4729-5-30 Manner of issuance of a prescription.

- (A) A prescription, to be valid, must be issued for a legitimate medical purpose by an individual prescriber acting in the usual course of <u>his/herthe prescriber's</u> professional practice. The responsibility for the proper prescribing is upon the prescriber, but a corresponding responsibility rests with the pharmacist who dispenses the prescription. An order purporting to be a prescription issued not in the usual course of bona fide treatment of a patient is not a prescription and the person knowingly dispensing such a purported prescription, as well as the person issuing it, shall be subject to the penalties of law.
- (B) All prescriptions issued by a prescriber shall:
 - (1) Be dated as of and on the day when issued.
 - (2) Contain the manually printed, typewritten, or preprinted full name, professional title, and address of the prescriber. <u>The prescriber's address shall include the physical address of the prescriber's practice location.</u>
 - (3) Indicate a telephone number where the prescriber can be personally contacted during normal business hours.
 - (4) Indicate the full name and residential address of the patient. <u>The patient's</u> residential address shall include the patient's physical street address.
 - (5) Indicate the drug name and strength.
 - (6) Indicate the quantity to dispense.
 - (7) Indicate the appropriate and explicit directions for use.
 - (8) Specify the number of times or the period of time for which the prescription may be refilled. If no such authorization is given, the prescription may not be refilled except in accordance with section 4729.281 of the Revised Code. A prescription marked "Refill P.R.N." or some similar designation is not considered a valid refill authorization.
 - (9) Not authorize any refills for schedule II controlled substances.
 - (10) Authorize refills for schedules III and IV controlled substances only as permitted by section 3719.05 of the Revised Code.

- (11) Not authorize a refill beyond one year from the date of issuance for schedule V controlled substances and for dangerous drugs that are not controlled substances.
- (12) Identify the trade name or generic name of the drug(s) in a compounded prescription.
- (13) Not be coded in such a manner that it cannot be dispensed by any pharmacy of the patient's choice.
- (14) For a controlled substance:
 - (a) Indicate the drug enforcement administration registration number of the prescriber pursuant to Title 21 CFR 1306.05 (3/31/2010).
 - (b) Except for veterinarians licensed pursuant to Chapter 4741. of the Revised Code, indicate either:
 - (i) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance is being used to treat. The code shall, at a minimum, include the first four characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M16.5).
 - (ii) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the Code on Dental Procedures and Nomenclature (CDT Code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription.
- (15) Except for veterinarians licensed under Chapter 4741. of the Revised Code, for all controlled substances and products containing gabapentin:

(a) Indicate the days' supply of the prescription.

- (16) For a managing pharmacist acting as an agent of a physician pursuant to section 4729.38 of the Revised Code and rules adopted thereunder, the prescription shall include the full name of the managing pharmacist.
- (14) For prescriptions issued to a patient by a prescriber, be:
 - (a) Manually signed on the day issued by the prescriber in the same manner as he/she would sign a check or legal document.
 - (b) Issued in compliance with rule 4729-5-13 of the Administrative Code.

- (15) For a controlled substance, indicate the drug enforcement administration registration number of the prescriber pursuant to Title 21 CFR 1306.05 (enacted on June 23, 2005).
- (16) If issued by a clinical nurse specialist, certified nurse-midwife, or certified nurse practitioner with prescriptive authority, contain the nurse's prescriber number found on the certificate to prescribe issued by the state board of nursing pursuant to rule 4723-9-09 of the Administrative Code.
- (17) If issued by a physician assistant with prescriptive authority, contain the certificate number of the physician assistant's certificate to prescribe pursuant to rule 4730-2-07 of the Administrative Code.
- (18)(17) Be issued in compliance with all applicable federal and state Ohio laws, rules, and regulations.
- (C) A pharmacist may make the following modifications to a prescription in accordance with this paragraph.
 - (1) A pharmacist may add or change the patient's address upon verification with the patient or patient's caregiver.
 - (2) For a schedule II controlled substance prescription, a pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescriber.
 - (3) For a schedule III-V controlled substance prescription, a pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescriber or agent of the prescriber.
 - (4) Except as provided for in paragraph (C)(7) of this rule, for a non-controlled substance prescription, a pharmacist may add or change the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with and agreement of the prescriber or agent of the prescriber.
 - (5) For all prescriptions, a pharmacist may add or change the days' supply, ICD-10-CM medical diagnosis code, or code on dental procedures and nomenclature only after consultation with and agreement of the prescriber or agent of the prescriber.
 - (6) A pharmacist may modify a prescription to specify if "dispense as written" or another phrase or indicator having a similar meaning applies to the following only after consultation with and agreement of the prescriber or agent of the prescriber:

- (a) Selection of a generically equivalent drug or interchangeable biological product in accordance with section 4729.38 of the Revised Code.
- (b) Dispensing a quantity or amount of a drug that varies from the quantity or amount of the drug that otherwise would be dispensed pursuant to the prescription in accordance with 4729.40 of the Revised Code.
- (7) For a non-controlled substance prescription, a pharmacist may change the dosage form, drug strength, drug quantity and directions for use without consultation with and agreement of the prescriber or agent of the prescriber in accordance with the following:
 - (a) The drug selected must have the same active chemical ingredients of equivalent strength, frequency and duration of therapy as the prescribed drug;
 - (b) The prescription is for a human patient;
 - (c) No modifications shall be made pursuant to this paragraph if "dispense as written" or another phrase or indicator having a similar meaning is indicated on the prescription pursuant to paragraphs (I) and (J) of this rule;
 - (d) The pharmacist who selects the drug to be dispensed pursuant to this paragraph shall assume the same responsibility for selecting the dispensed drug as would be incurred in filling a prescription for a drug using the prescribed form; and
 - (e) The pharmacist shall not permit substitution between long-acting and short-acting forms of a drug with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.
- (8) All consultations and corresponding changes performed in accordance with this paragraph shall be noted by the pharmacist on the prescription or in the patient's profile and shall be communicated to the patient or patient's caregiver.
- (9) A pharmacist shall not make changes to the patient's name, dangerous drug prescribed, except for generic substitution permitted by Ohio law, or the prescriber's signature.
- (D) All prescriptions issued on paper to a patient by a prescriber shall be:
 - (1) Manually signed on the day issued by the prescriber in the same manner as the prescriber would sign a check or legal document.

(2) Issued in compliance with rule 4729-5-13 of the Administrative Code.

- (C)(E) When forms are used that create multiple copies of a prescription issued to a patient by a prescriber, the original prescription that bears includes the actual signature of the prescriber must be issued to the patient for dispensing by a pharmacist.
- (D)(F) Oral transmission by the prescriber or the prescriber's agent of original prescriptions and refills authorized by a prescriber, pursuant to the requirements of this rule, may be transmitted by telephone only to:
 - (1) A pharmacist.
 - (2) A recording device within the pharmacy if the pharmacist is unavailable. The pharmacist must remove the prescription from the recorder and reduce it to writing. The pharmacist is responsible for assuring ensuring the validity of the prescription removed from the recorder.
 - (3) A licensed pharmacy intern if the pharmacist on duty who is supervising the activity of the intern determines that the intern is competent to receive telephone prescriptions.
 - (4) A certified pharmacy technician registered in accordance with section 4729.90 of the Revised Code but only with respect to accepting refill authorizations for dangerous drugs that are not controlled substances from a prescriber or the prescriber's agent, so long as there is no change from the original prescription.
 - (5) For any prescription transmitted by an agent of a prescriber, the prescriber's agent must provide the agent's full name when transmitting an oral prescription.

The prescriber's agent must provide his/her full name when transmitting an oral prescription.

- (E)(G) Original written prescriptions authorized and signed by a prescriber may be transmitted by the prescriber or the prescriber's agent by facsimile machine to a pharmacy pursuant to the following:
 - (1) The facsimile of the prescription must include the full name of the prescriber and, if applicable, the full name of the prescriber's agent transmitting the prescription to the pharmacy.

- (2) The original prescription signed by the prescriber from which the facsimile is produced shall not be issued to the patient. The original prescription signed by the prescriber must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.
- (3) If a prescription is transmitted from an institutional facility where it was not originally issued, only an individual licensed pursuant to Chapters 4723., 4729., 4730. or 4731. of the Revised Code may transmit the prescription as an agent of the prescriber.
- (3)(4) Prescriptions for schedule II controlled substances may not be transmitted by facsimile except for:
 - (a) A resident of a long term care facility pursuant to rule 4729-17-09 of the Administrative Code.
 - (b) A narcotic substance issued for a patient enrolled in a hospice. The original prescription must indicate that the patient is a hospice patient. The facsimile transmission must also meet the other requirements of this rule.
 - (c) A compounded sterile product prescription for a narcotic substance pursuant to rule 4729-16-03 of the Administrative Code.
- (4)(5) A facsimile of a prescription received by a pharmacy in any manner other than transmission directly from the prescriber or the prescriber's agent shall not be considered a valid prescription.
- (5)(6) The facsimile of the prescription must include header information identifying the origin of the facsimile.

(H) Electronic prescription transmission systems.

- (1) Except as provided in paragraph (H)(3) of this rule, outpatient prescriptions may be transmitted by means of an electronic prescription transmission system that complies with the requirements of paragraph (B) of this rule.
 - (a) If applicable, an outpatient prescription transmitted by means of an electronic prescription transmission system shall include the full name of the prescriber's agent transmitting the prescription.
- (2) A controlled substance outpatient prescription shall only be transmitted by means of an electronic prescription transmission system if the system meets

the requirements of 21 CFR 1311 (3/31/2010).

- (3) An institutional facility, as defined in rule 4729-17-01 of the Administrative Code, may only transmit inpatient prescriptions by means of a board approved electronic prescription transmission system provided that:
 - (a) The system requires positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code and the full name of any authorized agent of the prescriber who transmits the prescription.
 - (b) The computer data is retained for a period of three years.
 - (c) The approved system complies with the rule 4729-17-09 of the Administrative Code.
- (4) Except as provided in paragraphs (H)(5) and (H)(6) of this rule, no prescriptions may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image.
- (5) A non-controlled prescription may be transmitted by means of an electronic prescription transmission system that converts the prescription into a computer-generated fax or scanned image if all the following apply:
 - (a) The transmission is conducted by means of a board approved system that meets the prescription requirements in accordance with this rule; and
 - (b) The prescription transmission system operates within a closed-system. A closed system includes a system whereby prescription information is transmitted directly between:
 - (i) Any division, subsidiary, parent or affiliated or related company under the common ownership and control.
 - (ii) One or more contracted entities. Contracted means having a written agreement (to include business associate agreements) between one or more prescribers and a pharmacy and shall not include a third-party intermediary unless otherwise approved by the board.

(iii) Any other entities as approved by the board.

(6) A non-controlled prescription may be converted into a computer-generated fax by a board approved third-party intermediary only if the conversion is necessitated by a temporary telecommunication outage of the third-party intermediary or receiving pharmacy.

(I) Pursuant to section 4729.38 of the Revised Code, a pharmacist shall not select a

generically equivalent drug or interchangeable biological product if either of the following applies:

- (1) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W," "do not substitute." "brand medically necessary." or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.
- (2) In the case of an oral prescription, the prescriber or the prescriber's agent specifies that the drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.
- (J) Pursuant to section 4729.40 of the Revised Code, a pharmacist shall not dispense a quantity or amount of a drug that varies from the quantity or amount of the drug that otherwise would be dispensed pursuant to the prescription if the following applies:
 - (1) The prescriber included "dispense as written" or another phrase having a similar meaning on the prescription, or, when issuing a prescription electronically or orally, the prescriber did not specify that the quantity or amount of the drug to be dispensed may not vary from the quantity or amount specified in the prescription.
- (K) Failure of a prescription to contain the requirements set forth in paragraph (B)(14)(b) and (B)(15) of this rule or of the pharmacist to obtain the information set forth in paragraph (B)(14)(b) and (B)(15) of this rule shall not render the prescription, if dispensed in good faith, to be invalid.
- (F) A prescription may be transmitted by means of a board approved electronic prescription transmission system provided that:
 - (1) The system requires positive identification of the prescriber as defined in rule 4729-5-01 of the Administrative Code and the full name of any authorized agent of the prescriber who transmits the prescription.
 - (2) The computer data is retained for a period of three years at the prescriber's office.
 - (3) An electronic prescription transmission system meeting the requirements of 21 C.F.R. 1311 for both controlled substance and non-controlled substance prescriptions shall be considered approved by the state board of pharmacy.

(G) Pursuant to section 4729.38 of the Revised Code if a prescriber does not want a pharmacist to select a generically equivalent drug the prescriber must handwrite "dispense as written" or "DAW" on the prescription, or if ordering electronically or orally the prescriber specifies that the prescribed drug is medically necessary.

Effective:

Five Year Review (FYR) Dates:

10/16/2020

Certification

Date

 Promulgated Under:
 119.03

 Statutory Authority:
 3719.28, 4729.26

 Rule Amplifies:
 3719.05, 3719.06, 4729.01, 4729.281, 4729.37, 4729.39, 4729.38

 Prior Effective Dates:
 4/1/78, 1/1/81, 2/15/82, 7/1/90, 7/1/94, 11/25/94, 9/1/96, 2/1/98, 3/1/99, 3/31/00, 1/1/01, 2/1/02, 2/1/03, 2/1/05, 1 /1/06, 4/27/07, 10/19/07, 1/1/09, 1/1/10, 1/1/11, 10/27/11, 10/16/2015