Ohio Administrative Code

Rule 4729:7-2-01 Definitions - pharmacy compounding.

Effective: July 1, 2021

As used in this chapter of the AdministrativeCode:

(A) "Antineoplastic" means a dangerous drug that blocks the formation of neoplasms.

(B) "Beyond-use date" means either the date or time and date after which a compounded drug preparation must not be used or administration must not begin. The beyond-use date is determined from the date/time that preparation of the compounded drug is initiated.

(C) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(D) "Compounding" means the preparation, mixing, assembling, packaging, and labeling of one or more drugs. Compounding includes the combining, admixing, mixing, diluting, pooling, reconstituting, repackaging, or otherwise altering of a drug or bulk drug substance. A pharmacy engaged in the following shall not be required to comply with the provisions of this chapter:

(1) The preparation of non-hazardous, conventionally manufactured non-sterile products in accordance with the directions contained in the approved labeling provided by the product's manufacturer. A pharmacist shall perform the final check of the product.

(2) The preparation of radiopharmaceuticals as defined in agency 4729 of the Administrative Code.

(3) Sterile compounded drug preparations in accordance with rule 4729:7-2-02 of the Administrative Code.

(4) The addition of a flavoring agent to a conventionally manufactured drug product.

(E) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(F) "Dilution" means a process of reducing the concentration of a solute in solution, usually by mixing with a solvent.

(G) "Dispense" means the final association of a drug with a particular patient pursuant to a prescription, drug order, or other lawful order of a prescriber and the professional judgment of and the responsibility for interpreting, preparing, compounding, labeling, and packaging a specific drug.

(H) "Final check" means the final verification check for accuracy and conformity to the formula of the compounded preparation or product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

(I) "Hazardous drug" means any drug listed on the national institute for occupational safety and health's list of antineoplastic and other hazardous drugs in healthcare settings as referenced in rule 4729:7-1-01 of the Administrative Code.

(J) "Licensed health professional authorized to prescribe drugs" or "prescriber" has the same meaning as in rule 4729:5-1-02 of the Administrative Code but shall be limited to a prescriber practicing within the prescriber's applicable scope of practice.

(K) "Non-resident pharmacy" means any pharmacy, licensed as a terminal distributor of dangerous drugs in accordance with Chapter 4729:5-8-01 of the Administrative Code, located outside of Ohio that ships, mails, or delivers, in any manner, drugs at retail into Ohio.

(L) "Non-sterile compounded drug" means a dangerous drug preparation intended to be non-sterile. Non-sterile compounded drugs include, but are not limited to, the preparation of solutions, suspensions, ointments, creams, powders, suppositories, capsules, and tablets.

(M)

(1) "Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification such

as the following:

(a) A manual signature on a hard copy record;

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

(f) A board approved system of randomly generated personal questions;

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made readily retrievable; or

(h) Other effective methods for identifying individuals that have been approved by the board.

(2) A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier, such as a password, for entry into a secure mechanical or electronic system.

(N) "Preparation" means a drug compounded in a licensed pharmacy or other healthcare-related facility. Preparations may include the compounding of one or more drug products.

(O) "Product" means a drug in a commercially manufactured pharmaceutical dosage form that has been evaluated for safety and efficacy by the United States food and drug administration. Products are accompanied by full prescribing information, which is commonly known as the United States food and drug administration-approved manufacturer's labeling or product package insert.

(P) "Personal supervision" or "direct supervision" means a pharmacist shall be physically present in

the pharmacy, or in the area where the practice of pharmacy is occurring, and provide personal review and approval of all professional activities.

(Q) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(R) "Reconstitution" means the process of adding a diluent to a powdered drug to prepare a solution or suspension.

(S) "Responsible person" has the same meaning as in rule 4729:5-2-01 of the Administrative Code who is responsible for supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(T) "Sterile" means a dosage form free of living microorganisms (aseptic).

(U) "Sterile compounded drug" means a dangerous drug preparation intended to be sterile.

(V) "United States Pharmacopeia Chapter <795>" or "USP <795>" has the same meaning as in rule 4729:7-1-01 of the Administrative Code.

(W) "United States Pharmacopeia Chapter <797>" or "USP <797>" has the same meaning as in rule 4729:7-1-01 of the Administrative Code.

(X) "United States Pharmacopeia Chapter <800>" or "USP <800>" has the same meaning as in rule 4729:7-1-01 of the Administrative Code.