnishing shall be documented using positive identification.

(G) Counseling.

- (1) A prescriber, pharmacist or a delegate in accordance with paragraph (H)(1) of this rule shall personally offer to provide, or may provide in writing, the service of counseling pursuant to paragraph (G)(2) of this rule to a patient or caregiver whenever any dangerous drug is personally furnished. A prescriber or pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses, either verbally or in writing, the offer of counseling or does not respond to the written offer to counsel.
- (2) Prescriber or pharmacist counseling may include, but is not limited to, the following:

 - (a) The name and description of the drug;
 - (b) The dosage form, dose, route of administration, and duration of drug therapy;
 - (c) The intended use of the drug and the expected action;
 - (d) Special directions and precautions for preparation, administration, and use by the patient;
 - (e) Common adverse effects or interactions and therapeutic contraindications that may occur, including possible methods to avoid them, and the action required if they occur;
 - (f) Techniques for self-monitoring drug therapy;
 - (g) Proper storage and disposal;
 - (h) Action to be taken in the event of a missed dose; and
 - (i) The prescriber or pharmacist's comments relevant to the patient's drug therapy, including other necessary information unique to the specific patient or drug.

(H) Provision of dangerous drugs.

- (1) A prescriber may delegate a licensed healthcare professional acting within the scope of the professional's practice to distribute dangerous drugs personally furnished by a prescriber or pharmacist if all the following apply:

 - (a) A prescriber or pharmacist provides personal supervision;
 - (b) Counseling is offered in accordance with paragraph (G) of this rule; and

(c) This task may be delegated in accordance with applicable state laws and rules.

(2) Paragraph (H)(1)(a) of this rule does not apply under any of the following circumstances:

(a) The drug is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and the drug provided is either:

(i) Methadone for the purpose of treating drug dependence or addiction and a prescriber or licensed pharmacist is available for counseling by means of electronic communication during normal hours of operation; or

(ii) Buprenorphine for the purpose of treating drug dependence or addiction as part of an opioid treatment program and a prescriber or licensed pharmacist is available for counseling by means of electronic communication during normal hours of operation.

(b) The drug is being provided to a patient by a licensed pharmacist.

(c) A non-controlled dangerous drug is provided to the patient by a licensed health care professional, acting within the scope of the professional's practice, and a prescriber or pharmacist is available for counseling by means of electronic communication during normal hours of operation.

(I) No prescriber or pharmacist may personally furnish to a patient to whom there is no valid prescriber patient relationship, pursuant to applicable state and federal laws, regulations, and rules.

(J) Personally furnishing naloxone.

(1) Except as provided in paragraph (J)(3) of this rule, an authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with sections 4731.941 and 3707.561 of the Revised Code, shall do all of the following:

(a) Prepare, package, and label the naloxone in accordance with the requirements of this rule.

(b) Conduct the final association of the naloxone to the patient.

(c) Keep and maintain all records in accordance with this chapter.

(d) Conduct patient counseling, including training on the use of naloxone, as specified in the physician protocol.

(2) An authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with sections 4731.941 and 3707.561 of the Revised Code may personally furnish the drug to themselves in order to assist an individual who there is reason to believe is experiencing an opioid-related overdose if all of the following conditions are met:

(a) The authorized individual complies with the protocol established by the authorizing physician, including having completed the training required by the protocol.

(b) The authorized individual has received training instructing them to summon emergency services as soon as practicable either before or after administering naloxone.

(c) Such practice is authorized in the physician approved protocol.

(3) An authorized individual personally furnishing naloxone pursuant to paragraph (J)(2) of this rule shall not be required to comply with paragraph (J)(1)(a), (J)(1)(b) and (J)(1)(d) of this rule.

(4) A terminal distributor of dangerous drugs may also administer naloxone in accordance with section 4729.514 of the Revised Code.

(K) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule 4729:5-5-14 of the Administrative Code is the property of that patient and is not considered personally furnishing. No prescriber that provides a patient with a drug pursuant to rule 4729:5-5-14 of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(L) Paragraph (K) of this rule does not prohibit a prescriber from charging a patient for any of the following:

(1) The cost of an office visit or any expense related to the administration of a dangerous drug; or

(2) The cost of a dangerous drug dispensed by a pharmacy to a patient if paid for by the prescriber.

Effective:

Five Year Review (FYR) Dates:

Certification

Date

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