# Ohio Administrative Code

## Rule 4729:7-3-01 Definitions - prescriber compounding.

Effective: March 31, 2021

As used in Chapter 4729:7-3 of the AdministrativeCode:

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

(B) "Beyond-use date" or "beyond-use dating" means either the date or time after which a compounded drug preparation must not be used, or administration must not begin, and must be discarded. 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, reconstituting, or otherwise altering of a drug or bulk drug substance.

(E) "Controlled substance" has the same meaning as in section 3719.01 of the Revised Code.

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

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

(H) "Hazardous drug" means any antineoplastic drug listed in table one 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.

(I) "Immediate use" or "immediate use drug" means the immediate preparation of a sterile non-

hazardous compounded drug preparation in accordance with rule 4729:7-3-04 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-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.

(L) "Outsourcing facility" means a facility that is engaged in the compounding and sale of sterile drugs, is registered as an outsourcing facility with the United States food and drug administration, and is licensed in accordance with section 4729.52 of the Revised Code.

(M) "Personally furnish" or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting.

(N)

(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 that includes any of 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.

(O) "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.

(P) "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 FDA-approved manufacturer's labeling or product package insert.

(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 defined in rule 4729:5-2-01 of the Administrative Code and is responsible for the 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.