

APPROVED: SIGNATURE ON FILE IN EMS OFFICE
Executive Director

EFFECTIVE DATE: 4/15/2016
SUPERCEDES: _____

SIGNATURE ON FILE IN EMS OFFICE
Medical Director

REVIEW DATE: 4/2021
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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, Fentanyl and Midazolam.
- F. “In-Service ALS Unit” means any ALS unit that is currently operational and staffed by a Paramedic, who is responsible for the Controlled Substances on that ALS unit.
- G. "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. Advanced Life Support Providers 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**

AND/OR

- b. **Fentanyl:**

- Minimum amount on hand: 200mcg**

- Maximum amount on hand: 400mcg**

- 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 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 to keys allowing access to Controlled Substances shall be limited to the Paramedic assigned to an in-service ALS unit. 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 Agency. A complete list of personnel with access to the duplicate Controlled Substance keys must be submitted to the Agency. 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 (UOR) shall be filed with the Agency or his/her designee within 24 hours of discovery. The Agency 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 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 from the supply provided by the 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 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; a UOR shall be filed with the Agency within twenty-four (24) hours of findings. The

Agency will investigate the UOR and report their findings to the ALS provider management and Medical Director.

F. Record Keeping/Shift Change

1. Each ALS unit will maintain a standardized written record of Controlled Substance inventory (Controlled Substance Log) and keep it in the locked storage compartment with the Controlled Substances. The Controlled Substance Log shall be available to the Agency and 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 Substance(s) 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 Agency 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 Agency Duty Officer.
 - c. File an Unusual Occurrence Report with the Agency within twenty-four (24) hours of findings.
 - d. Be prohibited from going off duty until their supervisor and the Agency Duty Officer 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, 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 Agency. 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 may allow ALS service providers to utilize alternate procedures than are specified in Section V, Letter D. Alternate procedures shall be written as company policy and must have the written approval of the Agency. 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 Agency 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. Agency staff shall be available to assist ALS providers in establishing company policies that will meet Agency approval.