MEDICATION POLICY AND PROCEDURES GUIDANCE FOR VIRGINIA EMERGENCY MEDICAL SERVICES AGENCIES

PURPOSE

The purpose of this document is to provide Virginia EMS agencies with a reference guide for establishing policies and procedures for the full ownership of handling of medications by Virginia EMS agencies. The document outlines the minimum requirements and in combination of industry standards and expert opinion, the document describes best practices for handling Schedule II-V and Schedule VI medication in compliance with the Drug Enforcement Administration (DEA) Controlled Substances Act and Virginia Board of Pharmacy laws and regulations. References are provided where possible.

Consider referencing this guidance when developing your Policy and Procedure.

Acknowledgments

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DEFINITIONS

Controlled Substances are defined as DEA CII – CV within this policy.

Controlled Substance Registration (CSR) (aka Business CSR) is a license issued by the Virginia Board of Pharmacy (BOP) to authorize possession of drugs. A BOP license is required for DEA registration.

Controlled Substance Ordering System (CSOS)[1] allows for secure electronic transmission of Schedule I-V controlled substance orders. The alternative, without the supporting paper Form 222, requires submission to the supplier vendor prior to fulfilling of the order.

DEA Registrant[2] is the individual who signed, or is authorized to sign, the latest application for DEA Registration renewal. This is typically the same person authorized to grant Power of Attorney for ordering to other individuals. This person shall provide supervision for all aspects of practice related to controlled substances.

[1] CSOS Website: https://www.deaecom.gov/
[2] Who can serve as a DEA Registrant?: https://www.deaecom.gov/pop_registrant.html#:~:text=The%20Registrant%20is%20the%20individual,individuals%20employed%20by%20the%20organization.

DEA 222 Form: DEA form used to purchase or transfer CII medications. Transfer includes transferring to DEA registrants/numbers (i.e., EMS to wholesaler (for returns), or EMS to EMS (for transfer), or EMS to reverse distributor (for disposal))

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 as such on their DEA Registration and Business CSR applications.

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

Expiration date means that date placed on a drug package by the manufacturer or repackager 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.

Responsible Party means 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 per the Controlled Substance Registration.

Schedule VI[3] medication is the Commonwealth of Virginia definition of a prescription medication not in the federally classified Schedule CII – CV. For example, metoprolol is a schedule CVI medication only in Virginia.

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.

Supervising Practitioner for EMS agencies means the Operational Medical Director.

[3] Schedule VI Definition: https://law.lis.virginia.gov/vacode/title54.1/chapter34/section54.1-3455/

FRAMEWORK FOR MEDICATION MANAGEMENT

Virginia EMS agencies or regional councils that are managing Schedule II – VI controlled substances must maintain the following 4 elements of documentation:

1. **Virginia Board of Pharmacy Controlled Substance Registration (CSR) Certificate** that identifies:
    a. 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.
    b. Supervising Practitioner – the Operational Medical Director for EMS agencies
    c. Designated locations
    d. Description of processes/business practices

    Note: Please refer to the CSR/DEA Licensure Tool kit for specific requirements to obtain

2. **Federal DEA license** which allows the **DEA Registrant** to order and manage CII – CV under federal law and regulations.
    a. *Prior to finalization of DEA proposed rule for Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017:* If under current DEA requirements, designated locations will require their own DEA registrations per physical address. Reach out to local DEA agent to clarify whether they recommend to operate under anticipated DEA regulations or current DEA requirements.
    b. Identify your Diversion Field Office Contact: https://apps.deadiversion.usdoj.gov/contactDea/spring/fullSearch;jsessionid=6TnKdMqlT4Dv7uTa4iV2Ix-NpQI1CcmnHPNpgZ9p.web2?execution=e1s2
    c. Best Practice: Familiarize yourself with DEA regulations
        i. https://www.ecfr.gov/current/title-21/chapter-II

3. **Designated locations**. The agency or regional council will maintain a listing of all designated locations with the Virginia Board of Pharmacy and the Drug Enforcement Administration. All locations must have common ownership or have a formal agreement to serve as designated locations under a CSR/DEA registrant who is accountable for the Controlled Substances Act and Virginia Board of Pharmacy Law and Regulations.
    a. An agency may consider amending existing agreements to incorporate language for the CSR/DEA relationships.

    Best Practice Recommendation: Maintain a copy of the primary location's CSR and DEA at the "spoke" if using a "hub and spoke model". It needs to be able to be furnished upon inspection or request.

4. **List of Personnel who has Access to Medications**[4]. The supervising practitioner shall publish a list of personnel authorized to handle CII – CV, and CVI.
    a. Handling, counting CII – CV: Authorized in Virginia to administer medications or otherwise be approved in the Virginia Board of Pharmacy regulations. Personnel handling the controlled substances must be authorized by the DEA registrant and included on the agency roster of personnel authorized to manage controlled substances.

i. A witness, also included on the roster of personnel authorized to manage controlled substances, must participate in the receipt and documentation of the Schedule II – V controlled substances. A witness does not need to be authorized in Virginia to administer medications, as long as they observe the counting and do not handle CII – CV.

b. Persons who cannot handle CII – CV:
   i. § 1301.76 Other security controls for practitioners.[4]
      1. (a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

Note: It is a best practice to include in the list, a record of personnel's initials and signatures as part of this documentation. If there is an investigation, you will be able to identify the individuals whose wet ink signatures it is.

c. This list should be readily furnished on audit.
   i. During a regulatory audit, the surveyor may ask for a printed list, and then cross reference the documentation that validates the authorized personnel (e.g., Virginia EMT license)

Note: It is a best practice to include an annual licensure/certification validation process for all personnel within your HR policy. This supports how you explain the process of reviewing the personnel list and how you keep it up-to-date.

5. **Approved Medication List**[5]. The supervising practitioner shall approve the list of drugs that may be ordered by the holder of the CSR/DEA license. The list of approved medications shall be maintained at the address listed on the controlled substances registration.

ORDERING, RECEIVING AND INVENTORY MANAGEMENT OF MEDICATIONS

Ordering Medications

All medications must be ordered from an authorized drug wholesaler, third party logistics provider, manufacturer or 503A (e.g., hospital pharmacy)/ 503B (e.g., compounding pharmacy). 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.

[4] https://www.ecfr.gov/current/title-21/chapter-II/part-1301/subject-group-ECFRa7ff8142033a7a2/section-1301.76#p-1301.76(b)
[5] 18VAC110-20-700 Section D. List of Personnel Authorized with Access to Medications and Medication List

Practice Consideration: 503B compounding pharmacies can provide medications such as prefilled succinylcholine syringes that are not made by manufacturers. They can provide these products with extended beyond use dates based on stability data submitted to the FDA. These are helpful products, however, because they are outsourced compounding there are additional challenges to take into consideration such as monitoring the QA of the compounding facility and drug shortage management. If an EMS agency chooses to pursue this strategy, partner with your regional council pharmacy committee, local hospital pharmacy team or reach out to the Virginia Society of Health-System Pharmacist (contact@vshp.org).

Schedule II Controlled Substances

Schedule II controlled substances require use of the **DEA Form 222** or the **Controlled Substance Ordering System (CSOS)**. The CSOS allows for electronic ordering of CII through the wholesaler system. 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.

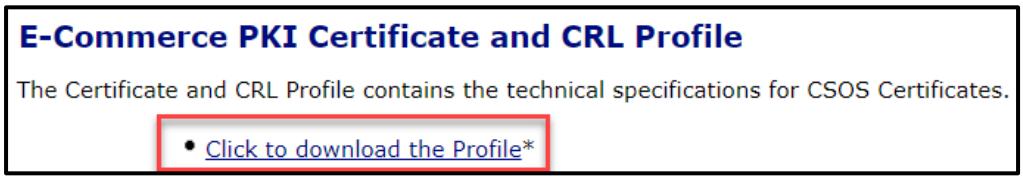
DEA 222 Form: It is imperative that the DEA 222 form is completed with 100% accuracy. If there is incorrect information, it will be returned to you with the request to submit a new DEA 222 form. You will need to write "VOID" on the returned form and retain for 2 years.

- See example for how to complete a DEA 222 Form: "7 Steps to Complete DEA Form 222"
- DEA Q&A webpage (go here if you find yourself in this situation)[6]
    - Who can sign executed DEA 222 Order Forms?
    - What should we do if a DEA Form 222 is lost or stolen?
    - How do I cancel a DEA Form 222 after it has been submitted to a supplier?

Note: Expert opinion recommends to proceed in obtaining CSOS access for efficient ordering, and utilizing DEA Form 222 if needing to use paper ordering process. (Refer to CSR and DEA Licensure Toolkit)

Note: Information Technology (IT) support may be required to activate the web browser certificate process required to use CSOS. It is recommended to involve IT staff early in the process. E.g., You may find that Firefox is the only web browser that works (and not Microsoft Edge, Chrome) https://www.deaecom.gov/about_certificates.html

Send the following file to your IT support:



Note: A best practice is to print out a copy of the CSOS order and attach with the invoice. This does not need to be immediately, but should be stored together (organize by numerical order). This helps to demonstrate a tight chain of custody (# of order form to match with the invoice). See example below:

[6] DEA Form 222 Q&A: https://www.deadiversion.usdoj.gov/faq/form-222-faq.html

Schedule III – V Controlled Substances

Schedule III – V may be ordered through the wholesaler platform or website. Copies of **CSR** and **DEA license** will be required to order from suppliers.

Note: There is some onboarding time between the wholesaler validating the DEA and CSR registration before the EMS agency can start to procure medications).

Schedule VI Controlled Substances

Schedule VI controlled substances do not have any additional regulatory requirements and only require an agreement with a supplier. Copies of **CSR** and **DEA license** will be required to order from suppliers.

Receiving the Medication Shipment for CII – CVI

The person taking delivery of the medication can be any member of the agency or regional council staff, however if the person is not authorized to administer medications, they will not be able to place the delivered medications into the storage room. The person accepting the medications from the delivery service (ie. FedEx) or direct from the wholesaler, validates the expected number of delivery boxes were received and signs confirming the delivery. This person leaves all the delivered medications within the original shipping containers and must oversee the medications until someone authorized to handle medications can properly store the delivery.

Requirements of Personnel Managing of CII – CV

Personnel handling Schedule II – V controlled substances must be authorized in Virginia to administer medications or otherwise be approved in the Virginia Board of Pharmacy regulations. Personnel handling the controlled substances must be authorized by the DEA registrant and included on the agency 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 Schedule II – V controlled substances.

The DEA does not explicitly describe this chain of custody process. The industry standard is to have 2 personnel that are licensed to administer medications. The agency can select the degree of risk tolerance in setting these expectations. The remaining preferred options are listed below (with the more preferred listed at the top):

1. 2 persons licensed to administer drugs
2. 1 person licensed + 1 witness
3. 1 person licensed + video surveillance (audited within 24 hours) by 2nd person OR 1 person licensed + within 24 hour 2nd person reconciliation audit

(Refer to Documentation section to validate what information is needed with regards to personnel handling of medications)

Unboxing of Medication Delivery and Reconciliation

1. Two personnel are strongly recommended to unbox and reconcile the delivery of CII – V compared to the invoice. Two personnel are not required to unbox Schedule VI medications; however, it is recommended as a practice to ensure Schedule II-V are not accidentally opened by only one person. Both personnel must be authorized in Virginia to administer medications or otherwise be approved in the Virginia Board of Pharmacy regulations. They must be authorized by the DEA registrant and included on the agency roster of personnel authorized to manage Schedule II – V controlled substances. (Refer to previous section for further discussion)

2. Invoices for all medications will be signed (first name and last name) and dated upon receipt and filed by two personnel for CII - CV. Segregation of invoices as below:
    a. Schedule VI
    b. Schedule III-V
    c. Schedule II (Schedule II invoices will be attached to completed DEA 222 forms or linked to DEA CSOS ordering records.)

3. Store the invoice and CSOS copy reconciliation for 2 years on the site of the DEA license registration.
    a. It is recommended to store as CII and CIII-CV files, by month to be readily retrievable.
    b. If need to store documentation at a different address, you need to send a request in writing to the DEA Division Office (Washington DC) (Refer to DEA Pharmacist's Manual, Central Recordkeeping for specifics.)[7]
    c. Schedule VI does not have the same requirements for order tracking and chain of custody as Schedule II – V medications, however, the primary agency location should store paper copies of the invoices onsite for 2 years. The Board of Pharmacy may request to review the invoices to validate that the agency is procuring medications from an authorized source (i.e., vendor that is licensed in Virginia).

    Note: The reconciliation of the CSOS electronic file and the received Schedule II – V controlled substances does not have to occur immediately but is recommended to be completed at the same time of invoice reconciliation.

4. After reconciliation, and restocking inventory: the receipt of controlled substances Schedule II-V will be documented in the master supply log(s). (Paper log CII-CV perpetual inventory or electronic perpetual inventory management software)
    a. The information documented will include:
        i. date and time,
        ii. name of the medication
        iii. strength,
        iv. quantity,
        v. expiration date,
        vi. manufacturer
        vii. lot number.
        viii. Signatures (first name and last name) of the receiving party and the witness on the invoice

[7] DEA Pharmacist's Manual, Central Recordkeeping: https://www.deadiversion.usdoj.gov/pubs/manuals/manuals.html Most recent revision was 2022.

5. Reconciliation of invoice and CSOS ordering information:
    a. Reconcile the invoice (what was received) and CSOS ordering information
    b. This diversion prevention strategy supports to audit potential buying diversion (i.e., someone is buying things that are not making it into the inventory)

Note: It is a best practice to perform once a month, request a summary of all CII – CV received this month. This document can then be cross walked with inventory. If same person is buying and receiving, this audit performed by the DEA registrant and/or designee(s) who can identify diversion patterns.

If DAMAGED medications were identified at unboxing:

1. If you receive damaged CII medications, contact the wholesaler to report the damage. The wholesaler may request to have it returned, and a DEA 222 will need to be completed.
2. If you receive damaged CIII -CV medications, contact the wholesaler to report the damage. Generate an invoice to track the transfer back to the wholesaler. Retain documentation of mail tracking.
3. If you received CVI medications, contact the wholesaler to report the damage and follow their return instructions.

Schedule II – V Inventory Requirements (Initial and Biennial Inventory)

1. Documentation Required for Initial or Biennial Inventory: Each inventory shall contain a complete and accurate record of all CII – CV on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples.
2. Each Designated Location: A separate inventory shall be made for each registered location (i.e., designated location) and each independent activity registered, except as provided in paragraph (e)(4) of this section. In the event that CII-CV in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible.
3. What is Included:
    a. DEA Registered and Designated Location: Perform a physical count of every CII – CV on site, which includes medications in the medication room and vehicles on site

4. When to Perform The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.
    a. Biennial = 2 years
    b. If the site is operated 24/7, the site selects a time in the day and records the date and time

Note: For your awareness, pharmacies are required at the state level to perform monthly inventory counts. EMS agencies are not required to perform this. Instead there is a 6 month audit. It is a good idea to perform 30- or 60- day counts (exclude EMS vehicles for practicality purposes) of CII – CV inventory counts. When there is a diversion investigation, one of the first questions will be when was the last inventory count performed? Consider this: if there is a suspected diversion due to missing quantity identified, the DEA and Board of Pharmacy will expect you to immediately perform an inventory count.

DEA Requirements for Counting: If the substance is listed in Schedules II, make an exact count or measure of the contents; or (ii) If the substance is listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

Note: It is a best practice to count every unit dose (e.g, vials) during the biennial inventory. If there are tablets or capsules in an unopened bottle, you do not need to count the bottle, and can use the quantity listed on the bottle.

For each controlled substance not included in paragraphs (e)(1) (i), (ii) or (iii) of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

Requirements for Inventory Documentation:

1. Separate the documentation of CII and CII – CV within the record.
2. For each CII – CV in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

Example Biennial Inventory Documentation[8]

Currently law would require a inventory cover sheet for each DEA number. Future publication of DEA regulations would permit the hub and spoke cover sheet to be on one documentation.

BIENNIAL CONTROLLED SUBSTANCE INVENTORY RECORDS

COVER SHEET

DEA Registrant Name: _____

DEA Registrant Address: _____

DEA Number: _____

CSR Registration Number: _____

Supervising Practitioner: _____

Date CS Inventory Conducted: _____

Time Inventory Conducted (open or close of business): _____

Signature of person(s) conducting inventory: **Date:**

_____

Signature of Witness(es): **Date:**

_____

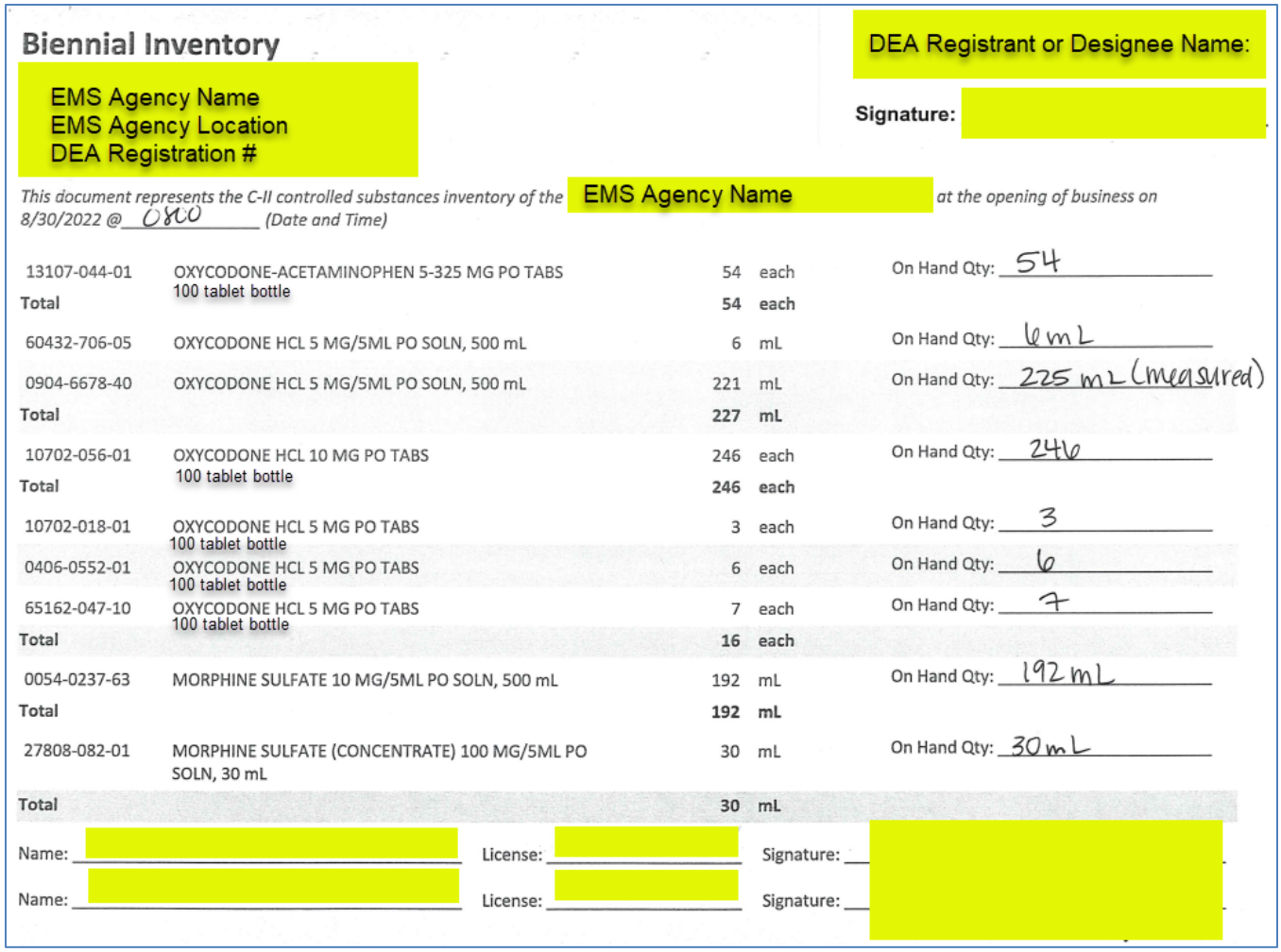
Inventory records filed in EMS location (describe):

_____

Signature of DEA Registrant or Designee via POA **Date:**

_____

[8] DEA Practitioner Diversion Awareness Conference: https://www.deadiversion.usdoj.gov/mtgs/pract_awareness/conf_2019/june_2019/ikner.pdf



Biennial Inventory

EMS Agency Name
EMS Agency Location
DEA Registration #

DEA Registrant or Designee Name:

Signature:

This document represents the C-II controlled substances inventory of the EMS Agency Name *at the opening of business on 8/30/2022 @ 0800 (Date and Time)*

13107-044-01	OXYCODONE-ACETAMINOPHEN 5-325 MG PO TABS 100 tablet bottle	54	each	On Hand Qty: 54
Total		**54**	**each**	
60432-706-05	OXYCODONE HCL 5 MG/5ML PO SOLN, 500 mL	6	mL	On Hand Qty: 6 mL
0904-6678-40	OXYCODONE HCL 5 MG/5ML PO SOLN, 500 mL	221	mL	On Hand Qty: 225 mL (measured)
Total		**227**	**mL**	
10702-056-01	OXYCODONE HCL 10 MG PO TABS 100 tablet bottle	246	each	On Hand Qty: 246
Total		**246**	**each**	
10702-018-01	OXYCODONE HCL 5 MG PO TABS 100 tablet bottle	3	each	On Hand Qty: 3
0406-0552-01	OXYCODONE HCL 5 MG PO TABS 100 tablet bottle	6	each	On Hand Qty: 6
65162-047-10	OXYCODONE HCL 5 MG PO TABS 100 tablet bottle	7	each	On Hand Qty: 7
Total		**16**	**each**	
0054-0237-63	MORPHINE SULFATE 10 MG/5ML PO SOLN, 500 mL	192	mL	On Hand Qty: 192 mL
Total		**192**	**mL**	
27808-082-01	MORPHINE SULFATE (CONCENTRATE) 100 MG/5ML PO SOLN, 30 mL	30	mL	On Hand Qty: 30 mL
Total		**30**	**mL**	

Name: License: Signature:

Name: License: Signature:

INITIAL inventory date

Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with paragraph (e) of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory. (AKA you actually need to document "0" CII – CV medications on-hand in writing). Your initial inventory will be "0"on "Day 1" when you receive the DEA Registration through the mail, to include CII – CV in EMS vehicles at the DEA registered location. Keep this document indefinitely.

On the day when the pharmacy supplied EMS boxes/kits are transferred to the EMS registered location, perform another full inventory. This will require opening of boxes/kits to perform this physical count.

BIENNIAL inventory date

After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date. Keep this documentation for two years.

Inventory date for newly controlled substances

On the effective date of a rule by the Administrator pursuant to §§ 1308.45, 1308.46, or 1308.47 of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to paragraph (c) of this section.

For example, if the DEA ruled that effective XX/XX/XXXX, gabapentin is now a federally schedule V medication, an inventory would need to be performed for all the gabapentin under the registered location on the effective date of rule. (Note: gabapentin is CV only in Virginia as regulated by the Board of Pharmacy)

Transferring Medications (i.e., "Hub and Spoke"): Registered Location to Designated Location OR Designated Location to Designated Location

This section outlines the process with the assumption that the "hub and spoke" model share the same DEA registration.

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 18VAC110-21-721.

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 **CSR/DEA registered location and a designated location**
    - Name of the drug
    - Finished form of the drug (e.g. 10-mg tablet or 10-mg concentration per fluid ounce or ml)
    - Number of units or volume of finished form in each commercial container Ie.g. 100 tablet bottle or 10 ml vials)
    - Number of commercial containers delivered
    - Date of delivery
    - Name and address of the designate location to which the substance is delivered, and
    - Name and title of the person in receipt of the controlled substances

2. For each **acquisition** of drug in Schedules II-VI **from another CSR/DEA registrant**
    - Name of the drug
    - Finished form of the drug (e.g. 10-mg tablet or 10-mg concentration per fluid ounce or ml)
    - Number of units or volume of finished form in each commercial container (e.g. 100-tablet bottle or 10 ml vial)
    - Number of commercial containers acquired
    - Date of the acquisition
    - Name, address and registration number of the person from whom the substance was acquired and
    - Name and title of the person acquiring the drug.
    - For CII, executed **DEA 222** or **DEA CSOS**

3. For each **distribution** of drug in Schedules II-VI **to another CSR/DEA registrant**
    - Name of the drug
    - Finished form of the drug (e.g. 10-mg tablet or 10-mg concentration per fluid ounce or ml)
    - Number of units or volume of finished form in each commercial container (e.g. 100-tablet bottle or 10 ml vial)
    - Number of commercial containers acquired
    - Date of the acquisition
    - Name, address and registration number of the person from whom the substance was acquired and
    - Name and title of the person acquiring the drug
    - For CII, executed **DEA 222** or **DEA CSOS**

Personnel authorized: Personnel providing transfer 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 transferred 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.

Chain of Custody Documentation: Whether paper or electronic, the information described above must be documented at the time of transferring and receiving the transferred CII – CV.

Note: It is best practice to ensure you have a process in place to extract/ recall the transactions for diversion investigations, DEA and/or Board of Pharmacy audits.

Transferring from Hospital or Another Designated Location during an Urgent Need

If there is an urgent need to provide an additional CII – CV medication to the patient during a transfer, the hospital or another designated location may supply that needed dose.

1. You will need to notify the designated location within 24 hours of receiving CII – CV from either a hospital or another designated location. The designated location must notify the agency's registered location. (i.e., the "spoke" needs to notify the "hub.") Follow the documentation procedures for receipt of CII – CV as part of the supplied information of the notification to the registered location.

2. Delivery of controlled substances in emergency situations.
   (a) Hospitals and emergency medical services agencies' registered locations, and designated locations may deliver controlled substances to each other, with written approval from the Special Agent in Charge of DEA for the area or DEA Headquarters, in the event of:
   (1) Shortages of such substances;
   (2) A public health emergency; or
   (3) A mass casualty event.

MEDICATION SUPPLY STORAGE, ACCESS, AND SECURITY

Medications will be at the registered location facility found at the single physical location and address (i.e., the "central hub") noted on the CSR/DEA registrant's license for that agency or service.

Access to Controlled Substance Storage

Who has Access?

Supervising practitioner should designate by developing a list of people who have restricted access to CII – CVI medications. Refer to FRAMEWORK FOR MEDICATION MANAGEMENT section.

Lock Requirements

	Schedule CII - CV	Schedule CVI
Medication Room Lock Requirements	Double Lock (as required by DEA Requirement) Lock #1: Lock on the room Lock #2: Internal secured storage. An example is a safe purchased at the local hardware store that is bolted to the floor, locked with a code. a. Tip for DEA audit: Be able to speak to who has access to the code, and what happens if someone leaves the organization Note: If there are CII – CV medications requiring refrigeration, the refrigerator requires its own lock	Lock #1: Lock on the room
Storage on Ground EMS Vehicle	Drugs in Schedules II - V stored on a ground EMS vehicle, 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 Schedules II through V stored on an EMS vehicle which is a licensed rotary aircraft shall be stored in a sealed, secured kit or device to deter theft or loss.	Not required to be stored in a sealed kit, but must be stored in a manner to deter theft or loss

Alarm System Requirements

If the facility is staffed 24 hours a day, meaning a member is always on site and there is never a time that staff may be out running a call, no alarm is required.

If the facility is 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. Installation and device shall be based on accepted alarm industry standards.
3. Maintained in operating order.
4. Have an auxiliary power source.
5. Be monitored in accordance with accepted industry standards.
6. Capable of sending an alarm to monitoring entity if breached and the communication line is not operational.
7. Access to alarm is restricted to only the designated and necessary persons.
8. Alarm systems shall be activated whenever the drug storage areas are closed for business.

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

	Schedule CII – CV	**Schedule CVI**
Primary Location	Alarm system required	Not required
Designated Location	Alarm system required	Not required
Temporary Circumstance*	Not required	Not required

***When the EMS vehicle or other EMS vehicle cannot maintain appropriate drug storage temperature or is out of service**

Alarm Notification

The CSR regulations do not specify who must be contacted for a breach of the alarm but it is reasonable that it would be the responsible party for the CSR since they are required to be a person who is regularly on site and have authority to access the drug stock.

Note: The responsibility party on the CSR should always receive the notification to follow-up later on cause of alarm breech and ensuring documentation of investigation. In reality, you can have multiple personnel receiving the alarm notification to ensure that the designated responsibility party for that particular shift/ duration receives the notification in a timely manner; as the responsible party on the CSR may not be the one always responding to the alarm notifications.

Temperature Monitoring (Schedule CII – CVI)

Follow the manufacturer's (i.e., medication packet insert) guidelines regarding storage of medications:

1. Store within the required temperature range
    a. Refrigerated storage: 2C-8C (36F-46F)
        i. CII – CV medications requiring refrigeration: the refrigerator requires its own lock

        Note: refrigerated mediation storage must have dedicated "drugs only" fridge

        Note: Rocuronium, succinylcholine and lorazepam are examples of drugs that must be refrigerated with room temperature storage allowed for shorter periods of time (see package insert for each brand of drug); product must be re-dated with new expiration date when moved from refrigerator to room temperature storage.

    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)

Best practice recommendation: If the temperature is outside of the range for more than 1 hour, the medications may not be utilized unless the manufacturer is contacted and can provided excursion information. Separate the affected medications and label/ add sticker to indicate that they were identified to be stored outside of the temperature ranges. It also may be helpful to reach out to your local hospital to see if they have that information on file before reaching out to the manufacturer. Provide the medication name, NDC, lot and expiration date when contacting the manufacturer or the pharmacy.

2. Protect from light as required

3. Temperature maintenance management:
    a. Manual documentation: Maintain a log that temperature is within range on a daily basis
    b. Wireless documentation: Ensure that the software is able to capture temperatures and store them in a readily retrievable manner
    c. Temperature range deviation: If the temperature is out of range for a period of time, document within the log, the temperature at the time the deviation was discovered, and the action taken to resolve the temperature deviation.

Processing Medications (Labeling Reminder)

Medications 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.

RFID Technology for Inventory Management and Storage

Refer to 18VAC110-20-505 on the Virginia Board of Pharmacy requirements for utilizing RFID technology and medication management.[9]

The supervising practitioner and/or the responsible party of the CSR must maintain the RFID software system's library and formulary of medications (i.e., NDCs) monitored by the system.

Tagging and Checking RFID Prior to Storing within Inventory

- Tagging RFIG on the drugs: person authorized to administer drugs or a pharmacy technician
- Verify accuracy of RFID placement: EMS responsible party or designee authorized to administer drugs

An EMS responsible party or designee authorized to administer drugs shall perform a weekly random check for verification of the accuracy of 5.0% of all kits prepared that week utilizing RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

- The date of verification;
- A description of all discrepancies identified, if any; and
- The initials of the EMS responsible party or designee authorized to administer drugs verifying the accuracy of the process.

Maintain a record for one year.

[9] 18VAC110-20-505. Use of radio-frequency identification.

Expired and Damaged Medications

These should be segregated and clearly marked on the box or shelf. You do not want these to make it to a patient. Regulatory bodies may ask how you managed expired and damaged medications. (HINT: the response is you segregate them and ensure that it does not mix with regular inventory). Refer to the DISPOSAL OF MEDICATIONS section for further information about reverse distribution.

Vehicle Storage and Security

Make every reasonable attempt to follow the manufacturer's guidelines regarding vehicle storage of each medication while in service:

1. Avoid exposure to temperature extremes
2. Protect from light as required
3. Security measures include:
    a. Tamper evident containers for Schedule II-V medications
    b. Secure storage (locked) for Schedule II-VI medications
4. Inventory of the Kit (CII-CV)
    a. Department needs to decide the scope of personnel handling and/or counting CII-CV:
        i. Example language: 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.

    Note: As a best practice for diversion prevention, reconciliation (i.e., witness counting) should occur at the change of the shift or at each personnel change

    i. This involves validating that the kit has not been opened (same contents as when it was last replenished), and has the same serial tag number and, if visible, that the contents have not been compromised (broken, cap off of vials, cap glued back on, expired, etc.). Document that the kit is still intact and sealed.

    ii. If it has been opened, validate the counts of medications remaining with what was administered to patients

DISPOSAL OF MEDICATIONS

Reverse Distribution (Sending to Vendor to Destroy Expired and/or Damaged CII – CVI medications)

Each agency or service will send expired and/or damaged CII – CVI medications to an authorized reverse distributor. This vendor will catalogue expired and/or damaged medications and provide documentation of what is being discarded.

- 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 CII – CV.

There are two primary methods in transferring the expired and/or damaged medications with the reverse distributor:

- If by mail: 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.
- If by person: The reverse distributor will come on-site and catalogue medications to be reverse distributed. Initial documentation on **DEA Form 222/ CSOS** for CIIs will occur.

Medications that are expired and/or damaged awaiting to be reverse distributed must be segregated from regular medication inventory. CII-CV must be secured. These segregated medications may be stored in the same medication supply room, as long as the segregation is visually distinct.

- If the reverse distributor will not accept the damaged CII – CV, consider completing the DEA Form 41 or contacting your local DEA agent for guidance[10].
- Maintain these records for 2 years onsite.

All reverse distribution will be documented in the primary 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.

The purchaser (i.e., the reverse distributor who is purchasing the CII medications from the EMS agency) fills out the DEA222, and the reverse distribution information is documented on the back of DEA 222. An example is provided below. It is imperative that the DEA 222 form is completed with 100% accuracy. If there is incorrect information, you will need to write "VOID" on the form and retain for 2 years.

[10] Registrant Record of Controlled Substances Destroyed – DEA Form 41
https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/surrend.html

Your local DEA office:

DALLAS DIVISION
DALLAS OFFICE
Telephone: 571-324-7535

If you are *not* an ARCOS reporter, you are required to provide a copy of the executed order form to DEA (21 CFR 1305.13). You can email a copy of your order form to: dea.orderforms@usdoj.gov

Reverse Distributor Address of Purchaser

Barcode for tracking

INSTRUCTIONS FOR DEA FORM 222 (see Title 21 CFR Part 1305 for details)

1. Purchasers and suppliers who use this form must have an active DEA registration that is not expired, revoked, or suspended. Both parties must be registered to handle the schedule 1 and 2 controlled substance(s) on the order form.
2. In accordance with 21 CFR 1305.06, an order for Schedule I and II controlled substances, whether on a DEA Form 222 or an electronic order, may be filled only by a person registered with DEA as a manufacturer or distributor.
3. In accordance with 21 CFR 1305.06(c), a person registered to dispense Schedule II substances may distribute the substances to another dispenser with either a DEA Form 222 or an electronic order only in the circumstances described in 21 CFR 1307.11.
4. Do not make erasures or alterations. A defective order form may not be corrected; it must be replaced by a new order form to be accepted. A supplier who receives a form that is incomplete, illegible, improperly prepared, or shows any sign of alteration should return it to the purchaser with the reason for refusal. The purchaser must void all defective forms and keep on file for two years after the date of the order form.
5. Order forms must be maintained separately from all other records for two years. The original must be kept on file by the supplier that fills the order for two years.
6. Lost or stolen order forms must be documented and reported to your local DEA office. See 21 CFR 1305.16 for details.
7. Unused order forms should be voided and returned to Drug Enforcement Administration, PO Box 2639, Springfield, VA 22152-2639. See 21 CFR 1305.18 for details.
8. For additional order forms, call the Customer Service Center at (800) 882-9539 or place your request on-line at www.deadiversion.usdoj.gov or contact the local DEA office.

PART 1. PURCHASER INFORMATION

1. The purchaser fills out no more than twenty line items in this section. If more items are needed, use another form.
2. Only one item may be entered on a single line. Enter the number of packages, the size of the package, and the name of the item.
3. Enter the total number of line items ordered.
4. Incomplete order forms will be returned to the purchaser for completion before the supplier is allowed to fill it. See 21 CFR 1305.15 for details.
5. The form must be signed and dated by a person authorized to sign a registration application for the purchaser, or a person authorized to execute order forms for the purchaser by a power of attorney. An officer or agent signing on behalf of the purchasing registrant will indicate the signature authority immediately after the signature. For example, "attorney-in-fact", "by power of attorney", "designated agent", or "secretary" may be used.
6. The order form must be signed and dated by the purchaser on the day it is submitted for filling. Purchaser must make a copy of the order form for its records before mailing the original to the supplier.

PART 2. SUPPLIER IDENTIFICATION - Enter the DEA number, name, and address of supplier.

PART 3. ALTERNATE SUPPLIER IDENTIFICATION - An order form made out to a supplier who cannot fill all or part of the order within the time limitation may be endorsed to another supplier to fill. Enter the DEA number of the alternate supplier. The person authorized by the first supplier (named in part 2) to obtain and execute order forms must sign and date the endorsement. The first supplier must mail the original order form to the alternate supplier.

PART 4. CONTROLLED SUBSTANCE SHIPMENT

1. This section is filled out by the supplier who actually fills the order. If the original supplier endorses this order to another supplier, then the alternate supplier will fill out this section.
2. Enter the number of packages furnished on each line item and the date shipped. The order may be filled in partial shipments up to 60 days after the date of the order form if it cannot be immediately supplied.
3. The controlled substance(s) may only be shipped to the purchaser and address preprinted on the order form.
4. Supplier must keep the original order form available for inspection for a period of two years.

PART 5. CONTROLLED SUBSTANCE RECEIPT

1. The purchaser fills out this section on its copy of the original order form.
2. Enter the number of packages received and date received for each line item.
3. Purchaser must keep its copy of each executed order form and all copies of unaccepted or defective forms and any attached statements or other related documents available for inspection for a period of two years.

In accordance with the Paperwork Reduction Act of 1995, no person is required to respond to a collection of information unless it displays a valid OMB control number. The OMB control number for this collection is 1117-0010. Public reporting burden for this collection of information is estimated to average 15 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Wasting of CII-CV

Wasting of controlled substances Schedule II-V residual to patient administration 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.

Note: If you are administering controlled substances in the field today, follow your current policy and procedure for compliant wasting.

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. Reconcile and submit documentation at the end of the shift to designated person or per current policy
   d. Maintain this documentation for 2 years

DOCUMENTATION

Documentation Checklist:

1. **Licenses/Registration**
   a. **CSR**
   b. **DEA**
2. **Policy and Procedure Appendixes**
   a. **List of Personnel who has Access to Medications**
   Note: Recommend to delineate who can: order, manage, count, and audit CII – CV, CVI
   b. **Approved Medication List**

3. **Controlled Substances CII – CV Documentation**
   a. Ordering documentation
      i. **CSOS** documentation and electronic file
      i. **Power of Attorney List and Forms** (Refer to DEA Power of Attorney template)[11]
   b. 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
   c. **DEA Form 41**
   d. **DEA Form 106**
2. **Inventory**
   a. **Paper Inventory invoices** (CII, CIII – CV, CVI separately)

[11] Power of Attorney Template: https://www.deaecom.gov/poa.html

   b. **Any Reconciliation Documentation** (that demonstrates an intact chain of custody)
      i. **At wholesaler level upon receipt (usually an electronic file)**
      ii. **Shift reconciliation**
   c. **Initial inventory** (keep indefinitely)
   d. **Biennial inventory**
3. **Reverse Distribution**
   a. **DEA 222 receipts**
   b. **CII – CV invoices**

4. These records will be:
   a. Maintained at and/or electronically accessible from the CSR and DEA registered location
   b. Available for inspection within forty-eight (48) hours
   c. Retained for a period of no less than two (2) years

Medication Administration Procedures and Documentation

Medications 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.

Follow current policy and procedures for medication administration.

Usage documentation will include:

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

INVESTIGATION, MITIGATION AND REPORTING OF SUSPECTED TAMPERING OR DIVERSION

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

Best Practices are described in the American Society of Health-System Pharmacists ASHP Guidelines on Preventing Diversion of Controlled Substances: https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/preventing-diversion-of-controlled-substances.pdf

Tampering, Theft and Diversion Prevention and Detection

Each agency should develop a policy regarding controlled substances 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
- Primary supply storage, security, and documentation
- Labeling and tracking
- Vehicle storage and security

- Medication administration and documentation
- Restocking procedures
- Disposal/ Reverse distribution
- 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

Schedule CII-CV Discrepancy Reporting[12] [13]

Each agency or service will establish a policy for reporting discrepancies of medications, including tampering, theft, loss, or diversion of controlled substances Schedule II-V. A discrepancy occurs anytime there is a mismatch in the counting of CII-CV at receiving, restocking, inventory counts, shift reconciliation, and other reconciliation activities. The policy will be established by the DEA registrant and must include immediate verbal reporting followed by written reports and investigation. The discrepancy should be investigated immediately.

Once a discrepancy is identified, complete a discrepancy form to report the number missing, context and how it was identified, including personnel involved (e.g., especially those who last handled the CII-CV and those who discovered the discrepancy). In addition, any suspected theft should be reported.

Notification to DEA for potential theft and investigation

1. Report to local DEA agent of any suspected theft in writing. (Eff. 7/24/23)
2. Email DEA agent immediately (regulations updated last summer to allow for email)
3. In first 24 hours to notify that investigation has begun
4. There is 45 days grace period to complete the DEA 106

The policy and procedure should describe the timelines of discrepancy resolution:

§ 1301.76 Other security controls for practitioners, Section B: The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant must also file a complete and accurate DEA Form 106 with the Administration through DEA's Diversion Control Division secure network application within 45 days after discovery of the theft or loss. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;
(2) The specific controlled substances lost;
(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
(5) Whether the specific controlled substances are likely candidates for diversion;

[12] Reporting Theft or Significant Loss of Controlled Substances: https://www.federalregister.gov/documents/2023/06/22/2023-13085/reporting-theft-or-significant-loss-of-controlled-substances

[13] DEA Theft/ Loss Reporting: https://deadiversion.usdoj.gov/21cfr_reports/theft/theft-loss.html

(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

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

Definition of Significant Loss
The definition of significant loss is determined by the DEA Registrant.

Factors to consider in deciding "significant loss"

1. https://www.federalregister.gov/documents/2003/07/08/03-17127/reports-by-registrants-of-theft-or-significant-loss-of-controlled-substances
2. When determining whether a loss is significant, a registrant should consider, among others, the following factors:
    a. (1) The actual quantity of controlled substances lost in relation to the type of business;
    b. (2) A pattern of such losses, and the results of efforts taken to resolve them; and, if known,
    c. (3) Local trends and other indicators of the diversion potential of the missing material.
3. Specific questions which a registrant should ask to identify whether a loss is significant include, but are not limited to:
    a. (1) Has a pattern of loss been identified? Would this pattern result in a substantial loss of controlled substances over that period of time?
    b. (2) Are specific controlled substances being lost, and do the losses appear to be random?
    c. (3) Are the specific controlled substances likely candidates for diversion?
    d. (4) Can losses of controlled substances be associated with access to those controlled substances by specific individuals? Can losses be attributed to unique activities which may take place involving the controlled substances?

Example threshold for significant loss: 10% of entire CII-CV inventory (practical for smaller inventories)

Reporting CII – CV Loss
1) Reporting to the DEA: Within 45 days from the initial date of discovery, report the loss by submitting 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

2) Reporting to the Virginia Board of Pharmacy

1. Distribute copies of report and keep a copy as follows (3 copies):
    a. 1 Copy: Virginia Board of Pharmacy Fax: 804-527-4472 Email: pharmbd@dhp.virginia.gov
    b. 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].
    c. 1 Copy: To be maintained at location of drug stock for your records
2. Virginia Board of Pharmacy Guidance Document: https://www.dhp.virginia.gov/pharmacy/guidelines/110-5.pdf

3) Report to OEMS
Follow current policy and procedures.

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. There are analytic labs that you can contract with to perform qualitative and quantitative testing. Note: some hospitals may have the ability to provide these services. Contact your local hospital to determine this need.

AUDITS

18VAC110-20-500. Section 11, H. Registered EMS agency headquarters and regional EMS councils shall audit the security of the drug storage location and perform a random audit of Schedule II-V drugs and required recordkeeping for accuracy at least every 6 months at each designated location under its CSR the controlled substances registration. 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.

Crosswalk of Controlled Substances Requirements

Federal Requirements

	CII – CV	**CVI**
Authority	DEA (Federal) and Board of Pharmacy (State) **note the state has the authority to control a substance that the DEA does not, for example gabapentin in Virginia is a CV, but not a control drug at the Federal level. The stricter classification is applied**	Board of Pharmacy (State) Virginia Specific
Ordering	Requires POA if someone other than registrant is ordering CSOS – DEA's secure electronic ordering program DEA 222 form – alternative to CSOS ordering, aka: paper form If utilizing 222 forms for ordering, additional requirements apply to the storage and use of these forms	No POA required No extra forms or steps Could be the same person authorized to order the CII - V
Receiving	Must be licensed to administer medications in Virginia to have access and handle 2 people required to unpack 2 signatures (first and last name) and date on each invoice, confirming what was received 2 people must enter the product into the inventory (paper log or electronic inventory system)	Must be licensed to administer medications in Virginia to have access and handle
Documentation	Record keeping and inventories are the responsibility of the registrant Must store paper II – V invoices on site (address of DEA license) unless DEA has been notified of intention to keep central records. must furnish to DEA or BOP upon inspection Match invoice to CSOS order placed to orders received (ie: invoice) -Store in numerical order, account for all CSOS or 222 orders placed Must be, "readily retrievable" Recommend storing paper II and paper III – V in two separate folders, by month	Must store paper VI onsite for two years and furnish for BOP inspection Recommend storing by month
Inventories	Must do initial inventory and keep indefinitely and then every two years after Must conduct a physical inventory of all C II – V every two years and keep on file to furnish for inspection (biennial inventory)	
Disposal	Must account for any, "waste" when administering to patients Utilize reverse distributor when possible to get rid of expired drugs Account for breakage/spillage (DEA form 41) **know where each drop of drug went** Consider DEQ guidance and interpretation	Follow DEQ guidelines -saline and electrolytes may go down the sink

Example EMS Medication Room Inspection Form

EMS MEDICATION ROOM INSPECTION FORM

LOCATION: _____

INSPECTION DATE: _____

STORAGE/SECURITY

Temperature

Med Room Temperature _____ °F/°C WNL? [ ] Y [ ] N Temp log missing readings [ ] Y [ ] N

Medication Refrigerator _____ °F/°C WNL? [ ] Y [ ] N Temp log missing readings [ ] Y [ ] N

Security

YES	NO	Question
		Alarm Notification Test: Did it alarm and notify the designated parties?
		Door to medication room is shut and locked always, unless authorized personnel are present
		CII – CV storage found to be locked upon entry

If NO to any of the questions above, describe the actions taken to resolve: _____

_____

_____

_____

Storage

YES	NO	Question
		Drug storage area(s) are clean/dust free
		All medications are stored within their designated storage containers/ cabinets
		Expired/ damaged medications are segregated and only stored in designated location
		Medications removed from refrigerator and stored at room temperature have correct beyond use dating

If NO to any of the questions above, describe the actions taken to resolve: _____

_____

_____

_____

CONTROLLED SUBSTANCES

YES	NO	Question
		Perform random inventory count of controlled substances (CII – CV) with a witness: **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ **Medication Name:** ______________________ Expected Quantity: ________ Counted Quantity: __________ If a discrepancy between expected quantity and counted quantity occurs, investigate immediately.
		Review the last 6 months of discrepancies reported. Were they investigated in an appropriate time period as defined by policy and procedure? Were they documented and reported to the appropriate regulatory bodies? If NO, describe actions to correct reconciliation or documentation errors: ______________ ____ ____ ____ ____

		Audit of Purchasing, Receiving and Inventory (Last 6 months)
		DEA Form 222 Control (if applicable) • Validate the DEA Forms 222 Control Log is complete, accurate and that all forms are secure and accounted for. • Match DEA Form 222 numbers and dates in the DEA Form 222 Control Log with the CS purchase summary report from the wholesaler and other CS source suppliers.
		CSOS Transactions (if applicable) • Validate that all CSOS purchase transactions are finalized and electronically or manual matched to the corresponding invoice and are readily retrievable (i.e. in a file or on a local server).
		CS Purchase History Summary Report • Review purchase history summary of all CS purchased to identify unusual changes in quantity or frequency. Review includes all CS purchasing sources i.e. wholesalers, outsourced compounding venders, etc..
		Separation in Process for Ordering and Receiving • Confirm separation in ordering and receiving process as evidenced by the signature or initials of two individuals (one pharmacist) either on the invoice and /or receiving records.
		CII Received to Inventory Transaction • Randomly select 3 CII deliveries per month. Validate complete documentation on the DEA 222 or DEA 222 and confirm documentation on the form matches units received as documented by invoice and receiving personnel with corresponding entry in the perpetual inventory.
		CIII-V Received to Inventory Transaction • Randomly select 3 CIII-V deliveries per month and confirm documentation of receipt on the invoice or receiving record matches the units received and the corresponding entry in the perpetual inventory.
		Invoice Control • Confirm that invoices for CII substances are signed and attached to the corresponding and complete DEA Form 222 or a copy of the CSOS purchase order or acknowledgement form. • Confirm that invoices for CII – CVI are readily retrievable and filed separately from other invoices (manually or electronically).
		Invoice to Purchase History Report • Invoices are reconciled to statements or wholesaler purchase history reports to detect missing invoices.
		CS Return to the Reverse Distributor • Verify that CS returned to the wholesaler or reverse distributor are reconciled with and match deductions in the perpetual inventory record (active or expired) and that there is a corresponding DEA Form 222 from the receiving party for the transfer of all CII substances.

If NO to any of the questions above, describe the actions taken to resolve: _____

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Inspecting DEA Registrant or Designee Name	Signature	Date

Witness (for inventory count)	Signature	Date

TRAINING AND EDUCATION CONSIDERATIONS

18VAC110-20-700 Section D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including storage, security, and recordkeeping.

HELPFUL LAWS AND REGULATIONS

DEA – Registering Emergency Medical Services Agencies Under the Protecting Patient Access to Emergency Medications Act of 2017: https://www.federalregister.gov/documents/2020/10/05/2020-21675/registering-emergency-medical-services-agencies-under-the-protecting-patient-access-to-emergency

FDA – Drug Supply Chain Security Act: https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

Virginia Board of Pharmacy Laws and Regulations:
https://www.dhp.virginia.gov/Boards/Pharmacy/PractitionerResources/LawsRegulations/