



Ohio Administrative Code

Rule 4729-15-04 Labeling of radiopharmaceuticals.

Effective: January 1, 2009

All radiopharmaceuticals dispensed for use by inpatients of an institutional facility are exempt from the labeling requirements of rule 4729-17-10 of the Administrative Code. All radiopharmaceuticals dispensed for use by outpatients are exempt from the labeling requirements of rule 4729-5-16 of the Administrative Code.

(A) No radiopharmaceutical may be dispensed unless a label is affixed to the immediate container bearing the following information:

- (1) The standard radiation symbol.
- (2) The words "Caution - Radioactive Material."
- (3) The prescription number.
- (4) The radionuclide and chemical form.

(B) No radiopharmaceutical may be dispensed unless a tamper-evident seal is applied and a label is affixed to the outer or delivery container of each dose bearing the following information:

- (1) The standard radiation symbol.
- (2) The words "Caution - Radioactive Material."
- (3) The radionuclide and chemical form.
- (4) The volume if in liquid form.
- (5) The requested activity and the calibration date and time.



(6) The prescription number.

(7) Labels for radiolabeled blood components and therapeutic dosages must always contain the patient's name at the time of dispensing. Where the patient's name is not available at the time of dispensing for diagnostic dosing, a seventy-two-hour exemption is allowed 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 a readily retrievable manner and must be retained for a period of three years.

(8) The telephone number of the nuclear pharmacy, and the name and address of the nuclear pharmacy as it appears on the terminal distributor of dangerous drugs license.

(9) The name of the end authorized user, who must also be a prescriber as defined in section 4729.01 of the Revised Code.

(10) The lot number of the preparation.