

EL DORADO COUNTY EMS AGENCY

FIELD POLICIES

Effective: July 1, 2011

Reviewed: July 12, 2012

Revised: July 1, 2018

Scope: ALS Personnel



EMS Agency Medical Director

CONTROLLED SUBSTANCES

PURPOSE:

This policy outlines the process used by ALS contractors to: obtain an initial stock, maintain the current stock, provide security for, and document controlled substances (Fentanyl/Morphine Sulfate/Versed).

AUTHORITY:

Code of Federal Regulations, Title 21,
California Health & Safety Code, Division 10
California Health & Safety Code, Division 2.5
California Code of Regulations, Title 22, Division 9, Chapters 3 & 4

POLICY:

1) Restock

- A. New medication supply will be signed into stock by 2 paramedics or 1 paramedic and 1 company officer. In the circumstance when afore mentioned staff are not available, an EMT partner may sign.
- B. Once controlled substances are obtained and prior to dispersion to field units a tamper proof holographic seal with an individual serial number shall be placed over the metal end (the end without a factory applied paper seal) of the individual pre-loaded controlled substance tamper proof container.

The responsibility to place and track the holographic seals rests with each ALS contractor. Holographic seals can be obtained from the JPA. (Item D)

- C. Holographic seals must also be placed on each individual vial of Versed for tracking purposes. Place the holographic seal so that it completely affixes the plastic tab to the vial on two (2) sides, but doesn't cover the expiration date or the lot number. (Move to item C.) (Do we need holographic seal on vials if not remove this bullet point)

2) Tracking

- A. Each individual preload, vial, and cylinder must be tracked on the controlled substance tracking/usage log. The tracking/usage log shall be initially completed on the first day of the month and must contain the following information:
 - I. (Apparatus)Unit number
 - II. Month/Year
 - III. Date (medication) received from the pharmacy **(this date needs to be carried forward each month)**
 - IV. Medication type: M = Morphine, V = Versed, N = Nitroxon , F = Fentanyl
 - V. Serial numbers (stamped on the cylinders)
 - VI. Lot numbers
 - VII. Holographic serial numbers
 - VIII. Expiration dates
 - IX. Date used (if applicable)

CONTROLLED SUBSTANCES

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- X. Incident number (if applicable)
- XI. Amount used (For Nitronox refer to Nitronox Section below*)
- XII. Amount wasted (if applicable)
- XIII. Paramedic name/signature
- XIV. Witness name/signature

The controlled substance tracking/usage log shall be updated any time a controlled substance is used or wasted. If a medication is restocked at any point during the month it must be added to the controlled substance tracking/usage log. This log does NOT need to be updated daily, only when there are changes to the inventory. Names and signatures are only required when a medication has been used or removed from service.

* Nitronox information:

The tracking/usage log shall be updated anytime nitronox is used.) A note of how many minutes used shall be documented in the amount used column. Names and signatures are required when nitronox is administered. Nitronox cylinders should be used until they are completely empty before restocking. If in doubt about whether a cylinder is empty, simply open the valve and allow a small amount of product to escape.

Note: If during administration to a patient it becomes apparent that the Nitronox is not working, check the cylinder (using the above method) to make certain it is not empty.

- B. Every shift/Work cycle inspection of the controlled substances shall include:
 - I. Security tag and container intact without evidence of tampering
 - II. Contents intact and no visible leaks (must be using clear case)
 - III. Presence of correct quantity of medications and verification that there is an appropriate amount of fluid
 - IV. Completion of the Controlled Substance Daily Log, which includes:
 - a. Date
 - b. Time
 - c. Paramedic's legible signature
 - d. Witnesses' legible signature, either paramedic or company officer. In circumstances when afore mentioned staff are not available an EMT signature may be used.
 - e. Morphine**
 - f. Versed**
 - g. Nitronox**
 - h. Fentanyl**
 - i. Security tag number – This is the tag that secures the controlled substances in the tamper proof container
 - j. Comments – If you have any brief comments such as "restocked" or "tag damaged" you would enter those in this section. Comments may be continued at the bottom of the page or, on the back side of the daily log if you run out of space

** "Start" – How much medication or how many cylinders of Nitronox (full or partially full) were on the unit at the start of shift
"Used" – If any medication was used, how much? For Nitronox how many minutes was it used?
"End" – How much medication or cylinders of Nitronox (full or partial) remain (if restocked this number may be higher).

CONTROLLED SUBSTANCES

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Medications:

- A. Controlled substances shall be kept in a tamper resistant box or bag that must be securely closed shut with a numbered security tag or approved locking mechanism. The numbered security tag or approved locking mechanism must be secured in such a manner that no medications may be removed from the LOCKED BOX or bag without removing the numbered security tag. For zippered pouches fasten the numbered security tag or approved locking mechanism around the base of the zippers vs. the zipper handles.
- B. The numbered security tag or approved locking mechanism must be replaced when damaged, broken, or removed. Document such a change in the comments section of the daily log; if additional space is needed write on the back of the daily log.
- C. The sealed container must be then kept in a secondary secure locked box, cabinet, or container.
- D. Controlled substances must be stored in an environmentally controlled environment.

Nitroxon:

- A. It is permissible to keep a single cylinder of Nitroxon in the rapid deployment bag to expedite its use.
- B. All additional cylinders of Nitroxon must be kept in a locked cabinet or box.

4) Verification/Documentation Procedures

A. Monthly or Opened Security Tag Verification:

- I. At the beginning of each month, or any time the numbered security tag or approved locking mechanism is removed, the medications must be thoroughly inspected. This thorough monthly inspection shall include:
 - a. Check for visible damage/tampering of tamper proof seals or containers
 - b. Make sure there is appropriate amount of liquid inside the medication containers
 - c. Check expiration dates
 - d. Confirm correct medication, concentration, and dose
 - e. Replacing the numbered security tag or approved locking mechanism with a new one. Documentation of this new security tag will be verified on the daily log at the beginning of the next shift.

5) General Information

- A. The controlled substance inventories shall be verified by two paramedics (or 1 paramedic and 1 EMT or supervisor if a second paramedic is not available).
- B. Once the numbered security tag or approved locking mechanism is in place it does not need to be removed until the medications are needed for patient treatment or the next monthly inspection, whichever comes first. (when using a clear box or zippered bag) If using a lock box, or pouch that does not allow for visual inspection, then the container must be opened and contents inspected as stated in item B. For situations where there is some controlled medication left over after administration to a patient or when a medication expires*, the medication must be wasted in front of a witness. This witness should be another healthcare provider (i.e., a registered nurse, physician, or another paramedic) whenever possible. WASTING EXCEPTION: a single cylinder of Nitroxon may be used for more than one patient. A minimum of at least one (1) completely full cylinder of Nitroxon shall be maintained at all times on transporting medic units.

***CSA 3 personnel to follow hospital pharmacy policy on expiring medications.**

6) Administration

- A. In order to be eligible to carry controlled substances, applicants shall first submit verification of the following items to the El Dorado County EMS Agency Medical Director for initial approval:
 - I. An internal process to:
 - a) obtain an initial stock of controlled substances for each ALS unit in service;
 - b) provide adequate security for all controlled substances (meeting the above listed requirements);
 - c) restock controlled substances following administration to a patient during prehospital care;
 - d) restock controlled substances following loss or breakage of a controlled substance container;
 - e) maintain records of controlled substances (records must be retained by the contractor for a period of not less than three (3) years)
 - II. An orientation program to be used for new employees and on-going training as per the County's paramedic accreditation packet.
 - III. An internal program to monitor the administration, security, and restock of controlled substances.
- B. Any unresolved discrepancy in a unit's controlled substance log or inventory shall be documented in an incident report and forwarded to the EMS Agency and the appropriate JPA Executive Director within twenty-four (24) hours. Immediately notify your supervisor if there is a discrepancy. Any suspected theft or loss of any controlled substance must also be reported on a DEA form 106.
- C. Each ALS contractor shall show documentation of an agreement with a California licensed physician to provide necessary prescribing and oversight as required by the United States Drug Enforcement Administration.