Ohio Administrative Code

Rule 4729:5-6-01 Definitions - nuclear pharmacies and radiopharmaceuticals.

Effective: February 1, 2022

As used in Chapter 4729:5-6 of the AdministrativeCode:

(A) "Radiopharmaceutical," "radiopharmaceutical preparation," or "radioactive drug" means a finished dosage form of a dangerous drug that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any nonradioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The terms "radiopharmaceutical" and "radioactive drug" are commonly used interchangeably.

(B) "Authorized nuclear pharmacist" means a licensed pharmacist that meets the requirements in rule 3701:1-58-20 of the Administrative Code.

(C) "Beyond-use date" means the assigned date and time beyond which the radiopharmaceutical must not be administered.

(D) "Compounding" has the same meaning as in USP <825>.

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

(F) "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.

(G) "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.

(H) "Kit" means a commercially manufactured package containing all ingredients required to prepare a radiopharmaceutical with the exception of the radionuclide.

(I) "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.

(J) "Non-sterile compounded drug" means a dangerous drug preparation intended to be nonsterile.

(K) "Nuclear pharmacy" is a pharmacy licensed as a terminal distributor of dangerous drugs where prescriptions for radiopharmaceuticals are prepared, compounded, dispensed, or repackaged. A nuclear pharmacy shall also be licensed by the United States nuclear regulatory commission or the appropriate state nuclear regulatory agency.

(L) "Personal supervision" means the person specified in rule shall be physically present at the licensed location to provide personal review and approval of all professional activities.

(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) "Preparing" or "preparation" means the act of combining a conventionally manufactured kit with a conventionally manufactured radionuclide following manufacturer's recommended instructions. Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.

(O) "Preparation with minor deviation" means the act of preparing conventionally manufactured radionuclide with volume, and/or radioactivity, and/or step-by-step deviations from the manufactures recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the beyond-use date.

(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 United States food and drug administration-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) "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.

(1) Except as provided in paragraph (R)(2) of this rule, a nuclear pharmacy shall have an authorized nuclear pharmacist as its responsible person. Responsible person shall also mean the "designated person" as used in USP 825.

(2) An institutional facility licensed as a terminal distributor of dangerous drugs with an on-site nuclear pharmacy that is engaged in the preparation, preparation with minor deviation, compounding, dispensing, or repackaging of radiopharmaceuticals shall comply with the following:

(a) Submit notification to the board, in a manner determined by the board, that the facility is engaged in the preparation, preparation with minor deviation, compounding, dispensing, or repackaging of radiopharmaceuticals.

(i) For new facilities, the institutional facility shall notify the board within ten days of the date the facility engages in the preparation, preparation with minor deviation, compounding, dispensing, or repackaging of radiopharmaceuticals.

(ii) For existing facilities, the institutional facility shall notify the board within ten days of the effective date of this rule.

(b) A nuclear pharmacy that ceases to engage in the preparation, preparation with minor deviation, compounding, dispensing, or repackaging of radiopharmaceuticals shall submit notification to the board, in a manner determined by the board, within ten days of cessation.

(c) The facility shall have a designated person who is an authorized nuclear pharmacist employed by the facility that is responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, prepare with minor deviation, compound, dispense, personally furnish, and repackage radiopharmaceuticals.

(i) For new facilities, the institutional facility shall notify the board of the designated person within

ten days of the date the nuclear pharmacy in a facility engages in the preparation, preparation with minor deviation, compounding, dispensing, personally furnishing, or repackaging of radiopharmaceuticals.

(ii) For existing facilities, the institutional facility shall notify the board of the designated person within ten days of the effective date of this rule.

(iii) If there is a change in the designated person, the board shall be notified within ten days of the effective date of the appointment of the new designated person.

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

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

(U) "United States Pharmacopeia Chapter <825>" or "USP <825>" means United States Pharmacopeia Chapter <825>, USP 42-NF 37 2S, or any official supplement thereto (12/1/2020).