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. Identity (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 From

B. Quarterly Report Form

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute Official Order Forms by granting a power of attorney to each such individual. The same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute Official Order Forms must sign the power of attorney. The person who signed the power of attorney may revoke the power of attorney at any time. It is necessary to grant a new power of attorney when the pharmacy completes a renewal registration, only if a different person signs the renewal application. The power of attorney should be filed with executed Official Order Forms as a readily retrievable record. The power of attorney is not submitted to DEA.

POWER OF ATTORNEY FOR DEA ORDER FORMS

_____ (Name of registrant)

_____ (Address of registrant)

_____ (DEA registration number)

I, William D. Mulkerin, M.D., FACEP, the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these present, do make, constitute, and appoint

_____ (name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for Schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (**21 U.S.C. 828**) and **part 1305** of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____
Signature of William D. Mulkerin, M.D., FACEP

I, _____ (name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that I agree to comply with the Controlled Substance Policy. The signature affixed hereto is my signature.

_____
Signature of attorney-in-fact

Witnesses:

1. _____ _____
Signature Printed Name

2. _____ _____
Signature Printed Name

Signed and dated on the _____ day of _____in the year_____ at _____.

NOTICE OF REVOCATION OF POWER OF ATTORNEY

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act or the Controlled Substances Import and Export Act. Written notice of this revocation has been given to the attorney-in-fact

_____ this same day.

_____
Signature of William D. Mulkerin, M.D., FACEP

I _____ am no longer involved and no longer have access to the controlled substances.

_____
Signature

Witnesses:

1. _____ _____
Signature Printed Name

2. _____ _____
Signature Printed Name

Signed and dated on the _____ day of _____, in the year_____ at _____

San Luis Obispo County Emergency Medical Services Agency
Quarterly Narcotic Report Form

NARCOTIC	♦ BEGINNING INVENTORY	ORDERED	USED	WASTED	DISPOSE	R-222	TOTAL	BACK STOCK	FRONT LINE	♦ ENDING INVENTORY
Fentanyl										
Midazolam (Versed)										
Ketamine										

AGENCY:	Quarter:	BEGINNING DATE:	ENDING DATE:

REPORTING PERSON:	DATE:

As a checks and balance - Total and Ending Inventory should be the same

Please remember to record inventory in milligrams not vials.

** Diazepam and Morphine ordering and use by order of EMS Agency Medical Director only.**

♦ Beginning and Ending inventory includes the following: Response Units, Supply and Supervisor Vehicle Inventory.

Revised 11/8/24