

## **4729-5-17 Personally furnishing dangerous drugs.**

(A) Whenever a prescriber personally furnishes a dangerous drug, other than a sample drug pursuant to section [3719.81](#) of the Revised Code, the prescriber 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. If the patient is an animal, the name of the owner and identification of the animal.
- (3) Name and strength of the dangerous drug.
- (4) Directions for use.
- (5) Date furnished.
- (6) If a compounded drug product, the statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label.

(B) Whenever a prescriber personally furnishes a dangerous drug, labeled as a sample pursuant to section [3719.81](#) of the Revised Code and where the directions for use are different from the directions on or in the sample container, the prescriber shall also provide, in written format, the following:

- (1) Name of the prescriber.
- (2) Name of the patient. If the patient is an animal, the name of the owner and identification of the animal.
- (3) Directions for use.

(C) For controlled substances, personally furnishing quantities are limited to a seventy-two hour supply and in any thirty day period the personally furnishing quantities supplied 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 C.F.R. 1306.07 (9/1/2015);

(2) Buprenorphine personally furnished to patients for the purpose of treating drug dependence or addiction as part of an opioid treatment program that possesses a terminal distributor of dangerous drugs license issued under section [4729.54](#) of the Revised Code, is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11 (9/1/2015), and meets either of the following criteria:

(a) Buprenorphine and methadone are personally furnished by physicians treating patients participating in the program.

(b) Buprenorphine, but not methadone, is personally furnished by physicians treating patients participating in the program, the program is accredited by a national accrediting organization approved by the substance abuse and mental health services administration, the service of personally furnishing buprenorphine has, notwithstanding section [5119.371](#) of the Revised Code, been certified by the department of mental health and addiction services under section [5119.36](#) of the Revised Code, and the program maintains in the record

of a patient to whom buprenorphine has been administered or personally furnished a copy of the physician's signed and dated written order for that act.

(c) 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) Paragraph (C) of this rule does not apply to a prescriber who is a veterinarian.

(F) A prescriber may designate a health care professional acting within the scope of the professional's practice and, under the supervision of the prescriber, to prepare and package a dangerous drug that will be personally furnished by the prescriber.

(G) A prescriber shall perform the final check of the dangerous drug prior to personally furnishing. The final check shall be documented using positive identification pursuant to rule [4729-5-01](#) of the Administrative Code.

(H) Counseling.

(1) A prescriber or the prescriber's designee shall personally offer to provide the service of counseling pursuant to paragraph (H)(2) of this rule to the patient or caregiver whenever any dangerous drug is personally furnished. A prescriber shall not be required to counsel a patient or caregiver when the patient or caregiver refuses the offer of counseling or does not respond to the written offer to counsel. In this situation, when counseling is refused, the prescriber or the prescriber's designee shall ensure that such refusal is documented in the presence of the patient or the patient's caregiver, unless the prescriber is a veterinarian.

(2) Prescriber 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;
- (h) Action to be taken in the event of a missed dose; and
- (i) The prescriber's comments relevant to the individual's drug therapy, including other necessary information unique to the specific patient or drug.

(I) Distribution of dangerous drugs.

(1) A prescriber may delegate an individual or individuals to distribute dangerous drugs personally furnished by a prescriber if all of the following apply:

- (a) A prescriber authorized to personally furnish dangerous drugs provides on-site supervision;
  - (b) The designated individual offers counseling to the patient or caregiver to be provided by the on-site prescriber in accordance with paragraph (H) of this rule; and
  - (c) This task may be delegated in accordance with applicable state laws and rules.
- (2) Paragraphs (I)(1)(a) and (I)(b) of this rule do not apply in any of the following:
- (a) The drug is provided to the patient by a 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; or
    - (ii) Buprenorphine for the purpose of treating drug dependence or addiction as part of an opioid treatment program that is the subject of a current, valid certification from the substance abuse and mental health services administration of the United States department of health and human services pursuant to 42 C.F.R. 8.11 (9/1/2015).
  - (b) The dangerous drug is being provided to a patient by a licensed Ohio pharmacist.
  - (c) The dangerous drug is being provided in accordance with paragraph (K) of this rule.
  - (d) A non-controlled dangerous drug is provided to the patient by a health care professional, acting within the scope of the professional's practice, and a prescriber authorized to personally furnish dangerous drugs is available for counseling by means of electronic communication during normal hours of operation.
- (J) No prescriber 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. This may include a requirement for a documented patient encounter.
- (K) Personally furnishing naloxone.
- (1) Except as provided in paragraph (K)(3) of this rule, an authorized individual personally furnishing naloxone on behalf of a physician pursuant to a protocol established in accordance with section [4731.941](#) of the Revised Code, shall do all of the following:
- (a) Prepare, package and appropriately label the naloxone.
  - (b) Conduct the final check of the naloxone prior to personally furnishing on behalf of the prescriber.
  - (c) Keep and maintain all records in accordance with rule [4729-9-22](#) of the Administrative Code.
  - (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 section [4731.941](#) 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 (K)(2) of this rule shall not be required to comply with the paragraph (K)(1)(a), (K)(1)(b) or (K)(1)(d) of this rule.

(L) Records of drugs personally furnished shall be kept in accordance with rules [4729-9-22](#) and [4729-9-14](#) of the Administrative Code.

(M) Any patient specific dangerous drug dispensed by a pharmacy that is provided to a patient by a prescriber pursuant to rule [4729-5-10](#) of the Administrative Code is the property of that patient and is not considered personal furnishing. No prescriber that provides a patient with a drug pursuant to rule [4729-5-10](#) of the Administrative Code shall charge any additional fees or require any additional monetary compensation for the dangerous drug.

(N) Paragraph (M) 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.

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