Ohio Administrative Code

Rule 4729:5-6-03 Preparation, compounding, labeling, dispensing, and repackaging of radiopharmaceuticals.

Effective: February 1, 2022

(A) A terminal distributor of dangerous drugs engaged in the preparation, compounding, dispensing, or repackaging of radiopharmaceuticals for humans and animals shall comply with USP <825>.

(B) All radiopharmaceuticals shall be dispensed pursuant to a patient-specific prescription issued by a licensed health professional authorized to prescribe drugs.

(1) A limited quantity may be prepared and distributed in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

(2) In the event a patient's name is not available at the time of dispensing, a nuclear pharmacy shall have up to seventy-two hours to obtain the name of the patient. No later than seventy-two hours after dispensing the radiopharmaceutical, the patient's name must be associated with the prescription in the dispensing records maintained in accordance with rule 4729:5-6-04 of the Administrative Code.

(C) All radiopharmaceuticals are exempt from the labeling requirements of division 4729:5 of the Administrative Code.

(1) Radiopharmaceuticals shall be labeled in accordance with USP <825>.

(2) In addition to the requirements in paragraph (C)(1) of this rule, the outer shielding shall also be labeled with the following:

(a) The name and telephone number of the pharmacy;

(b) The prescription number; and

(c) The patient's name (first name and last name or first initial and last name), if available at the time of dispensing.

(3) In addition to the requirements in paragraph (C)(1) of this rule, the immediate container shall also be labeled with the following information:

(a) The prescription number; and

(b) The patient's name (first name and last name or first initial and last name), if available at the time of dispensing.

(D) A terminal distributor shall ensure that all employees comply with all applicable local, state, and federal requirements for the proper labeling, environmental controls, integrity, and safety of all products transported.

(E) A terminal distributor shall ensure that all employees comply with all applicable local, state, and federal requirements for the disposal of radioactive and/or biohazardous waste in a manner so as not to endanger the health and safety of the public.

(F) All personnel trained to work with radiopharmaceuticals shall do so under the personal supervision of an authorized nuclear pharmacist.

(G) A terminal distributor shall report any event as a medical event, except for an event that results from patient intervention, to the Ohio department of health in accordance with rule 3701:1-58-101 of the Administrative Code.