

Storage and Security of Medications for EMS Controlled Substance Registered and Designated Locations

Note: document based on pending Virginia Board of Pharmacy Emergency Regulations as approved by the Board of Pharmacy May 2, 2024

Definitions

Designated location means a station, EMS Agency sub-station or satellite location, or other location approved by the DEA, if applicable, and designated by an emergency medical services agency or regional EMS council.

EMS vehicle has the same meaning as prescribed in 32.1-111.1 or the Code of Virginia

Expiration date means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

Other EMS vehicle means a vehicle used by EMS agency or EMS council for the purpose of providing or facilitating emergency medical care or transporting controlled substances to and from the registered and designated locations. Such vehicles must be either owned or registered to an EMS agency, council or jurisdiction and be operated by an EMS agency or council.

Registered EMS agency headquarters means the principal office and primary business location of an EMS agency that maintains a controlled substances registration issued by the board or a hospital-owned EMS agency that is covered by the registration of the hospital.

Registered location means for the purposes of emergency medical services, a location that appears on a DEA certificate of registration or controlled substances registration issued to an EMS agency or regional EMS council which shall be the location at which the agency or council receives controlled substances from entities authorized to distribute controlled substances.

Station means an enclosed structure that houses one or more EMS vehicles or other EMS vehicles in the state that the EMS agency is registered that is actively and primarily being used for emergency response by the EMS agency.

Requirements for storage and security for controlled substances registrants.

- A. Drugs shall be stored under conditions that meet USP-NF specifications or manufacturers' suggested storage for each drug. Drugs secured in an EMS agency, regional EMS council, EMS vehicle or other EMS vehicle shall be stored at an appropriate storage temperature pursuant to manufacturer's directions at all times. If the EMS vehicle or other EMS vehicle cannot maintain appropriate storage temperatures or is out of service, the drug kit may be temporarily maintained within the building of the EMS agency in compliance with regulation.
 - a. Refrigerated storage: 2C-8C (36F-46F)
 - b. Controlled room temperature: 20C-25C (68F-77F), with allowances for excursions between 15C-30C (59F-86F)
 - c. Excessive heat means any temperature above 40C (104F)

- B. Any drug that has exceeded the expiration date shall not be administered; it shall be separated from the stock used for administration and maintained in a separate, locked area until properly disposed.
- a. Registered EMS agency headquarters, regional EMS councils and designated locations of the registered EMS agency headquarters or regional EMS councils shall implement a process to review expiration dates not less than every 3 months to ensure drugs are not administered beyond the expiration date.
- C. If a controlled substances registrant wishes to dispose of unwanted or expired Schedules II through VI drugs, he shall transfer the drugs to another person or entity authorized to possess and to provide for proper disposal of such drugs (e.g reverse distributor)
- D. Drugs shall be maintained in a lockable cabinet, cart, device, or other area that shall be locked at all times when not in use. The keys or access code shall be restricted to the supervising practitioner and persons designated access in accordance with [18VAC110-20-700C](#).
- a. Access to the controlled substances shall be limited to the supervision practitioner or to those persons who are authorized by law to administer drugs in Virginia, other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements.
 - b. A registered EMS agency headquarters of regional EMS council may store controlled substances in an automated dispensing device which is located at a secured site at the registered location or designated location of the EMS agency or regional EMS council which is (i) installed and operated by the EMS agency or regional ESM council (ii) not used to directly dispense controlled substances to an ultimate user and (iii) is in compliance with the requirements of state law.
- E. In a facility not staffed 24 hours a day, the drugs shall be stored in a fixed and secured room, cabinet or area that has a security device for the detection of breaking that meets the following conditions:
1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.
 2. The installation and device shall be based on accepted alarm industry standards.
 3. The device shall be maintained in operating order, have an auxiliary source of power, be monitored in accordance with accepted industry standards, be maintained in operating order; and shall be capable of sending an alarm signal to the monitoring entity if breached and the communication line is not operational.
 4. The device shall fully protect all areas where prescription drugs are stored and shall be capable of detecting breaking by any means when activated.
 5. Access to the alarm system shall be restricted to only designated and necessary persons, and the system shall be activated whenever the drug storage areas are closed for business.
 6. An alarm system is NOT required for required for registered EMS agencies or regional EMS councils or designated locations of registered EMS agency headquarters or regional EMS councils stocking only

Schedule VI drugs or temporarily securing a secured drug kit which may contain Schedule II-VI medications when the EMS vehicle or other ESM vehicle cannot maintain appropriate drug storage temperature or is out of service.

F. A registered EMS agency headquarters or regional EMS council may store controlled substances at any of the following secured locations:

1. A registered location of the EMS agency or regional EMS council
2. A designated location of the EMS agency or regional EMS council of which the board has been notified and DEA has granted approval if stocking drugs in Schedules II-V
3. In an EMS vehicle or other EMS vehicle situated at a registered location or designated location of the EMS agency or regional ESM council, or
4. In an EMS vehicle or other EMS vehicle used by the EMS agency that is traveling from, or returning to, a registered location of the EMS agency or EMS council in the course of responding to an emergency, or otherwise actively in use by the EMS agency.

G. Drug Storage in EMS vehicles

1. Schedule VI drugs stored on an EMS vehicle or other EMS vehicle are not required to be stored in a sealed kit but must be stored in a manner to deter theft or loss.
2. Drugs in schedule II-V stored on a ground EMS vehicle or other EMS vehicle, or EMS vehicle which is a licensed fixed wing aircraft shall be stored in a sealed, secured kit or device within a locked cabinet that is accessible from the patient compartment of the vehicle. Drugs in schedule II-V stored on an EMS vehicle which is a licensed rotary wing aircraft shall be stored in a sealed, secured kit or device to deter theft or loss.
 - a. The method of sealing the kits shall ensure that once the seal is broken, it cannot be reasonably resealed without the breach being detected
 - b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The Ems registered EMGS agency headquarters, regional EMS councils or designated location sealing and resealing the kit shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.
 - c. In lieu of a sealed kit, a kit with a built-in mechanism preventing resealing or relocking once opened except by EMS personnel may be used

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