



Ohio Administrative Code

Rule 4729:6-3-08 Distributor of dangerous drugs samples and complimentary supplies.

Effective: August 31, 2024

(A) As used in this rule:

(1) "Sample" means a dangerous drug or pharmaceutical preparation that would be hazardous to health or safety if used without the supervision of a licensed health professional authorized to prescribe drugs, or a drug of abuse, and that, at one time, had been placed in a container plainly marked as a sample by a manufacturer. Except as provided in paragraph (E) of this rule, samples may only be provided to and furnished by a licensed prescriber as defined in rule 4729:5-1-02 of the Administrative Code in accordance with paragraph (B) of this rule.

(2) "Complimentary supply" also known as "starter packs," "initial dose packs," "starter stocks," "replacement programs," or any other similar supply means a drug or pharmaceutical preparation that is distributed without charge by licensed drug distributors to pharmacies licensed as terminal distributors of dangerous drugs or prescribers to assist patients in the initiation of drug therapy. A complimentary supply shall not contain the markings or labeling of a sample drug.

(B) No drug distributor or distributor's representative, including sales representatives, may sell or distribute a sample of a drug to a licensed prescriber unless requested by the prescriber and the entity:

(1) Is licensed as a distributor of dangerous drugs or is exempted from licensure in accordance with 4729.541 of the Revised Code; and

(2) Maintains a record of such distribution for five years from the date of sale or distribution. Such records shall be made readily retrievable.

(C) Complimentary supplies are subject to the same requirements as stock shipments of dangerous drugs pursuant to agency 4729 of the Administrative Code and Chapters 4729., 3719., and 3715. of the Revised Code.



(D) A drug distributor shall comply with rule 4729:6-3-04 of the Administrative Code prior to the sale or distribution of complimentary supplies and samples.

(E) Nothing in this rule prohibits a pharmacist working, regardless of compensation, in a charitable pharmacy from dispensing a sample drug to a person in accordance with section 3719.811 of the Revised Code and agency 4729 of the Administrative Code.

(F) Paragraph (A)(1) of this rule does not permit a pharmacist who is authorized to manage drug therapy pursuant section 4729.39 of the Revised Code from ordering, dispensing, or personally furnishing a sample within a pharmacy licensed as a terminal distributor of dangerous drugs.