Ohio Administrative Code

Rule 4729-16-03 Drugs compounded in a pharmacy.

Effective: February 15, 2016

(A) For all non-sterile compounded drug products, the pharmacy shall comply with the United States pharmacopeia chapter <795>, USP 38 - NF 33, or any official supplement thereto (9/10/2015).

(B) For all sterile compounded drug products, the pharmacy shall comply with the United States pharmacopeia chapter <797>, USP 38 - NF 33, or any official supplement thereto (9/10/2015).

(C) Comply with section 503A of the Federal Food, Drug, and Cosmetic Act (11/27/2013).

(D) Only a pharmacist or pharmacy intern under the personal supervision of a pharmacist is permitted to engage in dispensing and compounding.

(E) A qualified pharmacy technician pursuant to section 4729.42 of the Revised Code may assist a pharmacist in the compounding and dispensing of drugs in accordance with section 4729.01 of the Revised Code and according to the following requirements:

(1) May not engage in any procedure requiring professional judgment. The pharmacist is responsible for the drug compounded or dispensed.

(2) The system of drug distribution must provide exact control and assign immediate responsibility only to a pharmacist accountable at every point in the system between receipt of the order for a drug and final delivery for administration or use by the patient.

(3) May not engage in any procedure contrary to the intent of the statutes and rules regulating the dispensing and compounding of drugs.

(F) In order to compound drug products, a pharmacy shall meet the minimum standards for a pharmacy pursuant to rule 4729-9-02 of the Administrative Code.

(G) For all compounded drug products, the pharmacist shall:

(1) Inspect and approve the compounding process;

(2) Perform the final check of the finished product.

(H) For all compounded drug products, the pharmacist shall be responsible for:

(1) All compounding records pursuant to rule 4729-16-06 of the Administrative Code;

(2) The proper maintenance, cleanliness, and use of all equipment used in compounding.

(I) Personnel engaged in the compounding of drugs shall wear clean clothing appropriate to the operation being performed. Protective apparel shall be worn as necessary to protect personnel from chemical exposure and drug products from contamination.

(J) Except as otherwise provided in rules 4729-15-03, 4729-16-07, 4729-16-10 and 4729-16-12 of the Administrative Code, a prescription shall be compounded and dispensed only pursuant to a specific order for an individual patient issued by a prescriber. A limited quantity may be compounded in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns.

(K) The requirements for prescriptions received by a fluid therapy pharmacy are as specified in rule 4729-16-05 of the Administrative Code.

(L) A compounded drug product that is dispensed to an outpatient must be labeled according to rule 4729-5-16 of the Administrative Code. In addition, the label shall comply with paragraphs (N) and (A) or (B) of this rule. The statement "Compounded Drug Product"or other similar statement shall also be displayed prominently on the label.

(M) A compounded drug product that is dispensed to an inpatient must be labeled according to rule 4729-17-10 of the Administrative Code. In addition, the label shall comply with paragraphs (N) and

(A) or (B) of this rule. The statement "Compounded Drug Product" or other similar statement shall also be displayed prominently on the label.

(N) The requirements for the labeling of sterile product prescriptions in a fluid therapy pharmacy are as specified in rule 4729-16-05 of the Administrative Code.

(O) Labels for a compounded drug product that is prepared in anticipation of a prescription drug order shall contain, but not be limited to, the following:

(1) The name, strength, and quantity of each drug used in the compounded drug product;

(2) The identification of the repackager by name, by the final seven digits of its terminal distributor of dangerous drugs license number, or any other board approved identifier;

(3) Pharmacy control number;

(4) The pharmacy's expiration date or beyond use date;

(5) "Compounded Drug Product" or other similar statement.

(P) A sterile compounded drug product prepared in accordance with federal and state requirements that is for a schedule II narcotic substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous, or intraspinal infusion may be transmitted by the prescriber or the prescriber's agent to the dispensing pharmacy by facsimile or a board approved electronic prescription transmission system pursuant to rule 4729-5-30 of the Administrative Code. The facsimile shall serve as the original written prescription and shall be received and maintained pursuant to rules 4729-5-21 and 4729-5-30 of the Administrative Code. The original signed prescription must remain with the patient's records at the prescriber's office or the institutional facility where it was issued.

(Q) The pharmacys responsible person shall ensure the environmental control of all products shipped to the patient.

(R) The pharmacys responsible person shall ensure that there is a system for the disposal of cytotoxic and/or hazardous drug waste in a manner so as not to endanger the public health.

(S) A pharmacy that prepares hazardous and/or cytotoxic drugs shall do so in accordance with United States pharmacopeia chapter <797>, USP 38 - NF 33, or any official supplement thereto (09/10/2015).

(T) The pharmacy shall comply with the drug database reporting requirements for Chapter 4729-37 of the Administrative Code.

(U) This rule does not apply to nuclear pharmacies, unless the pharmacy meets the requirements in paragraph (A) of rule 4729-15-03 of the Administrative Code.