	Controlled Substances
	Operational Policy

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PURPOSE

To establish minimum requirements for compliance with the DEA Controlled Substances Act and Virginia Board of Pharmacy Law and Regulation by <name of agency> EMS Agency authorized or permitted first response agencies and/or transport services.

DEFINITIONS

CSR means Controlled Substance Registration. In the context of this policy, the category of CSR refers to EMS agency/registered location

DEA means Drug Enforcement Agency

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.

Controlled Substances

All first response agency locations and/or transport services will have common ownership or have a formal agreement to serve as designated location with a CSR/DEA registrant who is accountable for the agency or service's compliance with the Controlled Substances Act and Virginia Board of Pharmacy Law and Regulation. The DEA registrant will maintain a Virginia Board of Pharmacy Controlled Substances Registration and DEA license as a registered EMS agency or council and be responsible for maintaining a listing of all designated EMS agency/transport service locations with the Virginia Board of Pharmacy and Drug Enforcement Agency.

Security Mechanisms and Procedures

Ordering and Order Tracking

Each Registered location will order controlled substances from an authorized drug wholesaler, third party logistics provider, manufacturer or pharmacy. Schedule II controlled substances require use of the DEA Form 222 or the Controlled Substance Ordering System (CSOS). These orders will be delivered to the registered location facility found at the single physical location and address noted on the CSR and 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 controlled substances.

Receipt and Accountability

Controlled substances must be 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. Personnel receiving controlled substances must be authorized by the DEA registrant, hold licensure/registration in Virginia to administer medications or otherwise be approved in Virginia Boad of Pharmacy regulation. Personnel receiving controlled substances will be included on the agency or service's roster of personnel authorized to manage controlled substances. A witness, also included on the roster of personnel authorized to manage controlled substances, must participate in the receipt and documentation of the controlled substance(s) Schedule II-V.

The receipt of controlled substances Schedule II-V will be documented in the master supply log(s). The information documented will include: the date and time, the name of the medication, the strength, the quantity, the expiration date, the manufacturer, and the lot number. Signatures of the receiving party and the witness will be included as well.

Invoices for all medications will be signed upon receipt and filed. Segregation of invoices as below:

1. Schedule VI
2. Schedule III-V
3. Schedule II
    a. Schedule II invoices will be attached to completed DEA 222 forms or linked to DEA CSOS ordering records.

Master Supply Storage, Security and Documentation

The master supply storage of controlled substances will be at the register location facility found at the single physical location and address noted on the CSR/DEA registrant's license for that agency or service.

Follow the manufacturer's guidelines regarding storage of each controlled substance:

1. Store within the required temperature range
    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)
2. Protect from light as required

Master supply security measures will include:

1. Tamper evident containers
2. Storage under double lock
3. Alarm system
4. Witnessed counting, no less than once (1x) each month

Personnel handling and/or counting controlled substances at the master supply must be authorized by the DEA registrant and be licensed/registered in Virginia to administer medications or otherwise be approved in Virginia Board of Pharmacy regulation. Authorized personnel shall be included on the agency or service's roster of personnel authorized to manage controlled substances. A witness, included on the roster of personnel authorized to count controlled substances, must also participate in each count and its documentation.

Master supply documentation will include:
1. The agency or service's roster(s) naming personnel authorized to:
    a. Manage controlled substances
    b. Count controlled substances
    c. Administer controlled substances
    d. Audit controlled substances
2. Copies of each DEA Form 222, including voided forms; purchase records; a log(s) of all controlled substances ordered, received, stored, damaged during storage, placed into service, damaged while in service, administered, wasted, restocked, returned to master supply, reverse distributed, and/or transferred or exchanged between agencies and/or services; and a patient care record / electronic patient care record (PCR/ePCR) or other appropriate report corresponding to each administration, waste, damage, or expiration
3. These records will be:
    a. Maintained at and/or electronically accessible from the master supply location
    b. Available for inspection within forty-eight (48) hours
    c. Retained for a period of no less than two (2) years

Controlled Substance Labeling and Tracking

Controlled substances must remain in the original manufacturer's containers, Food and Drug Administration (FDA) compliant labels remaining intact and unaltered, until the time of administration unless repackaging is performed in compliance with Virginia Board of Pharmacy regulations.

Tracking of controlled substances will include documentation in the log(s) as described throughout this policy; including: the date and time of each transaction, the name of the medication, the strength, the quantity, the expiration date, the manufacturer, the lot number, and the party / parties involved, including signature(s). Additional methods of tracking are encouraged.

Vehicle Storage and Security

Make every reasonable attempt to follow the manufacturer's guidelines regarding vehicle storage of each controlled substance while in service:
1. Avoid exposure to temperature extremes
2. Protect from light as required

Vehicle storage security measures will include:
1. Tamper evident containers for Schedule II-V medications
2. Secure storage (locked) for Schedule II-VI medications
3. Witnessed counting/reconciliation with each change in personnel or change of shift but no less than once (1x) each day

Personnel handling and/or counting controlled substances while in service must be authorized by the CSR/DEA registrant and included on the agency or service's roster of personnel authorized to administer controlled substances. A witness, preferably included on that same roster, but, at minimum, included on the roster of personnel authorized to count controlled substances, must also participate in each transaction and its documentation.

Documentation while in service will include:
1. A log(s) of all controlled substances accepted into service, counted, damaged while in service, received as re-stock, and/or returned to master supply
2. These records will be:
    a. Maintained with the medications until submitted to and/or electronically accessible from the master supply location
    b. Available for inspection within forty-eight (48) hours
    c. Submitted to master supply at least once (1x) per month
        i. Maintained as master supply documentation for a period of no less than two (2) years

Usage Procedures and Documentation

Controlled substances will be administered by EMS providers only as authorized by Virginia Office of Emergency Medical Services, EMS Council and EMS agency policy manual currently in effect at the time of the use. Personnel administering controlled substances must be authorized by the CSR/DEA registrant and included on the agency or service's roster of personnel.

Usage documentation will include:
1. A record of all controlled substances administered
2. A PCR/ePCR corresponding to each administration
3. These records will be:
    a. Maintained with the medications until submitted to and/or electronically accessible from the master supply location
    b. Available for inspection within forty-eight (48) hours
    c. Submitted to master supply at least once (1x) per month
        i. Maintained as master supply documentation for a period of no less than two (2) years

Reverse Distribution

Each agency or service will send expired and/or damaged controlled substances to an authorized reverse distributor. Schedule II controlled substances must be transferred using the DEA's Form 222 or the Controlled Substance Ordering System (CSOS), while Schedule III – VI controlled substances may be transferred by invoice. These reverse distributions will be sent to the reverse distributor's facility found at the single physical location and address noted on the reverse distributor's DEA license. Each reverse distribution must be tracked in a manner that documents the parties sending and receiving the expired and/or damaged controlled substances.

Personnel sending controlled substances for reverse distribution must be authorized by the DEA registrant and included on the agency or service's roster of personnel authorized to manage controlled substances. A witness, also included on the roster of personnel authorized to manage controlled substances, must participate in the shipment and its documentation.

All reverse distribution will be documented in the master supply log(s) including: the date and time, the name of the medication, the strength, the quantity, the expiration date, the manufacturer, the lot number, and the sending party and the witness, including their signatures.

Disposal

Disposal of expired and/or damaged controlled substances will be performed as described above under "Reverse Distribution".

Disposal/destruction of controlled substances Schedule II-V residual to patient administration ("*wasting*") will be performed following the Virginia Board of Pharmacy Regulation. The destruction shall be accomplished by two (2) persons, one of whom shall be the EMS provider and the other shall be a second EMS provider, prescriber, nurse, pharmacist or pharmacy technician. Documentation shall be maintained in the EMS agency or the designated location of an EMS agency or regional EMS council for a period of two (2) years from the date of destruction.

Personnel wasting controlled substances must be authorized by the DEA registrant and included on the agency or service's roster of personnel authorized to administer controlled substances. A witness, preferably included on that same roster, but, at minimum, included on the roster of personnel authorized to count controlled substances, must also participate in each waste and its documentation.

Wasting documentation will include:
1. A log(s) of all controlled substances wasted
2. A PCR/ePCR corresponding to each waste
3. These records will be:
    a. Maintained with the medications until submitted to and/or electronically accessible from the master supply location

b. Available for inspection within forty-eight (48) hours
c. Submitted to master supply at least once (1x) per month
    i. Maintained as master supply documentation for a period of no less than two (2) years

Restocking Procedures

An EMS agency or a regional EMS council that has been issued a controlled substances registration pursuant to 18vac110-20-690 (G) and a registration from DEA in accordance with federal law may deliver or transfer drugs in Schedule II-VI to any designated location of the registered EMS agency headquarters or regional EMS council. Delivery of the drugs shall not constitute wholesale distribution.

For sites that are not designated locations of the entity providing the drug, nothing shall preclude an EMS agency or regional EMS council from transferring or distributing drugs in Schedule VI to another EMS agency, regional council or a designated location of either entity during a shortage of the drug or in any emergency.

An EMS agency, regional Ems council and designated locations may delivery drugs in Schedule II-V to each other, consistent with federal law, in the event of shortages of such substances, a public health emergency or a mass casualty event.

All entities transferring, delivering and receiving drugs shall comply with recordkeeping requirements listed in 18V AC110-21-721.

The following records shall be maintained for each acquisition of drug in Schedules II-VI from another registrant of the board, or each distribution of a drug in Schedules II through VI to another registrant of the board:

1. For each delivery of drug in Schedules II – VI between a registered location and a designated location
    a. Name of the drug
    b. Finished form of the drug (e.g. 10-mg tablet or 10-mg concentration per fluid ounce or ml)
    c. Number of units or volume of finished form in each commercial container Ie.g. 100 tablet bottle or 10 ml vials)
    d. Number of commercial containers delivered
    e. Date of delivery
    f. Name and address of the designate location to which the substance is delivered, and
    g. Name and title of the person in receipt of the controlled substances
2. For each acquisition of drug in Schedules II-VI from another registrant
    a. Name of the drug
    b. Finished form of the drug (e.g. 10-mg tablet or 10-mg concentration per fluid ounce or ml)
    c. Number of units or volume of finished form in each commercial container (e.g. 100-tablet bottle or 10 ml vial)
    d. Number of commercial containers acquired
    e. Date of the acquisition
    f. Name, address and registration number of the person from whom the substance was acquired and
    g. Name and title of the person acquiring the drug.
    h. For CII, executed DEA 222 or DEA CSOS
3. For each distribution of drug in Schedules II-VI to another registrant
    a. Name of the drug
    b. Finished form of the drug (e.g. 10-mg tablet or 10-mg concentration per fluid ounce or ml)
    c. Number of units or volume of finished form in each commercial container (e.g. 100-tablet bottle or 10 ml vial)
    d. Number of commercial containers acquired
    e. Date of the acquisition
    f. Name, address and registration number of the person from whom the substance was acquired and
    g. Name and title of the person acquiring the drug
    h. For CII, executed DEA 222 or DEA CSOS

Personnel providing restock of controlled substances must be authorized by the CSR/DEA registrant and included on the agency / service's roster of personnel authorized to manage controlled substances. Personnel receiving restocked controlled substances must be authorized by the CSR/DEA registrant or designated location included on the agency / service's roster of personnel authorized to administer controlled substances. Both parties must participate in and document the restocking.

Investigation, Mitigation and Reporting of Suspected Tampering or Diversion

Drug inventories and all related records are subject to inspection by Virginia Office of Emergency Management Services (OEMS), the Virginia Board of Pharmacy, the DEA, and the Justice Department's Bureau of Narcotic Enforcement.

Controlled Substance Testing

Testing personnel for controlled substances may be performed following the agency or service's internal policy. Such policies may provide for controlled substance testing that is random, routine, or in response to suspected tampering and/or diversion. Any such policy should be developed in consultation with the DEA registrant and legal counsel.

Discrepancy Reporting

Each agency or service will follow its internal policy for reporting discrepancies of medications, including tampering, theft, loss, or diversion of controlled substances Schedule II-V. This policy will be established by the DEA registrant and must include immediate verbal reporting followed by written reports and investigation. The DEA registrant must notify the DEA of the discrepancy within one (1) business day of discovery, using either the paper form #106, "Report of Theft or Loss of Controlled Substances," or online, here:
https://apps2.deadiversion.usdoj.gov/TLR/login.xhtml;jsessionid=xEDfDcJ9E1IdndP_302gftqC9j1i_ldYhvAJTEC2.web2

Additionally, the registered location must report the theft or loss to the Virginia Board of Pharmacy.

Distribute copies of report and keep a copy as follows:
1 Copy: Virginia Board of Pharmacy Fax: 804-527-4472 Email: pharmbd@dhp.virginia.gov

1 Copy: Drug Enforcement Administration Submit either via electronic submission or mail to local DEA office. If submitting electronically, be sure to print a copy for your records and to send to the Board. The DEA Form 106 can be completed via Theft/Loss Reporting Online (TLR) [apps2.deadiversion.usdoj.gov] or download the fillable PDF [deadiversion.usdoj.gov] version and submit to your Local Diversion Field Office [apps2.deadiversion.usdoj.gov].

1 Copy: To be maintained at location of drug stock for your records

Virginia Board of Pharmacy Guidance Document: https://www.dhp.virginia.gov/pharmacy/guidelines/110-5.pdf

Tampering, Theft and Diversion Prevention and Detection

Each agency or service's internal policy regarding controlled substances will comply with this policy, with the intent to prevent and detect the tampering, theft, loss, and/or diversion of controlled substances. Areas to be addressed will include:

- Ordering and order tracking
- Receipt and accountability
- Master supply storage, security, and documentation
- Labeling and tracking
- Vehicle storage and security
- Usage procedures and documentation
- Restocking procedures
- Reverse distribution and disposal
- Transferring or exchange of controlled substances between agencies and/or services
- Discrepancy reporting, tampering, theft and diversion prevention and detection

- Controlled substance testing
- Usage audits

Additionally, reporting the suspected tampering, theft, and/or diversion of controlled substances to local law enforcement is encouraged.

Usage Audits

Each agency or service will follow its internal policy for usage audits. These audits will:

1. Be conducted by the DEA registrant or designee
a. Any such designee must be authorized by the DEA registrant and included on the agency or service's roster of personnel authorized to audit controlled substances
2. Account for the current disposition of all controlled substances
a. Include review of forms, purchase records, logs, and PCRs/ePCRs
b. Identify and report discrepancies as required
3. Identify and investigate unusually high rates of administration
a. Establish a baseline rate of controlled substance administration among all individuals authorized to administer controlled substances during the time period being audited
b. Identify high outliers (i.e. - individuals with high rates of controlled substance administration)
c. Review each administration of controlled substances performed by these high outliers for accountability and clinical appropriateness
4. Be performed at least quarterly. Records of these audits will be:
    a. Maintained at and/or electronically accessible from the agency or service's quality assurance location
    b. Available for inspection within forty-eight (48) hours
    c. Retained for a period of no less than two (2) years

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