

 COUNTY OF SAN DIEGO EMERGENCY MEDICAL SERVICES	MEDICAL CONTROL		S-400
	MANAGEMENT OF CONTROLLED SUBSTANCES FOR ALS AGENCIES		
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I. PURPOSE

To ensure accountability for all controlled substances and devices issued to Advanced Life Support (ALS) Units.

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- II. AUTHORITY:** Health and Safety Code, Division 2.5, Sections 1797.172, and 1798-1798.6; California Code of Regulations, Title 22, Section 100096.01; and 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, 1305.05, 1307.02, and 1307.21; California Code, Business and Professions Code, Sections 4119 and 4126.5.

III. DEFINITION(S)

ALS Units: Ambulances or other emergency vehicles (e.g., engines, trucks, etc.) upon which paramedics are placed to render ALS care.

Controlled Substances: Pharmaceutical drugs categorized as Schedule II, III, or IV by the Drug Enforcement Administration (DEA).

1. Approved DEA Schedule II controlled substances for ALS Units include:
 - a. Morphine Sulfate
 - b. Fentanyl
2. Approved DEA Schedule III controlled substances for ALS Units include:
 - a. Ketamine
3. Approved DEA Schedule IV controlled substances for ALS Units include:
 - a. Midazolam (Versed)

IV. POLICY

All ALS agencies in the County of San Diego will have a physician registrant to purchase controlled substances with a DEA Form 222 from a pharmacy or pharmaceutical supply agency thereby retaining ownership, accountability, and responsibility of those controlled substances. ALS agencies which do not have a Medical Director may use the County of San Diego, Emergency Medical Services (CoSD EMS) Medical Director to assist with the purchase of controlled

substances (see CoSD EMS Policy S-416 “Supply and Resupply of Designated EMS Agencies and Vehicles”) if said agency signs a Memorandum of Agreement with the County of San Diego for the purchase of Dangerous Drugs and Devices. All ALS agencies will develop policies compliant with Code of Federal Regulations, Title 21 concerning the procurement, receipt, distribution, and waste management of controlled substances managed under their DEA registration number.

V. PROCEDURES

A. Procurement and Order Tracking

1. Each agency will order controlled substances from an authorized drug wholesaler or pharmacy.
2. Schedule II controlled substances require use of the DEA Form 222.
3. Each order must be tracked in a manner that documents the parties requesting, ordering, and receiving controlled substances.
4. Controlled substances will be ordered by the agency physician registrant and assigned to its ALS Units according to Drug Enforcement regulations

B. Receipt and Accountability

1. Controlled substances must be received at the agency facility found at a central location and address noted on the DEA license.
2. The receipts of controlled substances will be documented in the master supply log(s) including date, time, name of medication, strength, quantity, expiration date, manufacturer, lot number, and signatures from the receiving party and the witness.
3. If any ALS agency wishes to have more than one location from which to stock controlled substances, each location will have a separate DEA registration.
4. All ALS agencies will maintain a stock supply of controlled substances at a central location from which all that agency’s ALS Units must resupply.
5. All locations in an ALS agency shall be under the control of the agency person who is designated and authorized per agency policy to manage the controlled substances program at the agency for the CoSD EMS Medical Director.

C. Master Vault Supply Storage, Security, and Documentation

1. The master vault containing the storage of controlled substances will be at the agency address noted on the DEA license.
 - a. Controlled substances will be ordered by the agency physician registrant and assigned to its ALS Units according to Drug Enforcement regulations.
2. Master vault supply security measures will include:
 - a. Storage under double lock (may include electronic or biometric security):

San Diego County Emergency Medical Services Office
Policy / Procedure / Protocol

- 1) Tamper evident containers to increase security, accountability, and tracking all controlled substances
- 2) Witnessed counting no less than once each month or each time the master vault is accessed
- b. Follow the manufacturer's guidelines regarding storage of each controlled substance
- c. Copy of current DEA registration
3. Master Vault supply documentation will include:
 - a. Copies of DEA Form 222
4. All registered agencies shall maintain the following on-site for DEA:
 - a. An inventory of controlled substances and documentation of each controlled substance administered to a patient is to be maintained for a period of no less than two years. This record 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):
 - i. A physical count of all controlled substances in stock, including those on the vehicles, is to be taken.
 - ii. Enter this count on an inventory record.
 - 2) A biennial inventory is then taken every two years beginning within two years from the initial inventory date.
 - b. All original controlled substance purchase invoices and executed DEA Form 222's must be kept separately from the daily and maintenance logs.
 - c. The following logs must be maintained at the agency for a period of no less than three years:
 - 1) Controlled Drug Usage Record
 - 2) Controlled Drug Inventory Record
 - 3) Records for Schedule II controlled substances (Morphine Sulfate and Fentanyl) must be maintained separately from Schedule IV controlled substances (Midazolam)
 - 4) A log of all controlled substances ordered, received, stored, placed into service, administered, wasted, or restocked
 - 5) Patient care record or other appropriate reports corresponding to each administration, waste, damage, or expiration
 - d. All ALS agencies will 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
 - 3) Monthly counts
 - 4) Each time controlled substances are accessed
 - e. Available for inspection within 24 hours.
 - f. Maintained on-site and/or electronically accessible.

D. Labeling and Tracking

1. Controlled substances must remain in the original manufacturer containers until time of administration.
2. Tracking of controlled substances will include documentation of log(s) as described in this policy.

E. ALS Unit Security, Record Keeping, Documentation

1. ALS Unit Security

- a. Storage under double lock and key, security code, or biometric system.
- 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.

2. Record Keeping

- a. Each ALS Unit shall maintain a standardized written record of controlled substance inventory. Record shall be available to the physician registrant for routine inspection and shall be maintained by the agency for a period of three years in compliance with the State Board of Pharmacy.
- b. Controlled substances will be accessed and administered by agency approved personnel only.
- c. Controlled substances shall be inventoried by the ALS personnel at the beginning and at the conclusion of each shift. Documentation shall include the signatures of the person(s) performing the inventory and noted on the controlled substance inventory.
- d. Any time a controlled substance is administered, the date, the name of the controlled substance, dose administered, route, patient name, name of the licensed person who is administering the controlled substance, the receiving facility, and incident number (if available) shall be documented on the controlled substance inventory.
- e. Any controlled substance that has not been completely used must be disposed of in the presence of two medical personnel.
- f. Agency personnel must document any disposed controlled substance on the appropriate agency form. This form must document:
 - 1) The amount of controlled substance given to the patient
 - 2) The amount of controlled substance disposed
 - 3) The signatures of the two medical personnel who witnessed the disposal

3. Documentation

Each ALS Unit shall maintain a standardized written or printed:

- a. Log of all controlled substances
- b. A Patient Care Report/electronic Patient Care Report (PCR/ePCR) corresponding to each administration
- c. These records will be:

- 1) Maintained with the controlled substances until submitted to and/or electronically accessible from the master supply location
- 2) Available for inspection within 24 hours
- 3) Submitted to master supply at least monthly
 - i. Master supply documentation to be maintained for no less than three years

F. Management of Inventory Discrepancies

1. Any discrepancy between the written ALS Unit controlled substance inventory and the count of on board and/or master vault supply controlled substances shall be noted on the controlled drug inventory sheet and shall be signed by the ALS Team first, noting the discrepancy. That discrepancy shall be verbally reported immediately to the agency person responsible for the controlled substances at the agency.
2. Any discrepancy between the inventory and the actual amount of the controlled substances in the stock supply must be reported immediately to the physician registrant followed by a written report to the CoSD EMS within 24 hours.
3. Any discrepancy between the inventory and the actual amount of the controlled substances in the stock supply must be reported to the DEA immediately using Form DEA-106 "Report of Theft or Loss of Controlled Substances" on the DEA Diversion website (www.deadiversion.usdoj.gov).
4. Each agency will follow its internal policy for reporting discrepancies including tampering, theft, loss, or diversion of controlled substances.
5. Any agency personnel having knowledge of controlled substance diversion must report the situation to the DEA.

G. Controlled Drug Inspection and Usage Audits

1. Periodic announced or unannounced inspections or audits of controlled substances and/or controlled drug inventory shall be conducted no less than once per calendar year by the CoSD EMS Medical Director or designee to document compliance with this policy.
2. Each agency will follow its internal policy for usage audits. Audits will:
 - a. Be conducted by Agency designee
 - b. Account for the current disposition of all controlled substances
 - c. Include review of forms and logs
 - d. Identify and report discrepancies as required
 - e. Be performed at least every six months

VI. TAMPERING, THEFT, DIVERSION PREVENTION, AND DETECTION

- A.** Each agency internal policy regarding controlled substances will include the intent to prevent and detect the tampering, theft, loss, and/or diversion of controlled substances. Areas to be addressed include:
1. Ordering and order tracking
 2. Receipt and accountability
 3. Master supply storage
 4. Security
 5. Documentation
 6. Disposal
 7. Restocking procedures
 8. Controlled substance testing
 9. Discrepancy reporting
 10. Tampering
 11. Theft
 12. Diversion prevention
 13. Detection
 14. Usage audits
- B.** Additionally, reporting the suspected tampering, theft, and/or diversion of controlled substances to local law enforcement is encouraged. If tampering, theft, and/or diversion of controlled substances are substantiated, a written report must be made within 24 hours to CoSD EMS.
- C. Reverse Distribution**
1. Each agency will send expired and/or damaged substances to an authorized reverse distributor. Schedule II controlled substances must be transferred using the DEA Form 222, while Schedule III and IV 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.
 2. Personnel sending controlled substances for reverse distribution must be authorized by the agency roster to manage controlled substances. A witness, who must also be included on the agency roster of personnel authorized to manage controlled substances, must participate in the shipment and its documentation.
 3. All reverse distribution will be documented in logs that include date, time, name of controlled substance, strength, quantity, expiration date, manufacturer, and the signatures of the sending party and the witness.