Ohio Administrative Code

Rule 4729:5-8-05 Preparation, compounding, dispensing, and repackaging of radiopharmaceuticals by a nonresident pharmacy.

Effective: February 1, 2022

(A) Except as otherwise provided in this rule, terms used in this rule have the same meaning as in rule 4729:5-6-01 of the Administrative Code.

(B) Only a pharmacy licensed as a nonresident terminal distributor of dangerous drugs may dispense or sell patient-specific radiopharmaceuticals into this state and shall comply with all the following:

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

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

(b) In the event a patient's name is not available at the time of dispensing, a nonresident 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 by the nonresident pharmacy.

(2) Comply with the requirements of USP <825>.

(3) Shall have an authorized nuclear pharmacist licensed in this state as its responsible person. The requirement for the responsible person to obtain Ohio licensure shall take effect on June 30, 2022.

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

(1) In addition to the requirements in paragraph (C) 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.

(2) In addition to the requirements in paragraph (C) 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 pharmacy licensed as a nonresident 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 pharmacy licensed as a nonresident 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) A terminal distributor shall report any event as a medical event, except for an event that results from patient intervention, to the United States nuclear regulatory commission in accordance with 10 CFR 35.3045 (6/2/2020).

(G) A pharmacy licensed as a nonresident terminal distributor shall report to the state board of pharmacy, within seventy-two hours and in a manner determined by the board, any warning letters, injunctions, or decrees issued by the United States food and drug administration or any other federal or state agency.

(H) If a pharmacy is applying for an initial nonresident terminal distributor of dangerous drugs license, renewal, or their license has lapsed, the pharmacy shall provide any of the following, in a

manner determined by the board, as part of the initial or renewal application:

(1) The most recent inspection report that is less than two years old that demonstrates applicable compliance with USP <825> conducted by an agent of the regulatory or licensing agency in the pharmacy's resident jurisdiction or an agent of a regulatory or licensing agency from another licensing jurisdiction;

(2) The most recent inspection report that is less than two years old that demonstrates applicable compliance with USP <825> rule by the national association of boards of pharmacy's verified pharmacy program; or

(3) Any other documentation of compliance as determined by the state board of pharmacy.

(I) This rule does not apply to a pharmacy licensed as a nonresident terminal distributor of dangerous drugs that prepares compounded drug preparations in accordance with rule 4729:5-8-04 of the Administrative Code.