



POLICY NO:	OPS – 16
EFFECTIVE:	8/2019

MANAGEMENT OF CONTROLLED SUBSTANCES FOR AGENCIES

Purpose: The purpose of this policy is to ensure accountability for all controlled substances issued to advanced life support (ALS) units.

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 1797.172 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, 1304.03, 1304.04, 1304.11, 1304.21, 1304.22, 1307.02, 1307.21, 1305.05.

I. Security Mechanisms and Procedures

A. Procurement and Order Tracking:

1. Each agency shall order controlled substances from an authorized drug wholesaler or pharmacy.
2. Each order must be tracked in a manner that documents the parties requesting, ordering, and receiving controlled substances.
3. Controlled substances will be ordered by the agency physician registrant and assigned to ALS JPA Zones and ALS transport agency units according to DEA regulations.

B. Receipt and Accountability:

1. Controlled substances shall be received at the facility noted on the DEA license.
2. The receipt of controlled substances shall be documented in the master supply log (separate logs for each ALS JPA zones and ALS transport agency) and include: Date and time, name of medication, strength, quantity, expiration date, manufacturer, lot number and the receiving party and the witness, including their signatures. A camera may replace the witness requirement.
3. All distribution shall be under the control of the JPA supervisor who is designated and authorized per individual fire department or JPA policy to manage controlled substance and the controlled substance program at the JPA zone or ALS transport agency for the physician registrant.

C. Master Vault Supply Storage, Security and Documentation:

1. There shall be a master vault for each respective ALS JPA zone and ALS transport agencies. Controlled substances shall be ordered by the agency physician registrant and assigned to its ALS units according to DEA regulations. There is to be no co-mingling of controlled substance inventory with other JPAs.

APPROVED:

Nancy A. Lapolla, MPH, EMS Director

Gregory H. Gilbert, MD, EMS Medical Director

2. Master vault supply security measures must include storage under double lock; this may include electronic or biometric security, tamper evident containers. To increase security, accountability, and tracking of all controlled medications, witnessed counting shall occur no less than once each month or each time the master vault is accessed.
 3. Follow the manufacturer's guidelines regarding storage of each controlled substance.
 4. Each vault must have a copy of the DEA registration that is current.
 5. Master vault supply documentation shall include copies of completed DEA Form 222.
- D. All agencies utilizing the County of San Mateo Medical Director as the physician registrant shall maintain onsite records of the inventory of controlled substances and related documentation of each medication administered to a patient. These records shall be maintained for a period of not less than two years. These records must be written, typewritten, or printed and available for inspection. Inventory records must be kept separately from the logs.
1. Initial inventory (documented at the initial registration of the agency) must include a physical count of all controlled substances in stock; this count must be entered on the inventory record. Initial shipping records and packaging must be saved and stored separately as outlined above.
 2. After the initial inventory, a biannual inventory of all controlled substance stock on hand (vault and each apparatus) within six months of the initial inventory date. The biannual inventory may be taken on any date within the first six months of the initial inventory date.
- E. All original controlled substance purchase invoices and executed DEA 222 forms must be kept separately from the daily and maintenance logs.
- F. The following logs must be maintained by each respective ALS JPA agency or ALS transport agency for a period of not less than three years per section 4119 of the California Board of Pharmacy:
1. Controlled Drug Usage Record;
 2. Controlled Drug Inventory Record;
 3. Records for Schedule II controlled substances (morphine and fentanyl) must be maintained separately from Schedule IV drugs (midazolam); and
 4. A log(s) of all controlled substances ordered, received, stored, placed into service, administered, wasted or restocked. Patient care record or other appropriate report corresponding to each administration, waste, damage, or expiration.
- G. All ALS agencies shall keep a controlled substance log in a secure location and will document:
1. Receipt of the controlled substances;
 2. Distribution of controlled substances to the units for restock; and
 3. Monthly count and each time the controlled substances are accessed.

- H. Controlled substances shall be available for inspection within 24 hours.
- I. Controlled substances shall be maintained on site and/or electronically accessible.

II. Labeling and Tracking

- A. Controlled substances must remain in the original manufacturer containers until time of administration.
- B. Tracking of controlled substances shall include documentation of log(s) as described herein.

III. ALS Unit Security, Record Keeping, Storage and Stocking

- A. Controlled substances shall be stored under double lock.
- B. All controlled substances will be issued in tamper evident containers
- C. Witnessed counting with each change in personnel or change in shift, no less than once per calendar day is required.
- D. Each ALS unit shall maintain a standardized written record of controlled drug inventory, or if done electronically, shall be readily accessible for printing. This record shall be available to the physician registrant for routine inspection and shall be maintained by the respective agency for a period of three (3) years in compliance with the State Board of Pharmacy.
- E. Controlled substances will be accessed and administered by ALS JPA zone or ALS transport agency authorized personnel only.
- F. Controlled substances shall be inventoried by the assigned ALS personnel at the beginning and at the end of every shift or as soon as reasonably possible. Documentation of the inventory shall include the signatures or electronic verification of the personnel performing the inventory and noted on the controlled drug inventory.
- G. Any time a controlled substance is administered, the date, name of the drug, dose administered, route, patient name, name of the paramedic administering the drug, receiving facility, and EMS ePCR number shall be documented on the controlled drug inventory.
- H. Any controlled substance that has not been completely used must be disposed of in the presence of two medical personnel.
- I. Agency personnel must document any disposed controlled substance on the appropriate agency form. This form must include:
 - 1. Name of the patient;
 - 2. EMS event/run number;
 - 3. Date and time of administration;
 - 4. Amount of medication given to the patient;
 - 5. Amount of medication disposed; and
 - 6. Signatures of the two medical personnel who witnessed the disposal.

- J. Each ALS unit shall maintain the following in a standardized written or printed form:
1. Log of all controlled substances;
 2. An ePCR corresponding to each administration; and
 3. Records will be maintained with the medications until submitted to and/or electronically accessible from the master supply location, available for inspection within 24 hours, submitted to the master supply at least monthly. The master supply documentation is to be maintained for no less than three years.

IV. Management of Inventory Discrepancies

- A. Any controlled substance discrepancy shall be noted on the controlled drug inventory record sheet and shall be signed by the ALS crew first noting the discrepancy. That discrepancy shall be immediately reported to the immediate supervisor responsible for the controlled substances at the agency.
- B. Any discrepancy between the inventory and the actual amounts of the controlled substances in the stock supply must be reported immediately to the physician registrant, followed by a written report to the San Mateo County EMS Agency within 24 hours.
- C. Any discrepancy between the inventory and the actual amounts of the controlled substances in the stock supply must be reported to the DEA immediately using Form P-106 "Reporting of Theft of Loss of Controlled Substances" on the DEA Diversion website (www.deadiversion.usdoj.gov).
- D. Each ALS zone JPA and ALS transport agency will follow its internal policy for reporting discrepancies including tampering, theft, loss, or diversion of controlled substances.
- E. Any ALS zone JPA or ALS transport agency personnel having knowledge of drug diversion must report this situation to the DEA.

V. Controlled Drug Inspection

- A. Periodic inspections or audits of controlled substances or controlled substance inventory shall be conducted no less than once per calendar year by the EMS Medical director or designee if acting as the physician registrant to document compliance with this policy.
- B. Each ALS JPA zone or ALS transport agency will follow its internal policy for usage audits. Audits will:
1. Be conducted by the ALS Zone or ALS transport agency 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 related to the use of controlled substances;
 4. Identify and report discrepancies as required; and
 5. Be performed at least every six months.

VI. Tampering, Theft, and Diversion Prevention and Detection

- A. Each ALS JPA zone and ALS transport agency shall have internal policies regarding controlled substances to include prevention and detection of tampering, theft, loss and/or diversion of controlled substances.

VII. Reverse Distribution

- A. Each ALS JPA zone or ALS transport agency will send expired and/or damaged 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. Each reverse distribution must be tracked in a manner that documents the parties sending and receiving the expired and/or damaged controlled substances.
- B. Personnel sending controlled substances for reverse distribution must be authorized by the ALS JPA zone or ALS transport agency to manage controlled substances. A witness, also included in the agency roster of personnel authorized to manage controlled substances, must participate in the shipment and its documentation.
- C. All reverse distribution will be documented in logs including: Date and time; name of medication; strength; the quantity; expiration date; manufacturer; and the sending party and the witness, including their signature.



SAN MATEO COUNTY EMS CONTROLLED SUBSTANCE ADMINISTRATION & RE-SUPPLY FORM

MEDICATION:	<input type="checkbox"/>	Fentanyl	<input type="checkbox"/>	Administered
	<input type="checkbox"/>	Midazolam	<input type="checkbox"/>	Expired Date Expired: _____
			<input type="checkbox"/>	NOT Intact/Broken

ADMINISTRATION OF CONTROLLED SUBSTANCE

UNIT #: _____ DATE: _____ INCIDENT #: _____

PATIENT NAME: _____ CHIEF COMPLAINT: _____

AMOUNT ADMINISTERED: _____ mcg/mg AMOUNT WASTED: _____ mcg/mg

PARAMEDIC ADMINISTERING CONTROLLED SUBSTANCE

NAME: _____ SIGNATURE: _____ ID#: _____

PARAMEDIC OR NURSE WINESS TO REPORTED CONTROLLED SUBSTANCE DISPOSAL

NAME: _____ SIGNATURE: _____ ID#: _____

COMMENTS: _____

RESUPPLY OF CONTROLLED SUBSTANCE

PERSON RECEIVING CONTROLLED SUBSTANCE

NAME: _____ SIGNATURE: _____ ID#: _____

MANAGER RESTOCKING CONTROLLED SUBSTANCE

NAME: _____ SIGNATURE: _____ ID#: _____

RESTOCK DATE: _____ RESTOCK SITE: _____ RESTOCK TIME: _____

COMMENTS: _____

EMS AGENCY/SUPERVISORS COMMENTS: _____

SAN MATEO COUNTY EMS CONTROLLED SUBSTANCE ADMINISTRATION & RE-SUPPLY FORM – CONT.

Controlled Substance Administration Review Checklist

Please check each and sign:

- Administration Sheet attached
- Paramedic name is same on administration sheet
- Administration is consistent with SMCO protocol
- Amount administered is same on the ePCR and admin sheet
- Vitals and pain scale are documented after each administration
- Age and weight of patient are documented on the ePCR

Signature of Paramedic completing checklist:
