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| Operational Policy | | 3302 |
| Effective April 1, 2018 | | Expires March 31, 2019 |
| Policy: Controlled Substances | Approval: Medical Director Reza Vaezazizi, MD | Signed |
| Applies To: DEA Registrant, EMS System | Approval: REMSA Director Bruce Barton | Signed |

PURPOSE

The purpose of this policy is to establish minimum requirements for compliance with the Controlled Substances Act and Title 22 by County of Riverside EMS Agency (REMSA) authorized or permitted first response agencies and/or transport services.

AUTHORITY

[California Health and Safety Code - Division 2.5: Emergency Medical Services \[1797. - 1799.207.\]](#)
[California Code of Regulations, Title 22. Social Security, Division 9. Prehospital Emergency Medical Services](#)

Controlled Substances

Approved Drug Enforcement Administration (DEA) Schedule II controlled substances for paramedic staffed first response agencies and/or transport services include:

1. Fentanyl (Sublimaze)
2. Morphine Sulfate

Approved Drug Enforcement Administration (DEA) Schedule III controlled substances for paramedic staffed first response agencies and/or transport services include:

1. Approved Trial Study medication – Ketamine (Ketalar)

Approved DEA Schedule IV controlled substances for paramedic staffed first response agencies and/or transport services include:

1. Diazepam (Valium)
2. Lorazepam (Ativan)
3. Midazolam (Versed)

All paramedic staffed first response agencies and/or transport services will have a formal agreement with a DEA registrant who is accountable for the agency or service’s compliance with the Controlled Substances Act. The DEA registrant will maintain a separate DEA registration number for each agency or service that they affiliate with; separate from the DEA registrant’s own practice, and separate from any other legal entity. The DEA registrant will establish policies and procedures, compliant with this policy, for each agency or service they serve.

Security Mechanisms and Procedures

Ordering and Order Tracking

Each agency or service will order controlled substances from an authorized drug wholesaler or pharmacy. Schedule II controlled substances require use of the DEA Form 222 or the Controlled Substance Ordering System (CSOS). These orders will be delivered to the agency or service’s facility found at the single physical location and address noted on the DEA license. Each order must be tracked in a manner that documents the parties requesting, ordering, and receiving controlled substances.

Receipt and Accountability

Controlled substances must be received at the agency or service’s facility found at the single physical location and address noted on the DEA license. Personnel receiving controlled substances must be authorized by the DEA registrant and included on the agency or service’s roster of personnel authorized to manage controlled substances. A witness, also

included on the roster of personnel authorized to manage controlled substances, must participate in the receipt and its documentation.

The receipt of controlled substances will be documented in the master supply log(s) including: the date and time, the name of the medication, the strength, the quantity, the expiration date, the manufacturer, the lot number, and the receiving party and the witness, including their signatures.

Master Supply Storage, Security and Documentation

The master supply storage of controlled substances will be at the agency or service's facility found at the single physical location and address noted on the DEA license.

Follow the manufacturer's guidelines regarding storage of each controlled substance:

1. Store within the required temperature range
 - a. Lorazepam must be classified as "damaged" after 90 days of non-temperature controlled storage
2. Protect from light as required

Master supply security measures will include:

1. Tamper evident containers
2. Storage under double lock
3. Witnessed counting; no less than once each month

Personnel handling and/or counting controlled substances at the master supply must be authorized by the DEA registrant and included on the agency or service's roster of personnel authorized to manage controlled substances. A witness, included on the roster of personnel authorized to count controlled substances, must also participate in each count and its documentation.

Master supply documentation will include:

1. The agency or service's roster(s) naming personnel authorized to:
 - a. Manage controlled substances
 - b. Count controlled substances
 - c. Administer controlled substances
 - d. Audit controlled substances
2. Copies of each DEA Form 222, including voided forms; purchase records; a log(s) of all controlled substances ordered, received, stored, damaged during storage, placed into service, damaged while in service, administered, wasted, restocked, returned to master supply, reverse distributed, and/or transferred or exchanged between agencies and/or services; and a patient care record / electronic patient care record (PCR/ePCR) or other appropriate report corresponding to each administration, waste, damage, or expiration
3. These records will be:
 - a. Maintained at and/or electronically accessible from the master supply location
 - b. Available for inspection within 24 hours
 - c. For a period of no less than three years

Controlled Substance Labeling and Tracking

Controlled substances must remain in the original manufacturer's containers, Food and Drug Administration (FDA) compliant labels remaining intact and unaltered, until the time of administration.

Tracking of Controlled substances will include documentation in the log(s) as described throughout this policy; including: the date and time of each transaction, the name of the medication, the strength, the quantity, the expiration date, the manufacturer, the lot number, and the party(ies) involved, including signature(s). Additional methods of tracking are encouraged.

Vehicle Storage and Security

Make every reasonable attempt to follow the manufacturer's guidelines regarding vehicle storage of each controlled substance while in service:

1. Avoid exposure to temperature extremes

- a. Lorazepam must be classified as “damaged” after 90 days of non-temperature controlled storage
2. Protect from light as required

Vehicle storage security measures will include:

1. Tamper evident containers
2. Storage under double lock
3. Witnessed counting with each change in personnel or change of shift; no less than once each day

Personnel handling and/or counting controlled substances while in service must be authorized by the DEA registrant and included on the agency or service’s roster of personnel authorized to administer controlled substances. A witness, preferably included on that same roster, but, at minimum, included on the roster of personnel authorized to count controlled substances, must also participate in each transaction and its documentation.

Documentation while in service will include:

1. A log(s) of all controlled substances accepted into service, counted, damaged while in service, received as re-stock, and/or returned to master supply
2. These records will be:
 - a. Maintained with the medications until submitted to and/or electronically accessible from the master supply location
 - b. Available for inspection within 24 hours
 - c. Submitted to master supply at least monthly
 - i. Maintained as master supply documentation for a period of no less than three years

Usage Procedures and Documentation

Controlled substances will be administered by paramedics only as authorized in the REMSA Policy Manual currently in effect at the time of the use. Personnel administering controlled substances must be authorized by the DEA registrant and included on the agency or service’s roster of personnel so authorized.

Usage documentation will include:

1. A log(s) of all controlled substances administered
2. A PCR/ePCR corresponding to each administration
3. These records will be:
 - a. Maintained with the medications until submitted to and/or electronically accessible from the master supply location
 - b. Available for inspection within 24 hours
 - c. Submitted to master supply at least monthly
 - i. Maintained as master supply documentation for a period of no less than three years

Reverse Distribution

Each agency or service will send expired and/or damaged controlled substances to an authorized reverse distributor. Schedule II controlled substances must be transferred using the DEA’s Form 222 or the Controlled Substance Ordering System (CSOS), while Schedule III – V controlled substances may be transferred by invoice. These reverse distributions will be sent to the reverse distributor’s facility found at the single physical location and address noted on the reverse distributor’s DEA license. Each reverse distribution must be tracked in a manner that documents the parties sending and receiving the expired and/or damaged controlled substances.

Personnel sending controlled substances for reverse distribution must be authorized by the DEA registrant and included on the agency or service’s roster of personnel authorized to manage controlled substances. A witness, also included on the roster of personnel authorized to manage controlled substances, must participate in the shipment and its documentation.

All reverse distribution will be documented in the master supply log(s) including: the date and time, the name of the medication, the strength, the quantity, the expiration date, the manufacturer, the lot number, and the sending party and the witness, including their signatures.

Disposal

Disposal of expired and/or damaged controlled substances will be performed as described above under “Reverse Distribution”.

Disposal of controlled substances residual to patient administration, wasting, will be performed following the agency or service’s internal policy.

Personnel wasting controlled substances must be authorized by the DEA registrant and included on the agency or service’s roster of personnel authorized to administer controlled substances. A witness, preferably included on that same roster, but, at minimum, included on the roster of personnel authorized to count controlled substances, must also participate in each waste and its documentation.

Wasting documentation will include:

1. A log(s) of all controlled substances wasted
2. A PCR/ePCR corresponding to each waste
3. These records will be:
 - a. Maintained with the medications until submitted to and/or electronically accessible from the master supply location
 - b. Available for inspection within 24 hours
 - c. Submitted to master supply at least monthly
 - i. Maintained as master supply documentation for a period of no less than three years

Re-Stocking Procedures

Re-stocking of controlled substances will be performed following the agency or service’s internal policy that will include at minimum verification of administration, waste, damage, and/or expiration. If an agency or service chooses to require the retention and transport of used and/or damaged containers and/or sharps for restock purposes, internal policies will include the use of appropriate sharps containers.

Personnel providing re-stock of controlled substances must be authorized by the DEA registrant and included on the agency/service’s roster of personnel authorized to manage controlled substances. Personnel receiving re-stocked controlled substances must be authorized by the DEA registrant and included on the agency/service’s roster of personnel authorized to administer controlled substances. Both parties must participate in and document the re-stocking.

Re-stocking documentation will include:

1. A log(s) of all controlled substances restocked
2. A PCR/ePCR or other appropriate report corresponding to each administration, waste, damage, or expiration
3. These records will be:
 - a. Maintained at and/or electronically accessible from the master supply location
 - b. Available for inspection within 24 hours
 - c. For a period of no less than three years

Transfer or Exchange Between Agencies and/or Services

The transfer or exchange of controlled substances between agencies and/or services is discouraged.

If such a transfer or exchange is required it must be:

1. Approved by the DEA Registrants of both the supplying and the receiving agencies and/or services
2. Conducted between personnel included on each agency and/or service’s roster of personnel authorized to manage controlled substances; one supplying and one receiving
3. Witnessed by additional personnel included on each agency and/or service’s roster of personnel authorized to manage controlled substances; one supplying and one receiving
4. Documented by both the supplying and the receiving agencies and/or services, using the DEA Form 222 for Schedule II controlled substances and an invoice for while Schedule III – V controlled substances, and a log(s) of all controlled substances transferred or exchanged

Transfer or exchange documentation will include:

1. Copies of each agency and/or service's DEA Form 222 for Schedule II controlled substances
2. Copies of each agency and/or service's invoice for Schedule III – V controlled substances
3. Each agency and/or service's log(s) of all controlled substances transferred or exchanged
4. These records will be:
 - a. Maintained at and/or electronically accessible from agency and/or service's master supply location
 - b. Available for inspection within 24 hours
 - c. For a period of no less than three years

Investigation and Mitigation of Suspected Tampering or Diversion

Drug inventories and all related records are subject to inspection by REMSA, the California EMS Authority (EMSA), the California State Board of Pharmacy, the Federal Drug Enforcement Administration, and the Justice Department's Bureau of Narcotic Enforcement.

Controlled Substance Testing

Testing personnel for controlled substances may be performed following the agency or service's internal policy. Such policies may provide for controlled substance testing that is random, routine, or in response to suspected tampering and/or diversion. Any such policy should be developed in consultation with the DEA Registrant and legal counsel.

Discrepancy Reporting

Each agency or service will follow its internal policy for reporting discrepancies including tampering, theft, loss, or diversion of controlled substances. This policy will be established by the DEA Registrant and must include immediate verbal reporting followed by written reports and investigation. The DEA Registrant must notify the DEA of the discrepancy within one business day of discovery using DEA Form 106, "Report of Theft or Loss of Controlled Substances".

Tampering, Theft and Diversion Prevention and Detection

Each agency or service's internal policy regarding controlled substances will comply with this policy; with the intent to prevent and detect the tampering, theft, loss, and/or diversion of controlled substances. Areas to be addressed include: ordering and order tracking, receipt and accountability; master supply storage, security, and documentation; labeling and tracking, vehicle storage and security, usage procedures and documentation, reverse distribution, disposal, re-stocking procedures, transfer or exchange of controlled substances between agencies and/or services, controlled substance testing, discrepancy reporting; tampering, theft and diversion prevention and detection; and usage audits.

Additionally, reporting the suspected tampering, theft, and/or diversion of controlled substances to local law enforcement is encouraged. If the tampering, theft, and/or diversion of controlled substances is substantiated, written reports must be made within 72 hours to REMSA and EMSA for action against the responsible party's certification, license, or accreditation.

Usage Audits

Each agency or service will follow its internal policy for usage audits. These audits will:

1. Be conducted by the DEA registrant/designee
 - a. Any such designee must be authorized by the DEA registrant and included on the agency or service's roster of personnel authorized to audit controlled substances
2. Account for the current disposition of all controlled substances
 - a. Include review of forms, purchase records, logs, and PCRs/ePCRs
 - b. Identify and report discrepancies as required
3. Identify and investigate unusually high rates of administration
 - a. Establish a central tendency for the rate of controlled substance administration among all individuals authorized to administer controlled substances during the time period being audited
 - b. Identify high outliers, individuals with high rates of controlled substance administration
 - c. Review each administration of controlled substances performed by these high outliers for accountability and clinical appropriateness
4. Be performed at least quarterly

Records of these audits will be:

1. Maintained at and/or electronically accessible from the agency or service's quality assurance location
2. Available for inspection within 24 hours
3. For a period of no less than three years