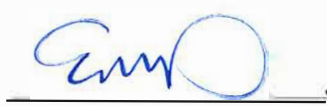



Tuolumne County Emergency Medical Services Agency
EMS System Policies and Procedures

Policy: Controlled Substances

#439.00

Medical Director:		Creation Date:	6-24-99
EMS Coordinator:		Revision Date:	02-27-2013, 05-26-2021
		Review Date:	05-2026

I. AUTHORITY

Division 2.5, California Health and Safety Code, Sections 1797.220, 1798 and; Title 22, California Code of Regulations, Chapter 4, Section 100168 (b)(3).

II. PURPOSE

The purpose of this policy is to establish the procedures which govern the supply, re-supply, storage, reverse distribution, diversion prevention and loss of controlled substances by Advanced Life Support (ALS) providers.

III. POLICY

- A. All ALS personnel and ALS service providers are responsible for the security of controlled substances in accordance with this policy and applicable state and federal statutes and regulations.
- B. When in-service each authorized Tuolumne County ALS ambulance shall be stocked with one set of controlled substances consisting of:
 - 1. Morphine sulfate 60mg
 - 2. Midazolam 30 mg
 - 3. Fentanyl Citrate.....600 mcg
- C. Controlled substances shall be supplied in tamper evident vials or ampules.
- D. The EMS Medical Director shall approve the ordering of all controlled substances and issue a DEA Form 222 and/or prescription as needed.
- E. All controlled substances shall be delivered to the EMS Medical Director or designee for inspection and inventory prior to distribution to ALS providers.
- F. All controlled substances shall be tracked, on Tuolumne County EMS Agency Form 439.01, from issuance of DEA Form 222 and/or prescription to distribution to ALS providers by the EMS Medical Director or designee.

- G. Supplies of controlled substances for the purpose of re-supplying shall be maintained at a location approved by the Tuolumne County EMS Agency
- H. No extra supply of controlled substances shall be maintained in any ALS unit, company building, except as authorized by III (G), or by any EMS personnel.
- I. All controlled substances shall be kept in a key locked storage box. Each type of controlled substance shall be stored separately in its own clearly marked container within the locked storage box. The keyed storage box shall be kept in a permanent key locked storage compartment within the ALS unit.
- J. Keys which allow access to the controlled substances shall be kept by 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.
 - 1. At no time shall controlled substance storage box keys be in the possession of off-duty personnel.
 - 2. A duplicate set of unmarked keys may be kept by ALS Service Providers. Duplicate keys shall be kept in a locked compartment, on company grounds, with access by no more than four (4) management personnel approved by the EMS agency Medical Director.
 - 3. If any key which allows access to controlled substances or to the duplicate set(s) of keys is lost or stolen, a Situation Report shall be filed with the EMS agency within twenty-four (24) hours.
- K. A Controlled Substance Log (EMS Form 439.05) shall be kept for each set of controlled substances and shall be located in the locked storage compartment with the controlled substances. 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.

IV. PARTIALLY USED OR DAMAGED CONTAINERS

- A. Any unused portion of the controlled substance must be disposed at the approved reverse distribution site and must be documented on the patient's PCR and the Tuolumne County EMS Agency Controlled Substances Reverse Distribution Form (Form 439.02):
 - 1. If the receiving hospital is an approved reverse distribution site, the excess controlled substances shall be disposed of in accordance with the policy of

the site. The Form 439.02 shall be signed by the Paramedic disposing of the controlled substance and witnessed by a physician, RN, pharmacist or physicians assistant.

2. If the receiving hospital is not an approved reverse distribution site, the excess controlled substances shall be taken to Adventist Health Sonora (AHS) for disposal in accordance with hospital policy. The Form 439.02 shall be signed by the Paramedic disposing of the controlled substance and witnessed by a physician, RN, pharmacist or physicians assistant.

- B. If damage to a controlled substance container has caused a loss of the substance or has possibly compromised the safety or sterility, the controlled substance shall be replaced immediately. The damaged container and a completed Form 439.02 must be placed in a tamper evident container (e.g. a self-sealing plastic bag or other engineered device) and placed into a locked metal container within the secure location designated in Section III (G) of this policy. The Form 439.02 shall be signed by the Paramedic disposing of the damaged container and witnessed by a Paramedic or EMT. The Paramedic replacing the damaged container shall immediately report the damaged container to their supervisor. An Unusual Occurrence Report shall be filed with the Tuolumne County EMS Agency. The damaged container placed in a locked metal container within the secure location designated in Section III (G) of this policy shall be disposed of at an approved reverse distribution site within an appropriate time period.

V. MISSING OR TAMPERED CONTROLLED SUBSTANCES

- A. If at any time the controlled substances appear to have been tampered with or if the count is incorrect and the missing substance(s) cannot be accounted for, Paramedics responsible for controlled substances on that unit shall:
 1. Immediately inform their supervisor of the incident.
 2. The supervisor shall immediately notify the EMS Medical Director or designee
 3. The supervisor shall notify the local law enforcement agency, if appropriate.
 4. An Unusual Occurrence Report, shall be filed with the EMS Agency within twenty-four (24) hours, including the law enforcement case number, if applicable,
 5. The EMS Agency Medical Director will determine if the Drug Enforcement Administration, United States Department of Justice, is to be notified, utilizing Form 106 referring to theft and loss of a controlled substance.

- C. With reasonable suspicion, the relevant employer or EMS Medical Director may require the involved EMS personnel to submit to biological fluid testing for alcohol and/or drug screening at a facility approved by the relevant employer and the EMS Medical Director.
1. Refusal or failure to comply with the required biological fluid testing may result in the immediate suspension of the Accreditation and/or Certification, pending disciplinary hearing(s).
 2. Any involved EMS personnel, whose biological fluid testing confirms the presence of an unprescribed controlled substance may immediately have their Accreditation and/or Certification suspended, pending disciplinary hearing(s)
- D. If an EMT is not employed by an ambulance service licensed by the Department of the California Highway Patrol or a public safety agency or if the ambulance service or public safety agency that employs the EMT chooses not to conduct an investigation, then the medical director of the local EMS agency shall conduct the investigations, and, upon a determination of disciplinary cause, take disciplinary action as necessary against the EMT.
- E. Pursuant to Division 2.5, California Health and Safety Code Section 1798.202, with reasonable suspicion the EMS Medical Director, after consultation with the relevant employer, may temporarily suspend the Accreditation of a Paramedic prior to hearing.
- F. EMS personnel involved in an investigation are prohibited from going off duty until they are released from duty as approved by the EMS Medical Director or designee.
- G. With reasonable suspicion that a vial or ampule has been tampered with or the contents diverted, testing of unused, partially used and empty vials or ampules to detect diversion of or tampering with the contents will be conducted.
- H. Tampering or diversion drills will be conducted to assure that tampering or diversions will be discovered and managed efficiently. Tampering or diversion drills will be a controlled exercise and will not include the use of any controlled substances. This drill will not be punitive in nature. The purpose of the drill will be to identify potential issues that could hamper an investigation.

VI. RESUPPLY

- A. All controlled substances will be stored in a computerized safe that has the capability to track access to the controlled substances using individually assigned personal identification numbers (PIN). The safe is to be located in a secure room at the headquarters of Tuolumne County Ambulance Service.

- B. Each Paramedic employed by Tuolumne County Ambulance Service shall be issued a PIN. The Paramedic shall take every reasonable precaution to maintain the security of their PIN. If a Paramedic believes that the security of their assigned PIN has been compromised they are to immediately contact their supervisor.
- C. The re-supply of controlled substances shall be conducted at the approved storage location, from the Tuolumne County EMS controlled substance supply.
- D. Tuolumne County Ambulances are authorized to re-supply controlled substances from the Tuolumne County EMS controlled substance supply.
- E. The substance and/or substance container shall be returned to the approved storage location at the time of exchange.

VII. STORAGE OF CONTROLLED SUBSTANCE ON OUT-OF-SERVICE ALS AMBULANCE

- A. When an ALS ambulance 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. The second member of the ALS unit or one of the management personnel approved by the Medical Director must also sign the Controlled Substance Log, confirming the condition and the count.
- B. The controlled substances and the Controlled Substance Log shall be kept in the permanent key locked storage compartment, located in the ALS unit or in a locked medications locker.
- C. Controlled substances on out-of-service or back-up units shall be checked at least weekly by the ALS provider with the condition and the count noted on the Controlled Substance Log.

VIII. CONTROLLED SUBSTANCES AUDITS

- A. ALS Provider management personnel approved by the EMS Agency Medical Director shall, by the 7th day of the month, audit controlled substance usage and inventory for the preceding month.
- B. The audit shall reconcile controlled substance usage, waste and inventory by reconciling the following documents:
 - 1. Controlled substances safe access logs
 - 2. Patient Care Reports

3. Tuolumne County EMS Agency Controlled Substances Reverse Distribution Form (Form 439.02)
 4. Controlled Substance Log (Form 439.05)
- C. Any unresolved discrepancies shall be immediately reported to the EMS Agency.
 - D. The ALS Provider shall provide a usage, waste and inventory report to the EMS Agency for reconciliation with the Tuolumne County EMS Agency Form 439.01.
 - E. An EMS Agency representative shall inspect the ALS provider's controlled substances records at least two (2) times per year.