

TITLE: **CONTROLLED SUBSTANCES**

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## **CONTROLLED SUBSTANCES**

### **I. AUTHORITY**

Division 2.5, California Health and Safety Code, sections 1797.220 and 1798(a) and; Title 22, California Code of Regulations, section 100146, section 100167, section 100168 (b)(1).

### **II. DEFINITIONS**

- A. "Advanced Life Support Provider" means an agency authorized by the Mountain-Valley EMS Agency to provide ALS services
- B. "ALS" means Advanced Life Support as defined in section 1797.52 of Health and Safety Code, Division 2.5.
- C. "Back-up ALS Unit" means a fully stocked, equipped and operational ALS unit intended to be put in service on an as-needed basis that is not currently staffed by a Paramedic, who is responsible for the Controlled Substances on that unit.
- D. "BLS" means Basic Life Support as defined in section 1797.60 of Health and Safety Code, Division 2.5.
- E. "Controlled Substances" means Morphine Sulfate and Midazolam.
- F. "Out-of Service ALS Unit" means any ALS unit that is neither currently operational nor staffed by a Paramedic, who is responsible for the Controlled Substances on that ALS unit.

### **III. PURPOSE**

To provide maximum security for Controlled Substances on ALS units while ensuring that a minimum necessary requirement for Controlled Substances on ALS ambulances are met.

### **IV. POLICY**

- A. All Advanced Life Support personnel and Advanced Life Support Service Providers are responsible for the security of Controlled Substances in accordance with this

policy.

- B. Approved Advanced Life Support Provider management personnel shall be allowed to have Controlled Substance prescriptions filled by a Base Hospital Pharmacy.
- C. Advanced Life Support Service Providers that have Controlled Substances supplied by a Base Hospital shall utilize a single Base Hospital for initial stocking and resupply of Controlled Substances.
- D. Advanced Life Support Providers that are not supplied with Controlled Substances by a Base Hospital shall have a physician in the role of Medical Director. This Medical Director may purchase Controlled Substances with Drug Enforcement Agency Form 222 from a pharmacy or pharmaceutical supply agency and supply these Controlled Substances to the Advanced Life Support Service Provider.

V. PROCEDURE

A Supply

- 1. Each authorized in-service ALS unit shall be stocked with the following Controlled Substances in the amounts listed:
  - a. **Morphine sulfate:**  
  
**Minimum amount on hand: 20 mg**  
**Maximum amount on hand: 60 mg**
  - c. **Midazolam:**  
  
**Minimum amount on hand: 20 mg**  
**Maximum amount on hand: 40 mg**
- 2. ALS Service Providers shall provide written notification to the Agency Medical Director of the number of units to be stocked with Controlled Substances.
- 3. All Controlled Substances shall be supplied in single-unit dose (tamper-evident, when possible) containers, protected from light, and maintained within the manufacturer suggested temperature range whenever possible. Providers shall address the stocking of single-unit dose tamper evident containers in their Provider Controlled Substance Policy.

**B. Storage and Access**

- 1 All Controlled Substances will be secured under double lock (two separate locking mechanisms) at all times except when being administered to a patient.
- 2 Access by personnel scheduled to staff an in-service ALS unit to the keys which allow access to the Controlled Substances shall be limited to the Paramedic responsible for Controlled Substances. These keys should be passed from the off-going Paramedic to the on-coming Paramedic when the Controlled Substance Log entry is completed for that shift change.
  - a. At no time shall Controlled Substance storage box keys be in the possession of off-duty personnel.
  - b. A duplicate set of unmarked keys may be kept by the ALS Service Provider. Duplicate keys must be kept in a locked compartment, on company grounds, with access by no more than three (3) management personnel approved by the EMS Agency Medical Director. A complete list of personnel with access to the duplicate Controlled Substance keys must be submitted to the EMS Agency Medical Director. This list must be updated within three (3) days of having someone removed or added to the list.
  - c. All Controlled Substance keys must be engraved "Do Not Duplicate."
  - d. If any key which allows access to Controlled Substances or to the duplicate set(s) of keys is lost or stolen, an Unusual Occurrence Report shall be filed with the EMS Agency Medical Director or his/her designee within 72 hours of discovery. The EMS Agency Medical Director will evaluate the report and decide the appropriate action necessary to resolve the situation.

**C. Initial ALS Unit Stocking Procedures**

1. Controlled Substances shall be obtained from the Base Hospital or purchased by the ALS Provider physician Medical Director and assigned to its ALS response vehicles according to Drug Enforcement Agency regulations. .
2. The person having the prescription filled and the Paramedic responsible for Controlled Substances must sign the Controlled Substance Log at the time the prescription is placed in an ALS unit.

D. Resupply of Controlled Substances

1. When a Controlled Substance is used in the field, resupply shall be provided on a one-to-one basis by the Pharmacist of the Base Hospital (or designee) or restocked from the supply provided by ALS Provider physician Medical Director.
  - a. Unused drugs must be wasted in the presence of the Emergency Department Registered Nurse and the ALS personnel seeking resupply. The Registered Nurse and the ALS personnel must co-sign to document the wasting of the unused drugs.

E. Exchange of Controlled Substances

1. Controlled Substances, soon to expire Controlled Substances, or damaged Controlled Substance containers must be replaced by the Pharmacist or designee at the Base Hospital or replaced by the ALS Provider physician Medical Director. The broken or out-dated drug must be presented to receive a replacement.
2. If damage to a Controlled Substance container has caused a loss of the substance or the substance is being exchanged due to findings resulting from an examination; an Unusual Occurrence Report shall be filed with the Base Hospital Nurse Liaison or ALS Provider physician Medical Director. The Base Hospital Nurse Liaison or physician Medical Director shall evaluate the Situation Report and forward it with his\her comments to the local EMS Agency.

F. Record Keeping/Shift Change

1. Each ALS unit shall maintain a standardized written record of Controlled Substance inventory (Controlled Substance Log) and kept in the locked storage compartment with the Controlled Substances. That record shall be available to the Base Hospital Pharmacist (or designee) or the ALS Provider physician Medical Director for routine inspection, and shall be maintained by the ALS Provider for a period of three (3) years in compliance with the State Board of Pharmacy.
2. At each crew change, , the off-going Paramedic responsible for Controlled Substances shall count and examine the Controlled Substances and date, time and sign the Controlled Substance Log over to the on-coming Paramedic responsible for Controlled Substances. The on-coming Paramedic will confirm the count and condition and accept responsibility for the Controlled Substances by signing the Controlled Substance Log. Signing the Controlled Substance Log confirms that the count and supply listed is correct and accurate at that time. A copy of the Controlled Substance Logs shall be made

available to the EMS Agency Medical Director or his/her designee immediately, upon request.

**G. Inventory Discrepancies**

1. If at any time the Controlled Substance count is incorrect and the missing substance(s) cannot be accounted for, the Paramedic responsible for Controlled Substances on that unit shall:
  - a. Immediately inform his\her supervisor of the incident.
  - b. Immediately notify the local law enforcement agency.
  - c. File an Unusual Occurrence Report, which shall include the law enforcement case number, with the EMS Agency Medical Director within seventy-two (72) hours of filing law enforcement report
  - d. Notify the Drug Enforcement Administration, United States Department of Justice, utilizing Form 106 referring to theft and loss of a Controlled Substance. A copy of this completed form must be submitted to the EMS Agency Medical Director along with the Unusual Occurrence Report.
  - e. Be prohibited from going off duty until their supervisor and the local law enforcement agency are notified.

**H. Removing an ALS Unit from Service**

1. The security and responsibility for Controlled Substances on out-of-service and back-up ALS units is as follows:
  - a. When an ALS unit is taken out-of-service or is being placed on back-up, the Paramedic responsible for Controlled Substances shall count and examine the Controlled Substances and enter the date and time, and sign the Controlled Substance Log. The Paramedic must also note on the Controlled Substance Log that the ALS unit is out-of-service or on back-up. A second ALS Provider staff person must also verify the count and accuracy of the Controlled Substance Log. This second person must either be another Paramedic, or a member of the ALS Service Provider's staff that has been approved by the EMS Agency Medical Director. This staff person must either be the sole resupply person or an assigned administrative staff person for the ALS Service Provider.
  - b. The Controlled Substances and the Controlled Substance Log shall be kept in the permanent key locked storage compartment, located in the

ALS unit. The outside doors of the ALS unit shall remain locked, while the unit is unattended.

- c. The Controlled Substance keys for that ALS unit shall be kept by the ALS Service Provider staff person as described in H.1. A.

2. Upon request the Agency Medical Director may allow ALS service providers to utilize alternate procedures than are specified in section V, D. Alternate procedures shall be written as company policy and must have the written approval of the Agency Medical Director. The Agency shall have the authority to enforce alternate procedures as Agency Policy.

#### I. Placing an ALS Unit in Service

1. The responsibility of Controlled Substances on out-of-service and back-up ALS units rests solely with the ALS Service Providers. ALS Service Providers are required to have a company policy and procedure that addresses the following:
  - a. The storage of Controlled Substances on out-of-service ALS units leaving company grounds.
  - b. The procedure for turning over Controlled Substance storage compartment and lock box keys to the on-coming crew when the unit has been out-of-service or unstaffed on back-up.
2. If an ALS stocked unit is placed in-service as a BLS unit, the responsibility for the Controlled Substances on that unit remains with the ALS Service Provider. The keys which allow access to the Controlled Substances must remain under the control of the ALS Service management.
3. Current ALS Service Providers must submit their company's Controlled Substance Policy and Procedure to the EMS Agency Medical Director for review and approval, within sixty (60) days of the effective date of this policy. New ALS service providers must submit the above policy for review and approval prior to the providing of service. EMS Agency staff shall be available to assist ALS providers in establishing company policies that will meet Medical Director approval.