



Ohio Administrative Code

Rule 4729:5-17-05 Dialysis Solutions - General Provisions.

Effective: September 1, 2019

(A) Each person, whether located within or outside this state, who sells peritoneal dialysis solutions in this state shall obtain a limited category II terminal distributor of dangerous drugs license. The requirements of this paragraph do not apply to persons currently licensed to purchase, possess, and sell dangerous drugs at retail in accordance with division 4729:5 of the Administrative Code.

(B) All areas where dialysis solution is stored shall be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures and conditions which will ensure the integrity of the dialysis solution prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(C) Dialysis solutions shall be secured in a tamper-evident manner to deter and detect unauthorized access.

(D) All retail sellers of peritoneal dialysis solutions shall maintain records of purchase of dialysis solutions at wholesale and sale of dialysis solutions at retail for three years at the licensed location. All records shall be readily retrievable.

(1) A terminal distributor intending to maintain records at a location other than the location licensed by the state board of pharmacy must notify the board in a manner determined by the board.

(2) Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the terminal distributor of dangerous drugs.

(E) Prior to making an initial sale of dialysis solutions to a patient, a terminal distributor of dangerous drugs must have an order issued by a prescriber.

(1) The order must include the full name and address of the patient, the signature of the prescriber, the manually printed, typewritten, electronically generated or preprinted full name and address of the



prescriber, the telephone number where the prescriber can be personally contacted during normal business hours, the date of issuance and the complete and accurate identification of each such product to be provided to the patient.

(2) The prescriber's order may be transmitted electronically to the retail seller.

(3) All orders issued in accordance with this paragraph are valid for a period of one year from the date of issuance.

(F) A terminal distributor of dangerous drugs shall report the theft or significant loss of dialysis solution pursuant to rule 4729:5-3-02 of the Administrative Code.