EMS Drug Kit 101

Regulatory and Operational Basics

December 5, 2024

Cindy Williams, BS Pharm, FASHP, FVSHP

Riverside Health/Virginia EMA Drug Kit Transition Workgroup vice-chair

Topics

- Framework for EMS Drug Kit Management
  - Oversight
  - Storage and Security
  - Licensure
    - Board of Pharmacy
    - DEA
  - Procurement
  - Disposal
  - Diversion
  - Audit
  - Future topics

Oversight

Each EMS agency will need to determine the structure for oversight of the program, including:

- Responsible Party - shall be a prescriber, nurse, pharmacist, or other person who is authorized by provisions of § 54.1-3408 of the Code of Virginia to administer controlled substances.
- Supervising Practitioner – the Operational Medical Director for EMS agencies
  - The supervising practitioner can authorize access to controlled substance to others who are licensed to administer controlled substances under 18VAC110-20-700.

TIP: Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board, and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

Locations

- "Registered location": 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 Schedules II through VI controlled substances from those entities authorized to distribute controlled substances.
- "Designated location“: a station, EMS agency substation or satellite location, or other location approved by the DEA, if applicable, and designated by an EMS agency or regional EMS council.
  - Designated locations operate under a Registered location’s CSR and DEA license.
  - Registered locations must notify the Virginia Board of Pharmacy and DEA of all designated locations operating under their licensure

TIP: Select a naming and address convention that will be used consistently and exactly for all licenses, group purchasing organization (GPO) rostering, and wholesaler account applications

Where can an EMS agency store medications?

- A registered EMS agency headquarters or regional EMS council may store controlled substances at any of the following secured locations:
  - A registered location of the EMS agency or regional EMS council;
  - 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 through V;
  - In an EMS vehicle or other EMS vehicle situated at a registered location or designated location of the EMS agency or regional EMS council; or
  - In an EMS vehicle or other EMS vehicle used by the EMS agency that is traveling from or returning to a registered location or designated 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.

Storage of medications at EMS location

- 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 18VAC110-20-700 C.
  - Tip: Ensure persons designated to have access are documented in SOP
- 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 Virginia Board of Pharmacy requirements
  - An alarm system is not required for Registered EMS agencies or regional EMS councils, or designated locations of registered EMS agency headquarters or regional EMS councils stocking only intravenous fluids, Schedule VI drugs or temporarily securing a secured drug kit that may contain Schedule II through VI drugs when the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service;

Automated Dispensing Cabinets

- A registered EMS agency headquarters or regional EMS council may store controlled substances in an automated dispensing device that is located at a secured site at the registered location or designated location of the EMS agency or regional EMS council that is
  - (i) installed and operated by the EMS agency or regional EMS council,
  - (ii) not used to directly dispense controlled substances to an ultimate user, and
  - (iii) is in compliance with the requirements of state law.

Storage and Security

- 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.
- Drugs in Schedules II through V stored on a ground EMS vehicle, other EMS vehicle, or EMS vehicle that 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 Schedules II through V stored on an EMS vehicle that is a licensed rotary aircraft shall be stored in a sealed, secured kit or device to deter theft or loss.

Storage and Security

- The method of sealing the kits shall ensure that once the seal is broken, it cannot be reasonably resealed without the breach being detected.
- If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication or resealing. The EMS registered agency headquarters, regional EMS council, 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.
  - TIP: unique numeric seals should be secured and inventoried in the same manner as Schedule II-V medications
- In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by EMS personnel may be used.

Licensure: Virginia Board of Pharmacy

- The Virginia Board of Pharmacy may issue a controlled substances registration to an EMS agency or regional EMS council to receive controlled substances in Schedules II through VI from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy.
  - The EMS agency or regional EMS council shall identify to the board any designated location to which the EMS agency or regional EMS council may deliver controlled substances.
- The EMS agency or regional EMS council shall identify on the controlled substances registration application the name and physical address of the designated locations and attest that at each designated location of the EMS agency or regional EMS council complies with the storage and security requirements of 18VAC110-20-710.
- Any changes to the designated locations shall be submitted to the board in advance of delivering or ceasing to deliver controlled substances to that location and the designated locations must be approved sites under federal law

Licensure

- An EMS agency receiving only Schedule VI drugs from a wholesale distributor, manufacturer, third-party logistics provider, warehouser, or pharmacy or temporarily storing a secured drug kit within the EMS building when the vehicle is incapable of maintaining appropriate drug storage temperature or is out of service shall obtain a controlled substance registration or operate as a designated location of a registered EMS agency headquarters.

Licensure: Drug Enforcement Agency (DEA)

- The EMS agency or regional EMS council shall also obtain a registration from DEA in accordance with federal law prior to delivery of Schedules II through V drugs.
  - An active Virginia Board of Pharmacy CSR is required prior to application for DEA license
- Agencies should request paper DEA 222 during application process
- Once the DEA license is issued, the registered EMS agency will notify the DEA local field office with a listing of all designated locations that will operate under the registered location. DEA will take approx. 30 days to update designated locations.
- Any changes to the designated locations shall be submitted to the DEA in advance of delivering or ceasing to deliver controlled substances to that location and the designated locations must be approved sites under federal law

Licensure Steps

- Identify Responsible Party and Supervising Provider
- Identify secure storage area
- Install alarm system as required
- Develop Standard Operating Procedures for agency drug kit program
- Determine designated locations under the registered location
  - Registered locations must notify the Virginia Board of Pharmacy and DEA of all designated locations operating under their licensure
- Submit CSR application to Virginia Board of Pharmacy
  - Virginia Board of Pharmacy will contact applicant to schedule on-site review (either in person or virtual)

Licensure Steps (continued)

- Once Virginia Controlled Substance Registration is obtained, DEA application can be filed
  - Request paper DEA 222 at time of DEA application for use while waiting for CSOS access or with change in responsible party
- DEA applications are currently taking 60-90 days to process
- Once DEA application is received:
  - Registered location to notify local DEA office of designated locations that will operate under their license. Processing time of 30 days
  - CSOS application can be filed
    - Note: CSOS is not required to order schedule II-V by DEA but may be by wholesale distributor. Paper DEA 222 can be used as back up.

CSR Licensure Tips

- Have a security system representative present for the inspection so they can demonstrate the system's features and answer questions, to include:
  - What are the redundant communication methods available if the primary system is offline?
  - Who will receive the notification of the alarm? i. Ensure this is someone authorized to access the medication room.
  - Test and confirm that the system covers every possible corner of the medication room. Security is the primary focus of pre-opening inspection.
- Maintain duplicative, paper copies of all necessary documents for inspection purposes.
- Do not stock medications in the room prior to passing inspection.
- Upon passing the inspection, the license will appear on the Board of Pharmacy website's License Lookup within one week.

CSOS Changes

- On December 9, 2024, DEA will launch a new, enhanced Controlled Substance Ordering System (CSOS) to ensure secure electronic ordering of Schedule I through V controlled substances without the supporting paper DEA 222 Order Form.
- Beginning December 9, 2024, new registrants choosing to utilize CSOS will be required to create an account on the CSOS portal at https://www.deaecom.gov/.
- Current CSOS subscribers will only need to create an enhanced CSOS account in the portal for the following task requirements:
  - Approvals - If you need to approve a new subscriber or certificate renewal.
  - Revocations - If you are revoking a certificate.
  - Renewals - If you are renewing a CSOS certificate. It is recommended to create a new account 45 days prior to the certificate expiration date.

Procurement

- Medications may be obtained from:
  - Wholesale distributor, third-party logistics provider or 503A/503B compounding facility licensed in Virginia
  - A pharmacy licensed in Virginia
  - A registered EMS agency
- All medications must be shipped to and received at the registered location facility found at the single physical location and address noted on the CSR/DEA registrant's license for that agency or service.
- Each order must be tracked in a manner that documents the parties requesting, ordering, and receiving the controlled substances.

Procurement

- To obtain the best possible price for class of trade, it is recommended that you join a Group Purchasing Organization (GPO). Examples include:
  - MMCAP (https://infuse-mn.gov/)
  - Vizient (through EMS council agreement)
  - National Procurement Partners Government
- Medication procurement is typically done through a wholesale distributor
  - Large distributors: Cardinal, McKesson, Cencora (formerly Amerisource Bergen)
  - Small distributors: Henry Schein, Curascript
  - Wholesaler distributor loads contract pricing from GPO

Disposal

- 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 no less often than every three months to ensure drugs are not administered beyond the expiration date.
- Unused medication:
  - 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.
  - 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)
    - Reverse distributor vendors are typically contracted with GPOs for preferential pricing
- Partial dose of medication
  - All partial doses of medications should be wasted in a manner that is compliant with Department of Environmental Quality (DEA). This includes wasting into a designated medication waste container
  - For Schedule II-V, the waste should be non-recoverable, witnessed and documented
    - RxDestroyer is a cost effective solution that offers mail back program (https://www.rxdestroyer.com/)

Preventing Diversion

- Review controlled substance (or other pharmaceutical) purchasing reports for any appearance of purchases (or usage) without reasonable explanation.
  - Note, this also applies for pharmaceuticals loaned to other agencies.
- Best practice is to have separate individuals order and receive medications
  - It is possible to set up ordering where one (1) person queues up the order and a second submits it.
  - Require a two (2) person process for check-in and entry into electronic or paper logs for controlled substances.
- Do not store personal backpacks or purses in the drug storage area
- Require approval to open any new accounts and maintain a log of the accounts.
  - Do not share passwords for purchasing site. Each user will need their own unique access.

Preventing Diversion

- Although not required, cameras in areas that store Schedule II-V provide additional security
  - Ensure tape back-up for investigative purposes
- Biometric access to controlled substances is more secure than code locks or passwords. If codes or passwords are used, they should be changed on a predetermined frequency.
  - Refer to the Board of Pharmacy guidance and DEA regulations for additional guidance on multi-layer security.
- Access to medications should be removed from departing employees on the day of departure.
- Pharmaceuticals should only be ordered for delivery on the days authorized staff are present to receive the delivery.
- Packing slips should be cross-checked upon delivery, to ensure all items are accounted for, as well as signed, dated, and filed.

Audits/Recordkeeping

- Registered EMS agency headquarters and regional EMS councils shall audit the security of the drug storage location and perform a random audit of Schedules II through V drugs and required recordkeeping for accuracy at least every six months at each designated location under the controlled substances registration.
  - Where possible, combine with other OEMS required audits
- Documentation verifying the completion of the audit for each designated location shall be maintained at the registered EMS agency headquarters or regional EMS council for two years from the date performed.

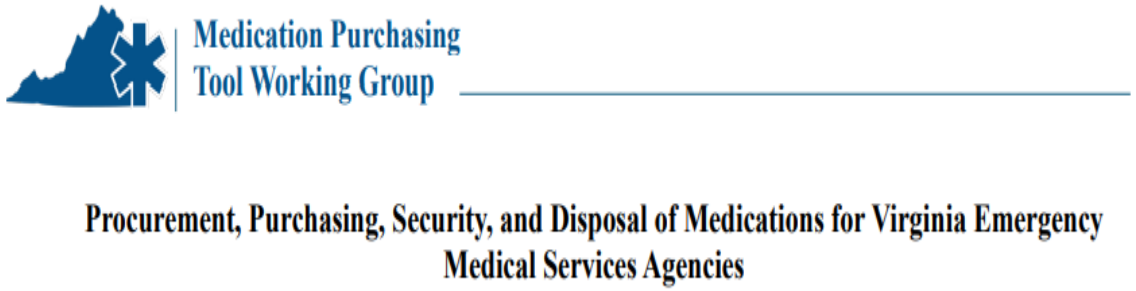
Audits/Recordkeeping

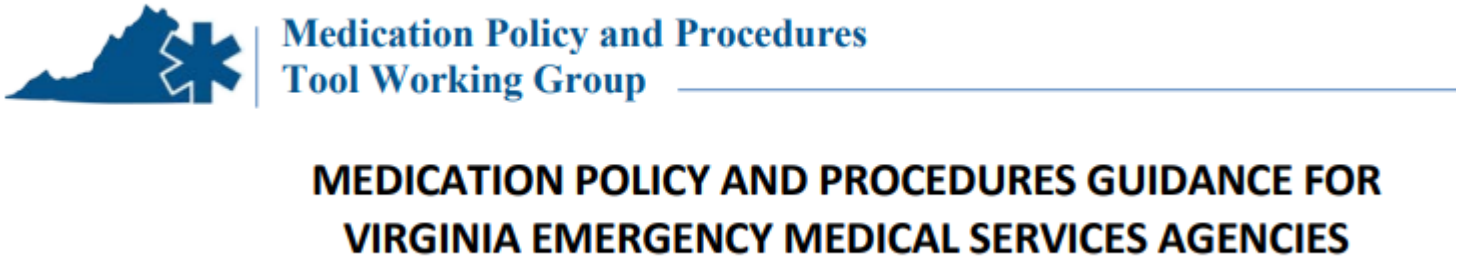
- The person named as the responsible party on the controlled substances registration shall be responsible for recordkeeping for Schedules II through VI drugs in accordance with provisions of § 54.1-3404 of the Code of Virginia to include the reporting of any drug theft or unusual loss.
  - See Virginia Board of Pharmacy Emergency Regulation for recordkeeping requirements

https://www.dhp.virginia.gov/media/dhpweb/docs/pharmacy/forms/leg/EmergencyRegsEMSLocations.pdf

Toolkits

- A number of toolkits have been developed by the state task force





Potential Future Topics

- A poll will be sent after the webinar to request input into future webinar topics. Please respond to assist us with planning and to ensure we meet EMS agency needs.

Questions?