

4729:5-14-03

Security and control of dangerous drugs.

- (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 agency 4729. of the Administrative Code.
- (B) A licensed EMS organization shall provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs.
- (C) All dangerous drugs must be secured in a tamper-evident manner with access limited to EMS personnel based on certification status, except for the following if stored in a sealed, tamper-evident manner:
- (1) Solutions labeled for irrigation use;
 - (2) Dextrose solutions;
 - (3) Saline solutions;
 - (4) Lactated ringers;
 - (5) Sterile water; and
 - (6) Naloxone hydrochloride.
- (D) Only the following may have access to any controlled substances maintained by the EMS organization:
- (1) A paramedic or emergency medical technician-paramedic certified in accordance with section 4765.30 of the Revised Code;
 - (2) An advanced emergency medical technician or emergency medical technician-intermediate certified in accordance with section 4765.30 of the Revised Code; and
 - (3) Licensed prescribers, nurses or pharmacists who are employed or affiliated with the EMS organization.
- (E) Other EMS organization personnel may have access to controlled substances only under the direct supervision of the individuals listed in paragraph (D) of this rule.

(F) Administration of dangerous drugs by EMS personnel is limited to the individual's scope of practice based upon certification level and either:

(1) The protocols established by the organization's medical director; or

(2) A verbal order by a prescriber received in-person or over an electronic communications device.

(G) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, 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.

(H) A dangerous drug that reaches its expiration date is considered adulterated and must 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.

(I) A non-controlled dangerous drug that is expired may be returned to the supplier where the drug was obtained or may be disposed of in a manner that renders the drug unavailable and unusable.

(J) Unless the EMS organization is registered with the United States drug enforcement administration (DEA), any controlled substance that is expired shall be returned to the hospital acting as the EMS organization's responsible DEA registrant.

(K) Except as provided in paragraph (L) of this rule, disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code by individuals listed in paragraph (D) of this rule.

(L) 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.

(1) Destruction of partially used controlled substances shall be conducted by two licensed/certified healthcare personnel, one of whom shall meet the qualifications listed in paragraph (D) of this rule.

(M) Any dangerous drug showing evidence of damage or tampering shall be removed from active stock and replaced immediately. The drug shall be stored no longer than one

year from the date of discovery of tampering or damage by the EMS organization and shall be stored in a manner that prohibits access by unauthorized persons.

(N) 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.

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CERTIFIED ELECTRONICALLY

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