4729:7-3-03 **Non-Hazardous Drugs Compounded by a Prescriber.**

(A) Except as provided in paragraph (L) of this rule, all non-hazardous, non-sterile compounded drug preparations shall be prepared in accordance with United States pharmacopeia chapter <795>.

(B) Except as provided in paragraph (C) of this rule, all non-hazardous, sterile compounded drug preparations, shall be prepared in accordance with United States pharmacopeia chapter <797>.

(C) For all immediate-use, non-hazardous sterile compounded drug preparations, a prescriber shall comply with either:

(1) Rule 4729:7-3-04 of the Administrative Code; or

(2) United States pharmacopeia chapter <797>.

(D) For all hazardous non-sterile and sterile compounded drug preparations, a prescriber shall comply with rule 4729:7-3-05 of the Administrative Code.

(E) The responsible person of a facility where a prescriber is engaged in the compounding of dangerous drugs shall be responsible for all of the following:

(1) Developing and implementing appropriate compounding procedures;

(2) Overseeing facility compliance with this rule;

(3) Compliance with Title 21 U.S. Code section 353a (11/27/2013) and all other applicable federal and state laws, regulations and rules;

(4) Ensuring documented training and competency of compounding personnel;

(5) Ensuring environmental control of the compounding areas;

(6) Ensuring compounded drug preparations maintain quality and sterility until administered or personally furnished;

(7) Maintaining drug compounding records pursuant to rule 4729:7-3-06 of the Administrative Code.

(8) The proper maintenance, cleanliness, and use of all equipment used in compounding; and

(9) Ensuring aseptic technique for the preparation of all sterile compounded drugs.

(F) A prescriber may designate an appropriately trained agent to prepare compounded drug preparations.

(G) For all compounded drugs prepared pursuant to this rule, a prescriber shall:

(1) Inspect and approve the compounding process; and

(2) Except as provided in paragraph (H) of this rule, perform medication validation ("final check") prior to the medication being administered.

(H) The requirements of paragraph (G)(2) of this rule do not apply to either of the following:

(1) A compounded drug preparation is being administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, at least two nurses that are approved by the responsible person to prepare or administer compounded drugs comply with the requirements in paragraph (I) of this rule; or

(2) A compounded drug preparation is prepared and administered to a patient in the facility by a nurse licensed under Chapter 4723. of the Revised Code pursuant to a prescriber's order and, prior to administration, the same nurse complies with paragraph (I) of this rule.

(I) All the following are required to administer a compounded drug preparation in accordance with paragraphs (H)(1) and (H)(2) of this rule:

(1) Verify patient identification using at least two identifiers (e.g., last name, medical record number, DOB, etc.).

(2) Confirm with the patient the patient's planned treatment, drug route, and symptom management.

(3) Verify the accuracy of:

(a) Drug name;

(b) Drug strength and dosage form;

(c) Drug volume;

(d) Rate of administration;

(e) Route of administration;

(f) Expiration dates/times;

(g) Appearance and physical integrity of the drugs.

(4) Indicate in the compounding record verification was completed;

(5) A licensed prescriber is on-site and immediately available.

(J) A prescriber shall not compound drug preparations unless a specific patient need exists. Compounding for anticipated needs or engaging in compounding practices where multiple non-patient specific doses are produced in a single activity is prohibited.

(K) A prescriber shall comply with the drug database reporting requirements for personally furnishing drugs pursuant to section 4729.79 of the Revised Code.

(L)

(1) Except as provided for in paragraph (L)(2) of this rule, the requirements of this rule do not apply to a prescriber who is a veterinarian licensed under Chapter 4741. of the Revised Code.

If preparing or handling compounded hazardous drugs, a prescriber who is a veterinarian shall comply with rule 4729:7-3-05 of the Administrative Code.

(2) A veterinarian engaged in the compounding of sterile and non-sterile drug preparations shall comply with the following:

(a) Unless administered immediately, the compounded drug preparation shall bear a label listing all of the following:

(i) Patient identification information, including the full name of the owner, if applicable, and the name or identification of the animal;

(ii) The name and quantity of each ingredient;

(iii) The date and time prepared;

(iv) The name or initials of the person who prepared the compounded drug preparation.

Replaces:	4729-16-04
Effective:	3/31/2021
Five Year Review (FYR) Dates:	03/31/2026

CERTIFIED ELECTRONICALLY

Certification

12/16/2020

Date

Promulgated Under:	119.03
Statutory Authority:	4729.26, 3719.28
Rule Amplifies:	4729.01, 4729.51, 4729.53, 4729.54, 4729.541 and 4729.55
Prior Effective Dates:	05/01/2016, 04/01/2017