Ohio Administrative Code

Rule 4729:5-14-03 Security and control of dangerous drugs.

Effective: December 1, 2025

(A) The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license. The responsible person may delegate the day-to-day tasks to EMS organization personnel who hold appropriate certification/licensure to access the dangerous drugs for which the personnel are responsible. A responsible person shall comply with the requirements set forth in rule 4729:5-2-01 of the Administrative Code.

(B) A licensed EMS organization shall provide effective controls and procedures to deter and detect the diversion of dangerous drugs.

(1) Except as provided in paragraph (B)(2) of this rule, only the following may have access to controlled substance dangerous drugs maintained by the EMS organization:

(a) A paramedic (emergency medical technician-paramedic) certified in accordance with Chapter 4765. of the Revised Code;

(b) An advanced emergency medical technician (emergency medical technician-intermediate) certified in accordance with Chapter 4765. of the Revised Code; and

(c) A licensed prescriber, registered nurse, or pharmacist who is employed or affiliated with the EMS organization.

(2) An emergency medical technician (emergency medical technician-basic) certified in accordance with Chapter 4765. of the Revised Code may have access to buprenorphine to administer an initial dose pursuant to paragraph (C) of rule 4729:5-14-05 of the Administrative Code. Buprenorphine maintained in accordance with this paragraph shall:

(a) Be physically secured with access limited to persons listed in paragraphs (B)(1) and (B)(2) of this rule.

(b) Stored in a manner that does not permit an emergency medical technician access to other controlled substance dangerous drugs maintained by the EMS organization.

(3) A certified emergency medical responder (emergency medical responder) and emergency medical technician certified in accordance with Chapter 4765. of the Revised Code may have supervised access to controlled substance dangerous drugs as follows:

(a) For the purpose of documenting the disposal of an unused portion of a controlled substance resulting from administration to a patient in accordance with paragraph (K) of this rule and only under the direct supervision of the persons listed in paragraph (B)(1) of this rule.

(b) For the purpose of documenting the disposal of controlled substances in accordance with paragraph (J) of this rule and only under the direct supervision of the persons listed in paragraph (B)(1) of this rule.

(C)

(1) All non-controlled dangerous drugs maintained by the EMS organization shall be maintained under the direct supervision of licensed or certified EMS personnel employed or affiliated with the EMS organization to deter and detect the diversion of dangerous drugs.

(2) If direct supervision is not possible, the licensed location is not currently in use, or the facility is being utilized to hold an event attended by persons other than licensed or certified EMS personnel, all non-controlled dangerous drugs shall be physically secured with access limited to licensed or certified EMS personnel, except for the following if stored in a sealed, tamper-evident manner:

(a) Solutions labeled for irrigation use;

(b) Dextrose solutions;

(c) Saline solutions;

(d) Lactated ringers;

(e) Sterile water; and

(f) Naloxone hydrochloride or other overdose reversal drug as defined in rule 4729-8-01 of the Administrative Code.

(D) Except as provided in paragraph (B)(2) of this rule, all controlled substance dangerous drugs maintained by the EMS organization shall be physically secured with access limited to persons listed in paragraph (B)(1) of this rule.

(E) All areas where dangerous drugs and devices are stored shall be dry, well-lit well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs.

(F) Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle

punctured) multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.

(G) A dangerous drug that is stored improperly, expired, damaged, tampered, or otherwise adulterated shall be separated from active stock to prevent possible administration to patients. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by the EMS organization. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons as required by this rule.

(H) A non-controlled dangerous drug that is expired or adulterated shall be disposed of in a manner that renders the drug unavailable and unusable.

(I) Unless the EMS organization is registered with the United States drug enforcement administration (DEA), any controlled substance that is expired or otherwise adulterated shall be returned to the institutional pharmacy or facility that is owned or operated by a hospital acting as the EMS organization's responsible DEA registrant.

(J) Except as provided in paragraph (K) of this rule, the disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code. The disposal of controlled substances shall be conducted by two licensed or certified EMS personnel, one of whom shall meet the qualifications listed in paragraph (B)(1) of this rule.

(K) The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method. The on-site method does not have to meet the definition of non-retrievable in rule 4729:5-3-01 of the Administrative Code but must render the drug unavailable and unusable.

The destruction of partially used controlled substances shall be conducted by two licensed or certified EMS personnel, one of whom shall meet the qualifications listed in paragraph (B)(1) of this rule.

(L) If there is a recall of oxygen by the manufacturer, all portable oxygen tanks affected by the recall

shall be handled in accordance with the manufacturer's recall instructions.