

POLICY #211: MANAGEMENT OF CONTROLLED SUBSTANCE

I. PURPOSE

- A. To ensure the security and accountability of, and establish standards and responsibilities for all controlled substances issued to and maintained by authorized Advanced Life Support (ALS) providers in the County of San Luis Obispo (SLO).

II. SCOPE

- A. This policy applies to all ALS providers, authorized by the County of SLO Emergency Medical Services (EMS) Agency and the County of SLO accredited Paramedics.

III. DEFINITIONS

- Controlled substance: Any substance listed as a Schedule I through IV drug in the Controlled Substance Act [i.e. Morphine Sulfate, or Midazolam].
- DEA: United States Department of Justice Drug Enforcement Administration
- DEA designee: That person who has been authorized by the EMS Agency Medical Director or other physician to procure controlled substances for the inventory of an ALS provider, and who is responsible to maintain the security measures and records required by federal and state law, and EMS Agency policy.
- Diversion: Loss of a controlled substance for any reason other than the intended use for the care of a specific patient, including theft, substitution, misappropriation for self-use or illegal sale, or violation in chain of responsibility resulting in inability to account for controlled substance.
- Field unit: An ambulance, fire apparatus, or other first response vehicle, excluding supervisory vehicles, that responds to medical emergencies as part of the County of SLO 911 system.

IV. POLICY

- A. All ALS providers must have a policy and procedure for obtaining; storing, disposing of, and tracking controlled substances that meets the requirements of all federal, state, and local laws and regulations.
- B. The EMS Agency Medical Director must approve the controlled substance policies and procedures for each ALS provider. Upon approval, authorization for the procurement of and the use of controlled substances by that provider, pursuant to all EMS Agency policies and medical protocols, may be given.
- C. Continued authorization as an ALS provider under Title 22 is contingent on the provider's continued adherence to established medical control, including this policy.

- D. A current copy of all ALS providers' controlled substance policies, procedures and required records, must be available to federal, state, and local authorities, including the EMS Agency, for inspection and audit of compliance.
- E. Only on-duty Paramedics will have access to controlled substances at any time.
- F. A Paramedic who is in possession of controlled substances is directly and individually responsible to ensure the security of those substances. Possession includes the physical possession of the substances, as well as the presence of the substances on any vehicle or stored in equipment to which that person is assigned.
- G. Responsibility for the security of the controlled substances is relinquished only when the controlled substances are transferred to another on-duty Paramedic (i.e. at change of shift, or when relieved from duty) or secured in the main inventory location.
- H. The main inventory must be secured in a safe or similar device and double-locked.
- I. The inventory in field units and supervisory vehicles must be stored in a metal (or other durable material) container, that locks and this container must be stored in a locked compartment in the unit. Optionally, there may be a locked durable container, accessed only with a key that secured in a separate locked device, thereby complying with the required "double-locked" security. The exterior passenger doors of any vehicle, containing controlled substances, are not considered part of this "double-locked" security.
- J. The keys (or security codes) to access the controlled substances must at all times be in control of the Paramedic assigned to that field unit, or a Paramedic or DEA designee responsible for storage or distribution of the main inventory. No other persons will have access to the controlled substance keys (or access codes), or to the controlled substances, at any time.
- K. Controlled substances must be ordered in sealed ampules or vials and stored in a manner to prevent breakage.
- L. A Paramedic will administer a controlled substance only when on-duty; following ALS protocol or ordered by a Base Hospital physician.
- M. ALS providers and/or their medical director's designee will conduct periodic audits of controlled substance procedures, records and quantities.
- N. Audit reports must be submitted to the EMS Agency quarterly, or as requested by the EMS Agency Medical Director and on the EMS Agency approved form.
- O. The EMS Agency Medical Director or the medical director's designee may conduct unannounced audits of controlled substance procedures, records and quantities.
- P. ALS Providers must have a process for staff to document, investigate and report any discrepancy involving a controlled substance. Should a discrepancy occur it must be classified as either a minor discrepancy or serious discrepancy, defined as follows:

1. Minor Discrepancy defined as incomplete or omitted documentation on a Patient Care Report, other documentation utilized by an approved ALS provider agency in the management of a controlled substances program, or a witnessed accidental breakage of a vial containing a controlled substance.
2. Serious Discrepancy is defined as an accidental loss of a controlled substance, an error in the administration of a controlled substance, theft, or tampering (open packaging, broken seals, broken locks), or missing documentation. In addition to internal notification, the EMS Agency Medical Director or designee must be notified immediately.

V. PROCEDURE

A. An ALS provider controlled substance policy and procedure must:

1. Identify the method of procurement that includes documentation of all requisitions or orders, the supplier, the amount received, and the date.
2. The signatures of two individuals attesting to the correct quantities of controlled substances received into inventory
3. State the place and manner of storing and securing the ALS provider's complete inventory of controlled substances, including:
 - a. The process for internal control tagging and numbering of controlled substance inventory (it is recommended to use a unique numbering series for each type of controlled substance).
 - b. Identify (by title) the person(s) responsible for the inventory of controlled substances on an ongoing basis.
4. Establish procedures for tracking each individual milligram of a controlled substance from placement in the main inventory through administration to waste or destruction.
5. State that the amount of controlled substances stocked on field units, which must conform to the amounts specified in EMS Agency Policy# 205: Advanced Life Support Ambulance, ALS and BLS First Responder, and ALS Special Use Medic Equipment and Supply. Modifications to these quantities require special permission from the EMS Agency Medical Director.
6. Establish procedures for distributing and tracking controlled substances issued to field units, which includes at a minimum:
 - a. The signatures of two individuals attesting to the correct quantities of controlled substances dispersed and upon transfer of responsibility.
 - b. Identify (by title) those responsible for monitoring the security of controlled substances distributed.
 - c. Procedures for maintaining continuous paramedic responsibility for controlled substances while in field units.
 - d. A continuous record of the quantity of all controlled substances maintained, by milligram.

- e. Maintain a continuous record of the chain of responsibility for all controlled substances, which includes, the quantity of controlled substances, date, tracking numbers, and paramedic name.
 - f. Maintain a record of administration and/or waste of each milligram of a controlled substance. This record must include the EMS run number, date and approximate time of administration, HIPAA compliant patient identification, identity of person administering the drug, and the identity of the person witnessing waste.
7. Establish a procedure for maintaining the controlled substances within the manufacturers' recommended temperature ranges.
 8. Develop a flow diagram that clearly identifies each element of the provider's management of controlled substance inventory process, from purchase to administration, waste or disposal.
 9. Establish a procedure for investigating discrepancies.
 10. Provide disciplinary sanctions for failure to comply with the policy.
- B. Authorization for the procurement of controlled substances for each ALS provider may be done in one of two ways:
1. The EMS Agency Medical Director may authorize the procurement of controlled substances directly or through granting power of attorney to a DEA designee. Any change in DEA designee personnel will require a completed "Power of Attorney to Sign an Official Order Form," and an audit of the ALS provider's controlled substances program by EMS Agency staff.
 2. An ALS provider may retain a medical director who may separately authorize procurement for that provider. The ALS provider's medical director will assume all liability related to compliance with all EMS Agency policies, and applicable federal, state, and local laws and regulations.

VI. AUTHORITY

- United States Code, Title 21, Controlled Substance Act
- California Health and Safety Code, Division 10, Uniform Controlled Substances Act
- California Health and Safety Code, Division 2.5, Sections 1797.204, 1797.220, and 1798
- California Code of Regulations, Title 22, Sections 100168, 100173, 100174, and 100175

VII. ATTACHMENTS

- A. Power of Attorney to Sign an Official Order Form
- B. Quarterly Report Form