

SUBJECT: MANAGEMENT OF CONTROLLED SUBSTANCES
FOR ALS AGENCIES

Date: 7/1/2016

I. **Authority:** California State Board of Pharmacy Business and Professions Code, Section 4119 and 4126.5, 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 California Code of 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; 1304.211304.22; 1307.02; 1307.21; 1305.05.

II. **Purpose:** To ensure accountability for all controlled substances and devices issued to advanced life support (ALS) units.

III. **Policy:** All Advanced Life Support (ALS) Agencies in the County of San Diego will have a physician registrant to purchase controlled substances with a Drug Enforcement Administration (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 EMS Medical Director to assist with the purchase of controlled substances (per Policy S-416) 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 Title 21 CFR regulations concerning the procurement, receipt, distribution, and waste management of controlled substances managed under their DEA registration number.

IV. **Definitions:**

A. **Controlled Substances:** Pharmaceutical drugs categorized as Schedule II, III or IV by the DEA.

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1. Approved DEA Schedule II controlled substance for ALS Units include:
Morphine Sulfate
2. Approved DEA Schedule IV controlled substances for ALS Units include:
Midazolam (Versed)

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

V. Security Mechanisms and 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 and time, name of medication, strength, quantity, expiration date, manufacturer, lot number and the receiving party and the witness, including their signatures.

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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 narcotics program at the agency for the Medical Director.

C. Master Vault Supply Storage, Security and Documentation

1. The master vault contains the storage of controlled substances, will be at the agency address noted on the DEA license.
 1. 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
 - (1) Tamper evident containers. To increase security, accountability and track all controlled medications
 - (2) Witnessed counting; no less than once each month or each time master vault is accessed.
 - b. Follow the manufactures' guidelines regarding storage of each controlled substance.
 - c. Copy of current DEA registration
 - d. Master Vault supply documentation will include:

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(1) Copies of DEA Forms 222

3. All registered agencies shall maintain the following on site for DEA an inventory of controlled substances and documentation of each medication administered to a patient is to be maintained for a period of not 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):

a. Initial inventory (documented at the initial registration of the agency)

1) A physical count of all controlled substances in stock, to include those on the vehicles is to be taken.

2) Enter this count on an inventory record.

b. A biennial inventory is then taken each two years beginning within two years of the initial inventory date.

4. All original controlled substance purchase invoices and executed DEA-222 forms must be kept separately from the daily and maintenance logs

5. The following logs must be maintained at the agency for a period of not less than three years.

a. Controlled Drug Usage Record

b. Controlled Drug Inventory Record

c. Records for Schedule II narcotics (Morphine Sulfate) must be maintained separately from Schedule IV drugs (Midazolam).

d. A log (s) of all controlled substances ordered, received, stored, placed into service, administered, wasted or restocked. Patient care record or

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other appropriate report corresponding to each administration, waste, damage, or expiration.

6. All ALS agencies will keep a controlled substance log in a secure location and will document:
 - a. Receipt of the controlled substances.
 - b. Distribution of controlled substances to the units for restock
 - c. Monthly count and each time controlled substances are accessed.
7. Available for inspection within 24 hours
8. Maintained on site and/or electronically accessible

D. Labeling and Tracking

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

E. ALS Unit Security, Record keeping, Storage, and Stocking:

1. 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 of shift, no less than once per calendar day
2. Record keeping
 - a. Each ALS Unit shall maintain a standardized written record of controlled drug

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inventory, Record shall be available to the physician registrant for routine inspection, and shall be maintained by the agency for a period of three (3) years in compliance with the State Board of Pharmacy.

- b. Controlled substances will be accessed and administered by agency approved personnel only.
 - c. Drugs shall be inventoried by the ALS Personnel at the beginning and at the conclusion of each shift, and documentation shall include the signatures of the person(s) performing the inventory and noted on the controlled drug inventory.
 - d. Any time a controlled substance is administered, the date, name of the drug, dose administered, route, patient name, name of the licensed person who is administering the medication, receiving facility and the QCS run number, if available, shall be documented on the controlled drug inventory.
 - e. Any medication that has not been completely used must be disposed of in the presence of two medical personnel.
 - f. Agency personnel must document any disposed narcotic on the appropriate agency form. This form must document:
 - 1) The amount of the medication given to the patient
 - 2) The amount of the medication 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 PCR/ePCR corresponding to each administration

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c. These records will be:

- 1) Maintained with the medications 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
 - a. 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 drug inventory and the count of on board or master vault supply drugs 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 narcotics at the agency.
2. Any discrepancy between the inventory and the actual amounts of the narcotics in the stock supply must be reported immediately to the physician registrant, followed by written report to the EMS Branch within 24 hours.
3. Any discrepancy between the inventory and the actual amounts of the narcotics in the stock supply must be reported to the DEA immediately using Form P-106 "Reporting 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

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5. Any agency personnel having knowledge of drug diversion must report this situation to the DEA.
- G. Controlled Drug Inspection and Usage Audits:
1. Periodic announced or unannounced inspections or audits of controlled drugs and/or controlled drug inventory shall be conducted no less than once per calendar year by the 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 and 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: ordering and order tracking, receipt and accountability; master supply storage, security, and documentation, disposal, restocking procedures, controlled substance testing, discrepancy reporting; tampering, theft and diversion prevention and detection and 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 is substantiated, a written report must be made within 24 hours to San

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Diego County EMS Branch.

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's Form 222, while Schedule III-V controlled substance 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, also included on the agency roster of personnel authorized to manage controlled substance, must participate in the shipment and its documentation.
3. 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 signatures.

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