# Monterey County EMS System Policy

Policy Number: 4012
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# CONTROLLED SUBSTANCES

## I. PURPOSE

To establish minimum requirements for compliance with the Controlled Substances Act and California statutes and regulations by Monterey County authorized Advanced Life Support (ALS) provider agencies.

## II. POLICY

A. The following medications are considered "controlled substances" and are approved for use in the Monterey County system:

1. Schedule II - Fentanyl; Morphine Sulfate
2. Schedule III - Ketamine; *Buprenorphine
3. Schedule IV - Midazolam

*Provider agencies must have approval from the EMS Agency in order to participate in this local optional scope of practice (LOSOP) item.

B. All paramedic service provider organizations will have a formal agreement with a DEA registrant who is accountable for the agency or service's compliance with the Controlled Substances Act.

1. The DEA registrant will maintain a separate DEA registration number for each agency or service that they affiliate with; separate from the DEA registrant's own practice and separate from any other legal entity.
2. The DEA registrant will establish policies and procedures, which are compliant with this policy, for each agency or service they serve.

C. The paramedic service provider organization will designate personnel authorized to manage controlled substances for the organization.

## III. PROCEDURE

A. Security Mechanisms and Procedures

1. Ordering and Order Tracking

a. Each agency or service will order controlled substances from a DEA registered distributor or pharmacy.

b. Schedule II controlled substances require use of the DEA Form 222 or the Controlled Substance Ordering System (CSOS). These orders may only be

delivered to the agency or service's facility found at the single physical location and address noted on the DEA license.

c. Each order must be tracked in a manner that documents the parties requesting, ordering, and receiving controlled substances.

2. Receipt and Accountability

a. Controlled substances must be received at the agency or service's facility found at the single physical location and address noted on the DEA license.

b. Personnel receiving controlled substances must be authorized by the DEA registrant and included on the agency or service's roster of personnel authorized to manage controlled substances.

c. A witness, also included on the roster of personnel authorized to manage controlled substances, must participate in the receipt and its documentation.

d. The receipt of controlled substances will be documented in the master supply log(s) including: the date and time, the name of the medication, the concentration, the quantity of vials, the expiration date, the manufacturer, the lot number, and the receiving party and the witness, including their signatures.

3. Master Supply Storage, Security and Documentation

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

b. Controlled substances must be stored in a "securely locked, substantially constructed cabinet" as required under the Controlled Substances Act.

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

1) Store within the required temperature range

2) Protect from light as required

d. Master supply security measures will include:

1) Tamper evident containers

2) Witnessed counting; no less than once each month

e. Personnel handling and/or counting controlled substances at the master supply 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, included on the roster of personnel authorized to

count controlled substances, must also participate in each count and its documentation.

f. 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) The original 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 an electronic patient care record (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 24 hours by the EMS Agency

c) Maintained for a period of no less than two years (older records should be shredded)

4. Controlled Substance Labeling and Tracking

a. 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.

b. 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 concentration, the quantity of vials, the expiration date, the manufacturer, the lot number, and the party(ies) involved, including signature(s). Additional methods of tracking are encouraged.

5. Vehicle Storage and Security

a. 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

b. Vehicle storage security measures will include:

1) Tamper evident containers

2) Witnessed counting with each change in personnel or change of shift; no less than once each day (24 hours)

6. In-Service Record Keeping

a. Personnel handling and/or counting controlled substances while in service must be authorized by the DEA registrant and included on the agency or service's roster of personnel authorized to administer controlled substances.

b. 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.

c. 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 24 hours by the EMS Agency

c) Submitted to master supply at least monthly

d) Maintained as master supply documentation for a period of no less than two years

7. Usage Procedures and Documentation

a. Controlled substances will be administered by ALS providers only as authorized per EMS policy and protocols currently in effect at the time of use. Personnel administering controlled substances must be authorized by the DEA registrant and included on the agency or service's roster of personnel so authorized.

b. Usage documentation will include:

1) A log(s) of all controlled substances administered

2) An 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 24 hours by the EMS Agency

c) The corresponding PCR must be accessible for matching with these records

d) Maintained as master supply documentation for a period of no less than two years

8. Reverse Distribution

   a. Each agency or service will send expired and/or damaged controlled substances to an authorized reverse distributor.

      1) Schedule II controlled substances must be transferred using the DEA's Form 222

      2) Schedule III – V controlled substances may be transferred by invoice.

      3) 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 registration.

      4) Each reverse distribution must be tracked in a manner that documents the parties sending and receiving the expired and/or unwanted controlled substances.

   b. 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.

      1) A witness, also included on the roster of personnel authorized to manage controlled substances, must participate in the shipment and its documentation.

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

9. Disposal

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

   b. Disposal of controlled substances residual to patient administration, wasting, will be performed following the agency or service's internal policy.

1) This policy must include a method of wasting which renders the remaining medication non-retrievable as defined by the DEA.
2) Disposal in a sharps container and sewering of controlled substances are both methods which do not meet the DEA requirement.
3) Process for disposition of the empty, or partially empty, narcotics container shall be described in the policy.

c. 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.
    1) 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.
    2) The witness shall observe the wasting of the substance from its original container.

d. Wasting documentation will include:
    1) A log(s) of all controlled substances wasted
    2) An 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 24 hours by the EMS Agency
        c) Submitted to master supply at least monthly and maintained for a period of no less than two years

10. Re-Stocking Procedures

a. Re-stocking of controlled substances will be performed following the agency or service's internal policy that will include at minimum verification of administration, waste, damage, and/or expiration.

b. If an agency or service chooses to require the retention and transport of used and/or damaged containers and/or sharps for restock purposes, internal policies will include the use of appropriate sharps containers if a used sharp is retained following administration.

c. Personnel providing re-stock of controlled substances must be authorized by the DEA registrant and included on the agency/service's roster of personnel authorized to manage controlled substances.

d. Personnel receiving re-stocked controlled substances must be authorized by the DEA registrant and included on the agency/service's roster of personnel authorized to administer controlled substances.

1) Both parties must participate in and document the re-stocking.

e. Re-stocking documentation will include:

1) A log(s) of all controlled substances restocked

2) An 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 24 hours by the EMS Agency

c) Maintained for a period of no less than two years

11. Transfer or Exchange Between Agencies and/or Services

a. The transfer or exchange of controlled substances between agencies and/or services is highly discouraged. There are additional federal requirements and documentation necessary for this process to take place; the process has proven problematic when done in other areas. If a provider experiences or expects to experience a shortage of a controlled substance, that provider should contact the EMS Agency as per policy # 4011 – Medication/Solution Shortages.

B. Investigation and Mitigation of Suspected Tampering or Diversion

1. Drug inventories and all related records are subject to inspection by the EMS Agency, the California EMS Authority (EMSA), the California State Board of Pharmacy, the Federal Drug Enforcement Administration, and the Justice Department's Bureau of Narcotic Enforcement.

2. Controlled Substance Testing

a. Testing personnel for controlled substances may be performed following the agency or service's internal policy.

b. Such policies may provide for controlled substance testing that is random, routine, or in response to suspected tampering and/or diversion.

c. Any such policy should be developed in consultation with the DEA Registrant and legal counsel.

3. Discrepancy Reporting

a. Each agency or service will follow its internal policy for reporting discrepancies including tampering, theft, loss, or diversion of controlled substances.

b. This policy will be established by the DEA Registrant and must include immediate verbal reporting followed by written reports and investigation.

c. The DEA Registrant must notify the DEA of the discrepancy within one business day of discovery using DEA Form 106, "Report of Theft or Loss of Controlled Substances."

d. In addition, the EMS Agency must be notified within eight (8) hours utilizing an Unusual Occurrence form as per policy # 6020.

4. Tampering, Theft and Diversion Prevention and Detection

a. 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.

b. Areas to be addressed 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, reverse distribution, disposal, re-stocking procedures, transfer or exchange of controlled substances between agencies and/or services, controlled substance testing, discrepancy reporting; tampering, theft and diversion prevention and detection; and usage audits.

c. Reporting the suspected tampering, theft, and/or diversion of controlled substances to local law enforcement is required.

1) If the tampering, theft, and/or diversion of controlled substances is substantiated, written reports must be made within eight (8) hours to the EMS Agency and EMSA for action against the responsible party's certification, license, or accreditation.

5. Usage Audits

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

1) Be conducted by the DEA registrant/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 ePCRs

b) Identify and report discrepancies as required

3) Identify and investigate unusually high rates of administration
    a) Establish a baseline for the rate of controlled substance administration among all individuals authorized to administer controlled substances during the time-period being audited
    b) Identify high outliers, 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

b. Records of these audits will be:
    1) Maintained at and/or electronically accessible from the agency or service's quality assurance location
    2) Available for inspection within 24 hours by the EMS Agency
    3) Maintained for a period of no less than two years

6. Biennial On-Hand Inventory

    a. In addition to daily and other routine running inventories, the DEA requires a separate Biennial On-Hand Inventory. This inventory includes all controlled substances, including those in a central facility and those which have been deployed. It also includes those in the reverse distribution process. It is a "snapshot" count in time. These counts should be scheduled by every provider in such a way that they are not forgotten.

**END OF POLICY**

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