



**SAN MATEO COUNTY HEALTH
EMERGENCY
MEDICAL SERVICES**

EMS POLICY	520
Effective:	April 2024
Approval: EMS Director Travis Kusman, MPH	Signed:
Approval: EMS Medical Director Greg Gilbert, MD	Signed:

MANAGEMENT OF CONTROLLED SUBSTANCES

I. PURPOSE

This policy establishes minimum requirements for compliance to ensure accountability for all controlled substances authorized by the San Mateo County EMS Agency's Medical Director for use by authorized Advanced Life Support Emergency Medical Responder Agencies on Advanced Life Support First Responder Units and emergency ambulances.

II. AUTHORITY

California State Board of Pharmacy Business and Professions Code, Section 4119 and 4126.5; California Health and Safety Code 2.5, Chapter 3, Section 1797.200 and Chapter 5, Section 1798 through 1798.6; Code of California Regulations, Title 22, Division 9, Chapter 4, Article 7, Section 100168, Code of Federal Regulations, Title 21, Sections 1301.11, 1301.12, 1301.75, 1301.76, 1301.91, 1301.92, 1307.02, 1307.21, 1305.05.

III. DEFINITIONS

Advanced Life Support ("ALS"): Special services designed to provide definitive prehospital emergency medical care, including, but not limited to: cardiopulmonary resuscitation, cardiac monitoring, cardiac defibrillation, advanced airway management, intravenous therapy, administration of specified drugs and other medicinal preparations, and other specified techniques and procedures administered by authorized personnel under the direct supervision of a base hospital as part of a local EMS system at the scene of an emergency, during transport to an acute care hospital and while in the emergency department of an acute care hospital until responsibility is assumed by the emergency or other medical staff of that hospital.

Advanced Life Support ("ALS") Emergency Medical Responder Agency: An Emergency Medical Responder Agency authorized by LEMSA which provides paramedic personnel with ALS equipment to respond to medical emergencies with the capabilities to provide immediate ALS medical care prior to arrival of an ambulance.

Advanced Life Support ("ALS") Ambulance [or "Paramedic Ambulance"]: An ambulance authorized by LEMSA to provide ALS emergency services within San Mateo County.

Advanced Life Support ("ALS") First Responder Unit ("FRU"): A first responder unit

authorized by LEMSA to provide ALS emergency services within San Mateo County.

Controlled Substances: Any schedule II, III or IV medications authorized by the LEMSA Medical Director for use in the EMS system for direct patient care.

DEA Registrant: A qualified, licensed medical practitioner authorized to prescribe, dispense, and administer scheduled drugs defined by the U.S. Drug Enforcement Administration.

Drug Enforcement Administration (“DEA”): The U.S. Drug Enforcement Administration.

Electronic Health Record (“EHR”): The official and legal patient record completed by EMS personnel. Formerly referred to as ePCR.

Emergency Medical Services Agency (“LEMSA”) [or “Agency”]: The San Mateo County EMS Agency is designated as the Local Emergency Medical Services Agency (LEMSA) and is statutorily charged with primary responsibility for administration and medical control of emergency medical services in San Mateo County.

EMS Supervisor: A paramedic approved by the LEMSA responsible for operational and clinical leadership and supervision of emergency medical services at the provider agency level.

IV. CONTROLLED SUBSTANCES AUTHORIZATION

All ALS Emergency Medical Responder Agencies shall have a formal agreement with a DEA Registrant who is accountable for the agency’s compliance with the Controlled Substances Act. The DEA Registrant shall maintain a separate DEA registration number for each agency that they affiliate with, which shall also be separate from the DEA Registrant’s own practice and separate from any other legal entity. The DEA Registrant shall conform to this policy and may establish separate procedures for each agency they serve, which shall not conflict with this policy.

V. CONTROLLED SUBSTANCE LABELING

Controlled substances shall remain in the original manufacturer containers with original, unaltered Food and Drug Administration compliant labels until the time of administration.

VI. DOCUMENTATION REQUIREMENTS

All ALS Emergency Medical Responder Agencies shall use and maintain a controlled substance management software system or process approved by the DEA Registrant and LEMSA Medical Director. These records shall be maintained at and/ or electronically accessible from the supply location and be made available for inspection by the LEMSA within twenty-four (24) hours of request. All records shall be maintained for a period of no less than three (3) years.

A. Master Vault (Master Vault Log) documentation shall include:

1. A copy of the current DEA Registrant’s license; and
2. Copies of completed DEA Form 222, including voided forms completed within the past three (3) years; 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, and/or returned to the Master Vault; distributed, reverse distributed, and/ or transferred or exchanged between agencies; and an EHR event number(s) or other appropriate report corresponding to each administration, waste, damage, or expiration.

3. All original controlled substance packing slips and executed DEA 222 forms must be maintained separately from vault inventory logs.
4. Receipt of controlled substances that includes: ALS Agency name, date and time, name of controlled substances(s), strength, quantity, expiration date, manufacturer (if documentation field is available), and lot number. The name and signature of the receiving party shall also be included.
5. Distribution of controlled substances that includes: ALS Agency name, date and time, name of controlled substances(s), quantity, expiration date, manufacturer (if documentation field is available), and lot number. The name and signature of the EMS Supervisor distributing controlled substances shall also be included.
6. If present at the time and location of any inventory, a witness should witness the inventory count. If used, a camera with functional recording that contains an unobstructed view of the transaction may replace the witness. Storage of recordings of videos shall be maintained for a minimum of thirty (30) days.

B. Restock Vault (Restock Vault Log) documentation shall include, if used:

1. Receipt of controlled substances into the Restock Vault that includes: ALS Agency name, date and time, name of medication(s), quantity, and expiration date.
 - a. The name and signature of the EMS Supervisor adding inventory to the Restock Vault.
 - b. A Restock Vault inventory shall be taken and documented in the Restock Vault inventory log when controlled substance inventory is altered.
2. Distribution of controlled substances from the Restock Vault that includes: ALS Agency name, date and time, name of medication(s), quantity, and expiration date.
 - a. The ALS ambulance or ALS FRU unit number for which controlled substances are being removed for the purposes of restock.
 - b. The name and signature of the EMS Supervisor or paramedic removing inventory from the Restock Vault.
 - c. A Restock Vault inventory shall be completed and documented in the Restock Vault inventory log when controlled substance inventory is altered.
3. If present at the time of inventory, a witness should witness the inventory count. If used, a camera with functional recording that contains an unobstructed view of the transaction may replace the witness. Storage of recordings of videos shall be maintained for a minimum of thirty (30) days.

C. Vehicle Vault (Vehicle Vault Log) documentation shall include:

1. Each ALS ambulance and ALS FRU shall maintain a standardized written record of controlled drug inventory, or if done electronically, shall be readily accessible for printing. The standardized written record shall be maintained with controlled substances until submitted to and/ or electronically accessible from the Master Vault supply location and include, at a minimum:
 - a. A count of all controlled substances accepted into service for each unit.
 - i. The name(s) and signature(s) of paramedic personnel counting/ handling controlled substances;
 - ii. The date and time of inventory;
 - b. Administration of controlled substances shall be documented on 904 – Controlled Substance Administration and Resupply Form or electronic equivalent;
 - c. If controlled substances are damaged, said damage shall be documented on 904 – Controlled Substance Administration and Resupply Form or electronic equivalent; and
 - d. When controlled substances are restocked, restock shall be documented in the Vehicle Vault Log.
 - e. Count of controlled substances returned to Master Vault supply location, which includes the date(s) and time(s) controlled substances are removed from service.
2. Any controlled substance that has not been completely used during treatment of a patient must be disposed of in the presence of two medical personnel and documented electronically and on 904 – Controlled Substance Administration and Resupply Form or electronic equivalent.

VII. ORDERING, TRACKING, AND RECEIPT REQUIREMENTS

A. Procurement and Order Tracking

1. Controlled substances orders shall be approved by the DEA Registrant, ordered by the DEA Registrant's designee, received by the ordering agency, and assigned to the agency's ALS units.
2. Each agency shall order controlled substances from an authorized drug wholesaler or pharmacy.
3. Each order must be tracked in a manner that documents the parties requesting and receiving controlled substances and all associated quantities.

B. Receipt and Accountability

1. Upon receipt of a controlled substance order, inventory shall be physically validated to confirm quantity received compared to shipping manifest. Partial shipments should be noted on order paperwork and stored with 222 Form associated with the order.
2. The receipt of controlled substances shall be added to and documented in the agency's Master Vault. Documentation shall comply with Section VI of this policy.

3. All distribution of controlled substances shall be under the control of the EMS Supervisor(s) designated by the DEA Registrant and authorized to manage the ALS provider agency's controlled substance program.

VIII. MASTER VAULT STORAGE AND SECURITY

- A. There shall be a functional Master Vault for the agency listed on the DEA Registrant's license. There shall be no co-mingling of controlled substance inventory amongst ALS provider agencies of differing addresses associated with the DEA Registrant.
- B. Master Vaults shall be installed and follow the manufacturer's guidelines for storage of controlled substances, including being in a climate-controlled area.
- C. Master Vault supply location security measures shall include:
 1. Storage under double lock. This includes the lock(s) on the safe and a limited access lock to the room in which the master vault is located. Electronic or biometric security locks are authorized;
 2. An inventory count shall occur no less than once each month or each time the Master Vault is accessed. Documentation shall comply with Section VI of this policy; and
 3. The use of camera(s) with functional recording are strongly encouraged but shall not be a substitute for the double lock requirement.
- D. Personnel handling and/ or counting controlled substances at the Master Vault supply location shall be authorized by the DEA Registrant and included on the agency or service's roster of personnel authorized to manage controlled substances. Authorized personnel, as defined by the DEA Registrant include accredited paramedics employed by the ALS agency and select management personnel. If present at the time and location of inventory, a witness, should also participate in each count and its documentation.

IX. VEHICLE STORAGE AND SECURITY

- A. A reasonable attempt to follow the manufacturer's storage guidelines for controlled substances shall be made, which includes the following:
 1. Avoiding exposure to extreme temperatures; and;
 2. Protection from direct sunlight.
- B. Vehicle Vault storage security measures shall include:
 1. Utilization of LEMSA approved tamper-evident seal for storage box containing controlled substances;
 2. Storage under double lock, which may include vehicle door/ compartment lock and cabinet/ safe lock (Vehicle Vault) with corresponding personnel access controls approved by LEMSA;
 3. Witnessed counting with each change in paramedic responsible for controlled substances on each apparatus, or alternatively, paramedic returns entire controlled substance container to its identified secure locker under 24/7 functional video surveillance at the end of shift; and

4. When the apparatus is not in active ALS service, controlled substances shall be removed from the apparatus and stored securely under the direction of the EMS Supervisor.
- C. Each ALS ambulance and ALS FRU shall maintain a standardized written record of controlled drug inventory, or if done electronically, shall be readily accessible for printing. Documentation shall comply with Section VI of this policy.

X. MANAGEMENT OF INVENTORY DISCREPANCIES

- A. Controlled substance inventories and all related records are subject to inspection by the LEMSA, Emergency Medical Services Authority (“EMSA”), California State Board of Pharmacy, DEA, and other government agencies. Each ALS agency shall have internal policies regarding controlled substances to include prevention and detection of tampering, theft, loss, and/or diversion of controlled substances.
- B. Testing personnel for controlled substances shall be performed in accordance with prevailing law.
- C. Suspected controlled substance discrepancies shall be clearly noted in the appropriate controlled substance log and be signed by the personnel noting the suspected discrepancy. The suspected discrepancy shall be immediately reported to the agency’s EMS Supervisor. EMS personnel and EMS Supervisors are responsible for reporting suspected discrepancies including tampering, theft, loss, or diversion of controlled substances. Any person having knowledge of drug theft or diversion must immediately report the concern to local law enforcement, the EMS Agency Duty Officer, and to the to the DEA. A written EMS event report in accordance with Policy 523 – EMS Event Reporting shall also be submitted.
- D. Discrepancy between the ALS ambulance or ALS FRU controlled substance log and the actual amounts of controlled substances in the Vehicle Vault stock must be reported to the DEA. The EMS Supervisor shall forward a completed Form DEA-106 – Report of Theft or Loss of Controlled Substances¹ to the EMS Agency Duty Officer not more than 24 hours after discovery. The DEA Registrant is required to submit Form DEA-106 within one (1) business day of discovery.

XI. INSPECTION AND AUDITS

- A. Initial inventory (documented at the initial registration of the agency) shall include a physical count of all controlled substances stocked in the Master Vault, Restock Vault (if used), and Vehicle Vaults. This count shall be entered on the inventory record. Initial shipping records and packaging slips shall be saved and stored in accordance with Section VI of this policy.
- B. Twice-yearly inventory – an inventory of all controlled substance stock on hand shall be conducted twice each year. Twice-yearly inventory may be completed on any dates agreed upon by the agency and DEA Registrant.

¹ https://www.deadiversion.usdoj.gov/21cfr_reports/theft/DEA_Form_106.pdf - search=form 106

- C. Controlled substances shall be available for inspection by LEMSA upon request.
- D. Periodic inspections and audits of controlled substances and controlled substance inventory shall be conducted not less than once per calendar year by the LEMSA Medical Director or her/ his designee if acting as the DEA Registrant to document compliance with this policy.
- E. Each EMS Supervisor shall follow its internal policy for usage audits. Audits shall:
 - 1. Be conducted by the EMS Supervisor or designee;
 - 2. Account for the current disposition of all controlled substances;
 - 3. Include review of forms and logs as well as the applicable patient care protocols and EHR documentation related to the use of controlled substances;
 - 4. Identify and investigate unusually high rates of administration by EMS personnel authorized to administer controlled substances during the time period being audited;
 - 5. Identify and report discrepancies as required; and
 - 6. Be performed not less than in conjunction with twice yearly audits.

XII. RESTOCKING

- A. Restocking of controlled substances shall be performed in accordance with the agency’s internal policy and shall include, at minimum: Verification of administration, waste, damage, and/ or expiration. If an agency chooses to require the retention and transport of used and/ or damaged containers and/ or sharps for restock purposes, internal policies shall include the use of appropriate sharps containers.
- B. Documentation shall comply with Section VI of this policy.

XIII. TRANSFER OR EXCHANGES BETWEEN AGENCIES

- A. The transfer or exchange of controlled substances between agencies is strongly discouraged.
- B. If a transfer or exchange of controlled substances is required, it must be:
 - 1. Approved by the DEA Registrant(s) of both the supplying and the receiving agency;
 - 2. Conducted between personnel included on each agency’s roster of personnel authorized to manage controlled substances; one (1) supplying and one (1) receiving;
 - 3. Witnessed by at minimum the supplying and receiving personnel directly involved in the transfer and who shall be included on each involved agency’s roster of personnel authorized to manage controlled substances; and
 - 4. Documented by both the supplying and the receiving agency using the DEA Form 222 for Schedule II controlled substances, an invoice for Schedule III – V controlled substances, and a log(s) of all controlled substances transferred or exchanged.
- C. Transfer or exchange documentation shall include:
 - 1. Copies of each agency’s DEA Form 222 for Schedule II controlled substances;

2. Copies of each agency's invoice for Schedule III – V controlled substances; and
3. Each agency's log(s) of all controlled substances transferred or exchanged.

These records shall be maintained at and/ or electronically accessible from the Master Vault supply location, available for inspection, and retained for a period of not less than three (3) years.

XIV. REVERSE DISTRIBUTION

- A. The ALS agency shall 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, while Schedule III-V controlled substances may be transferred by invoice. 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 and the associated quantities of each substance being returned.
- B. Personnel sending controlled substances for reverse distribution must be authorized by the agency and included on the agency's roster of personnel authorized to manage controlled substances. A witness, also included in the agency's roster of personnel authorized to manage controlled substances, must participate in the inventory of controlled substances to be sent to an authorized reverse distributor and documentation.
- C. All reverse distribution will be documented in appropriate logs, including date and time; name of medication; strength; quantity; expiration date; manufacturer (if documentation field is available); and the names of the sending party and the witness, including their signatures.
- D. A copy of receipt sent by the reverse distributor shall be kept with the order's documentation.